

From: [Legare, Carole \(HC/SC\)](#)
Sent: 2021-05-26 3:35 PM
To: [Mineau, Philippe \(HC/SC\)](#)
Subject: FW: Ivermectin
Attachments: Merck Canada Statement on STROMEKTOL® (ivermectin) use
During the COVID-19 Pandemic.pdf

From: Chang, Vivian (HC/SC) <vivian.chang@canada.ca>
Sent: 2021-05-26 3:17 PM
To: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Cc: MacKay, Ian (HC/SC) <ian.mackay@canada.ca>
Subject: FW: Ivermectin

Hi Carole,

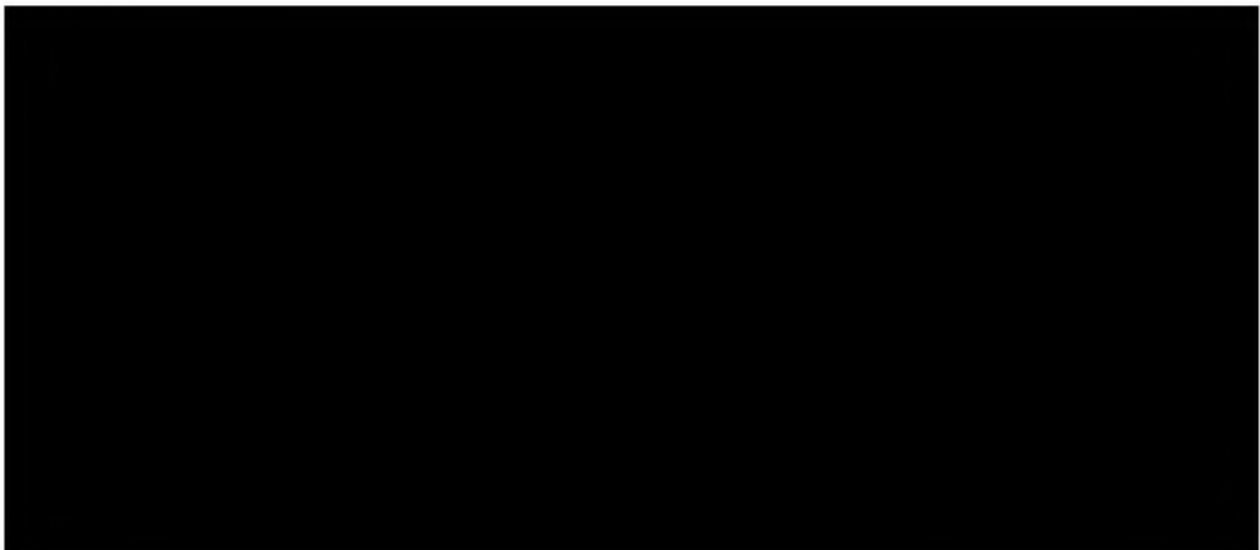
Please see below, most recent update on the status of Ivermectin. Attached is Merck's statement on the use of Ivermectin in the context of COVID-19; this statement was issued in February.

Vivian

From: Burnett, Rodrigue (HC/SC) <rodrigue.burnett@canada.ca>
Sent: 2021-05-05 1:07 PM
To: Chang, Vivian (HC/SC) <vivian.chang@canada.ca>
Cc: MacKay, Ian (HC/SC) <ian.mackay@canada.ca>; Lostracco, Anthony (HC/SC) <anthony.lostracco@canada.ca>
Subject: RE: Ivermectin

Hi Vivian,

Requester agreed to
Remove 3rd Party Info





Let me know if you have any other questions.

Thanks,
Rod

Requester agreed to
Remove 3rd Party Info

From: Chang, Vivian (HC/SC) <vivian.chang@canada.ca>
Sent: 2021-05-05 3:43 PM
To: Lostracco, Anthony (HC/SC) <anthony.lostracco@canada.ca>; Burnett, Rodrigue (HC/SC) <rodrique.burnett@canada.ca>
Cc: MacKay, Ian (HC/SC) <ian.mackay@canada.ca>
Subject: RE: Ivermectin

Hi Anthony and Rod,

We're wondering if there's an update on the Ivermectin file?

Thanks,
Vivian

-----Original Appointment-----

From: Chang, Vivian (HC/SC)
Sent: 2021-04-28 10:06 AM
To: Lostracco, Anthony (HC/SC); MacKay, Ian (HC/SC)
Subject: Ivermectin
When: 2021-04-28 1:15 PM-1:45 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

Microsoft Teams meeting

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+1 647-557-1930,,558738468# Canada, Toronto

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[Find a local number](#) | [Reset PIN](#)

[Learn More](#) | [Meeting options](#)

From: Mineau, Philippe (HC/SC)
Sent: 2021-07-15 2:12 PM
To: Lostracco, Anthony (HC/SC)
Subject: FW: Ivermectin updates

Hey Anthony,

Sharing because I thought it might be of interest,

PHAC is finalizing its review of literature around COVID-19 – some meta-analyses of randomized clinical trials showing no stat-significant effect on outcomes, others showing a stat-significant effect, but with low-moderate statistical certainty. So the jury is still out...

The Ivermectin for the treatment of COVID-19 disease: Too good to pass up or too good to be true is a short, interesting read.

P

From: Waddell, Lisa (PHAC/ASPC) <lisa.waddell@canada.ca>
Sent: 2021-07-07 9:17 PM
To: Janicki, Rachelle (PHAC/ASPC) <rachelle.janicki@canada.ca>
Cc: Cornelisse, Mette (PHAC/ASPC) <mette.cornelisse@canada.ca>; Lingohr, Erika (PHAC/ASPC) <erika.lingohr@canada.ca>
Subject: RE: Ivermectin review edits

Hi all,

I am just sharing a couple **Ivermectin related publications that may be of interest to HC that were published yesterday.**

So today I came across a very eloquently written reflection on the Ivermectin situation.

This may be good to share with HC as well. Ivermectin for the treatment of COVID-19 disease: Too good to pass up or too good to be true? And goes with a new meta-analysis published today: Hill et al. Meta-analysis of randomized trials of ivermectin to treat SARS-CoV-2 infection

- This MA lines up with some of the others. They have some unpublished data I have not seen before (via contacting trial PIs it looks like).

Lisa

From: [Lingohr, Erika \(PHAC/ASPC\)](#)
Sent: 2021-07-08 11:37 AM
To: [Mineau, Philippe \(HC/SC\)](#)
Cc: [Waddell, Lisa \(PHAC/ASPC\)](#); [Cornelisse, Mette \(PHAC/ASPC\)](#);
[Lingohr, Erika \(PHAC/ASPC\)](#)
Subject: FW: Ivermectin updates

Good morning Philippe;
Lisa Waddell kindly flagged the following updates to our attention.

Thanks and regards;

Erika

From: Waddell, Lisa (PHAC/ASPC) <lisa.waddell@canada.ca>
Sent: 2021-07-07 9:17 PM
To: Janicki, Rachelle (PHAC/ASPC) <rachelle.janicki@canada.ca>
Cc: Cornelisse, Mette (PHAC/ASPC) <mette.cornelisse@canada.ca>; Lingohr, Erika (PHAC/ASPC) <erika.lingohr@canada.ca>
Subject: RE: Ivermectin review edits

Hi all,

I am just sharing a couple **Ivermectin related publications that may be of interest to HC that were published yesterday.**

So today I came across a very eloquently written reflection on the Ivermectin situation. This may be good to share with HC as well. [Ivermectin for the treatment of COVID-19 disease: Too good to pass up or too good to be true?](#) And goes with a new meta-analysis published today: [Hill et al. Meta-analysis of randomized trials of ivermectin to treat SARS-CoV-2 infection](#)

- This MA lines up with some of the others. They have some unpublished data I have not seen before (via contacting trial PIs it looks like).

Lisa

From: Legare, Carole (HC/SC)
Sent: 2021-08-30 1:16 PM
To: Mineau, Philippe (HC/SC)
Subject: FW: URGENT: For Review - PA - Do not use ivermectin for
treatment of COVID-19
Attachments: Merck Canada Statement on STROMECTOL® (ivermectin)
use During the COVID-19 Pandemic.pdf

fyi

From: MacKay, Ian (HC/SC) <ian.mackay@hc-sc.gc.ca>
Sent: 2021-08-30 12:48 PM
To: Legare, Carole (HC/SC) <carole.legare@hc-sc.gc.ca>
Cc: Keene, Daniel (HC/SC) <daniel.keene@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC)
<deborah.dinakaran@hc-sc.gc.ca>; Chang, Vivian (HC/SC) <vivian.chang@hc-sc.gc.ca>; Badenduck,
Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>
Subject: FW: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Hi folks. [REDACTED] thought I should weigh in on this given the
significance of the story in the US and beyond. Thanks to Vivian for confirming some these
facts today.

Even though Mectizan is approved for sale in Canada we (SAP) have been drawn into a
number of issues related to the possible use of the drug in COVID by virtue of the long history
of the drug on SAP. We successfully referred inquiries back to the company and the market.

There was one inquiry last winter/spring when there was concern about the Canadian supply
of the drug; that is, there was concern about a shortage of the drug in Canada. This prompted a
few hospitals to ask about whether HC was aware of the shortage and what we might be able
to do about it and whether alternatives namely albendazole, which is an SAP drug was
available as a back-up. [REDACTED]

[REDACTED]

Requester agreed to
Remove 3rd Party Info



It's also worth noting that we heard many stories over many years of human patients who sought access to the Canadian approved vet version of the drug as well as physicians who either did or threatened to prescribe this version for human patients out of general frustration that the drug was not available on the Canadian market.

IM

Requester agreed to
Remove 3rd Party Info

Sent from my iPhone

On Aug 30, 2021, at 11:47 AM, Dinakaran, Deborah (HC/SC)
<deborah.dinakaran@hc-sc.gc.ca> wrote:

Good Day to all,

Please see below, email trail regarding ivermectin and a PA being developed by CPAB. As ORM has not been involved in the ivermectin issue this is being forwarding to OCT/SAP and DGO for follow up.

Please let me know who will be taking the lead from the TPD perspective on this so that I can direct ROEB and CPAB to connect with the appropriate individuals and provide any additional information as required.

Thanking you in advance,
Deborah

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>

Sent: 2021-08-30 11:35 AM

To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>

Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimirad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

justin@hc-sc.gc.ca>

Subject: RE: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Hi Aldege,

We have no reason to believe consumers have/are purchasing ivermectin for human use to treat COVID-19 as human use products require a prescription. Like the title, the messaging could be to not use any form of ivermectin to treat/prevent COVID-19. The US FDA article focuses on describing the ingredient general and then advising on how vet use products should not be used on humans.

I understand if CPAB needs to keep the focus on only Ivermectin vet products as per your process.

Will wait for TPD to chime in.

Thanks!

Mimi

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>

Sent: 2021-08-30 11:25 AM

To: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>

Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Subject: RE: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Hello All:

The US FDA and media articles are specifying veterinary version of ivermectin. Do we have reason to believe the human version is being used? I think we should keep it to the vet version but can add human version in advice to healthcare professionals.

Please advise ASAP as the PA needs to go out today.

Thanks.

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>

Sent: 2021-08-30 11:01 AM

To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC)

<bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC)
<deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-
sc.gc.ca>
Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim
(HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-
justin@hc-sc.gc.ca>
Subject: RE: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Hi Aldege,

I'd added some initial comments as I feel the PA should be worded on ivermectin in
general and not just that the vet version to treat COVID-19 is dangerous. I've added
some preliminary thoughts.

<< File: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1015 (002) ML.docx >>
Let me know if you need a VDD contact otherwise, TPD please advise.

Thanks!

Mimi

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Sent: 2021-08-30 10:25 AM
To: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC)
<marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC)
<bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC)
<deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-
sc.gc.ca>
Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim
(HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-
justin@hc-sc.gc.ca>
Subject: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19
Importance: High

Hello All: Attached is the first draft. This is urgent because I am told that senior
management would like it out, today. Please add any missing info, as required. Cheers.

<< File: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1015.docx >>

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Sent: 2021-08-30 9:50 AM
To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Nahum, Marilyne
(HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC)
<bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC)

<deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>

Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Subject: RE: Issue IU - Do not use ivermectin for treatment of COVID-19

Importance: High

Thanks Aldege! My advice would be to issue a similar advisory as what the US FDA did. I've copied our TPD colleagues as they would be our experts on providing advice to the public.

@TPD ORMS: Sorry for not including you in the first outreach to CPAB. In light of the articles published (US FDA and CBC) regarding consumers purchasing ivermectin to treat COVID-19, our ADM is supportive of an advisory to be issued today/tomorrow to inform the Canadian public against this use. HC has not issued any statement related to this matter. Could you please provide advice to CPAB on what the public should be made aware of and what they should do? We'd likely what to advise: what is ivermectin authorized for?, it is not authorized to treat COVID-19 and shouldn't be used in this way, what are the risks and to consult HCPs should they be seeking treatment or have questions.

I have not looped in our colleagues from VDD despite it seem like consumers are seeking the veterinary form of ivermectin as we would like to communicate on human health risk.

Thank you!

Mimi

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>

Sent: 2021-08-30 9:31 AM

To: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>

Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Subject: RE: Issue IU - Do not use ivermectin for treatment of COVID-19

Thanks, Mimi. CPAB is in agreement on issuing a PA. Please forward any info. Cheers,

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>

Sent: 2021-08-30 9:27 AM

To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Francis-Lamb, Laura (HC/SC) <laura.francis-lamb@hc-sc.gc.ca>

Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Subject: Issue IU - Do not use ivermectin for treatment of COVID-19

Importance: High

Good morning Aldege,

I hope you had a fantastic weekend!! I saw you're covering for Laura today hence reaching out.

There have been multiple media articles indicating consumers may be purchasing ivermectin (veterinary version) to treat COVID-19. Ivermectin, an antiparasitic agent, is not recommended for prophylaxis or treatment of coronavirus disease 2019 (COVID-19). The idea of using ivermectin to treat COVID-19 seems to have returned and be more apparent in West Coast Canada. In addition, MHPD STARS received multiple advertising complaints on this matter.

US FDA: advising against it's use <https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>

Recent CBC Article: <https://www.cbc.ca/news/canada/calgary/ivermectin-alberta-covid-1.6157200>

Our ADM is supportive of HC issuing an article (similar to US FDA) to advise against the use of ivermectin to treat COVID-19. We would like to seek CPAB's advise on issuing an IU on this matter.

Please advise,

Mimi

Mimi Lin
(she/elle)

Senior Corporate Regulatory Compliance & Enforcement Advisor,
Health Product Compliance & Enforcement Unit / Regulatory Operations and Enforment Branch
Health Canada / Government of Canada
Mimi.Lin@hc-sc.gc.ca / Tel: (343)573-2580

Conseillère principale ministériel de conformité et d'application de la loi,
Unité de Conformité des produits de santé et application de la loi / Direction générale des
opérations réglementaires et de l'application de la loi
Santé Canada / Gouvernement du Canada
Mimi.Lin@hc-sc.gc.ca / Tél: (343)573-2580

From: [Soo, Evelyn \(HC/SC\)](#)
Sent: 2021-06-10 3:17 PM
To: [Legare, Carole \(HC/SC\)](#)
Subject: FW: URGENT ACTION REQUEST - Petition 432-01030
Attachments: 432-01030 Notice.docx
432-01030 HC Response.docx

Hi Carole

I have a quick question for you. We will be updating these responses but not sure if you have anything to add from the CT perspective? I believe there are trials that have been authorised but not sure if there have been any read outs and if there are any new data that suggests a positive effect for ivermectin and COVID19.

Thanks
Evelyn

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-06-09 5:20 PM
To: Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>; McLean, Martin (HC/SC) <martin.mclean@canada.ca>
Cc: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>; Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Subject: FW: URGENT ACTION REQUEST - Petition 432-01030

Hey there BGIVD,

So now we have a parliamentary petition asking us to approve ivermectin as OCT for COVID-19.

I've reused some of the text you provided previously in the attached response – would you be able to let me know what you think by end of day Monday?

Thank you so much,
P

From: Ngo, Ursula (HC/SC) <ursula.ngo@canada.ca>
Sent: 2021-06-09 11:32 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Zimmermann, Margaret (HC/SC) <margaret.zimmermann@canada.ca>; Smith4, Melissa (HC/SC) <melissa.smith4@canada.ca>; Morgan, Ed (HC/SC) <ed.morgan@canada.ca>
Subject: URGENT ACTION REQUEST - Petition 432-01030

Hi Philippe,

As per our conversation, please find attached the petition and official tasking for a response.

Health Canada has received the following petition:

- *We, the undersigned, physicians, scientists, and other concerned citizens and residents of Canada, call upon the Government of Canada to urgently examine the evidence in favour of ivermectin and give due consideration to making ivermectin available immediately to Canadians as a schedule II medication, which can be obtained directly from a pharmacist.*

Please provide a DG approved response to me by **Wednesday, June 16th**

Attached are the Petition Notice (for complete wording) and the PCO Template (for completion).

Please confirm receipt.

Thank you,

Ursula

Ursula Ngo
(she | elle)

Senior Advisor to Director General | Conseillère principale au directeur général
Policy, Planning and International Affairs Directorate | Direction des politiques, de la planification et
des affaires internationales
Health Products & Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
✉: Ursula.ngo@canada.ca
☎ 613.203.1367

ATIA - 13(1)(b)

Abdulla, Rosemin (HC/SC)

From: Cain, Francoise (HC/SC) on behalf of Randall, Bruce (HC/SC)
Sent: 2021-10-26 9:34 AM
To: Abdulla, Rosemin (HC/SC)
Subject: FW: COVID-19 Related: [REDACTED]
[REDACTED] EMA communication: EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials
Attachments: Ivermectin - 03-2021 - public health communication.docx

[REDACTED]

Also, if you can go and look and see what I have added that would help me a lot...I didn't have very many at all...

From: Cain, Francoise (HC/SC) <francoise.cain@canada.ca> **On Behalf Of** Randall, Bruce (HC/SC)
Sent: 2021-06-25 9:12 AM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Subject: FW: COVID-19 Related: [REDACTED] EMA communication:
EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials

From: Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>
Sent: 2021-03-19 3:26 PM
To: Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>; Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Cc: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: FW: COVID-19 Related: [REDACTED] EMA communication:
EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials

FYI

From: Soltys, Kathy (HC/SC) <kathy.soltys@canada.ca>
Sent: 2021-03-19 11:54 AM
To: Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>
Cc: Sun, Rong (HC/SC) <rong.sun@canada.ca>; Irfan, Nashwa (HC/SC) <nashwa.irfan@canada.ca>
Subject: FW: COVID-19 Related: [REDACTED] EMA communication:
EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials

Hi Evelyn,
Just flagging this to you, and I am sure you are already aware. Please let MHPD know if TPD needs our input on anything related to this.
Thanks.
Kathy

ATIA - 13(1)(b)

From: Srivastava, Tanya (HC/SC) <tanya.srivastava@canada.ca> **On Behalf Of** MHPD_International / DPSC_International (HC/SC)

Sent: 2021-03-19 8:08 AM

To: Abdelmesih, Mariam (HC/SC) <mariam.abdelmesih@canada.ca>; Alhaddad, Saj (HC/SC) <saj.alhaddad@canada.ca>; Bawolak, Marie-Therese (HC/SC) <marie-therese.bawolak@canada.ca>; Campbell, Catherine (HC/SC) <catherine.campbell@canada.ca>; Chen2, Yong (HC/SC) <yong.chen2@canada.ca>; Chretien, Louise (HC/SC) <louise.chretien@canada.ca>; Comarova, Natalia (HC/SC) <natalia.comarova@canada.ca>; Dai, Jiazhen Minnie (HC/SC) <jiazhenminnie.dai@canada.ca>; del Campo, Eduardo (HC/SC) <eduardo.delcampo@canada.ca>; Djulus, Josephine (HC/SC) <josephine.djulus@canada.ca>; Duguay, David (HC/SC) <david.duguay@canada.ca>; Eng, David (HC/SC) <david.eng@canada.ca>; Filfil, Rana (HC/SC) <rana.filfil@canada.ca>; Hazelwood, Tracey (HC/SC) <tracey.hazelwood@canada.ca>; HC.F HPF MHPD OPEDA F.SC <HPF_MHPD_OPEDA@canada.ca>; HC.F MHPD BBRS Assistants / MHPD BBRA Assistants F.SC <hc.mhpdbbbsassistants-mhpdbbraassistants.sc@canada.ca>; HC.F MHPD BBRS Management / MHPD BBRA Management F.SC <hc.mhpdbbbsmanagement-mhpdbbbramanagement.sc@canada.ca>; HC.F MHPD HPSEB Managers / DPSC HPSEB Gestionnaires F.SC <hc.mhpdpsebmanagers-dpschpsebgestionnaires.sc@canada.ca>; HC.F MHPD MPB MANAGEMENT F.SC <hc.mhpdpmpbmanagement.sc@canada.ca>; HC.F MHPD MPB SCIENTIFIC STAFF F.SC <hc.mhpdpmpbscientificstaff.sc@canada.ca>; HC.F MHPD OPRAA Management F.SC <hc.mhpdp.opraa.management.sc@canada.ca>; MBBNHPB ENVIROSCANS / BPBBSNC (HC/SC) <hc.mbbnhpb.enviroscans-bpbbsnc.sc@canada.ca>; Meszaros, Michele (HC/SC) <michele.meszaros@canada.ca>; MHPD_International / DPSC_International (HC/SC) <hc.mhpdp international-dpsc international.sc@canada.ca>; MPB RPM / GPR BPPC (HC/SC) <hc.mpb.rpm-gpr.bppc.sc@canada.ca>; Murty, Hima (HC/SC) <hima.murty@canada.ca>; Plante, Isabelle (HC/SC) <isabelle.plante@canada.ca>; Rose, Jhona (HC/SC) <jhona.rose@canada.ca>; Salem, Myriam (HC/SC) <myriam.salem@canada.ca>; Shehata, Marlene (HC/SC) <marlene.shehata@canada.ca>; Sleno, Rory (HC/SC) <rory.sleno@canada.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@canada.ca>; Springuel, Pascale (HC/SC) <pascale.springuel@canada.ca>; Tremblay, Patrice (HC/SC) <patrice.tremblay@canada.ca>; Williams, Lee (HC/SC) <lee.williams@canada.ca>; Xu, Xiao (HC/SC) <xiao.xu@canada.ca>; Yammine, Elena (HC/SC) <elena.yammine@canada.ca>

Cc: Robinson2, Kelly (HC/SC) <kelly.robinson2@canada.ca>; Bettel, Megan (HC/SC) <megan.bettel@canada.ca>; Lehman, Kelly (HC/SC) <kelly.lehman@canada.ca>; Hazelwood, Tracey (HC/SC) <tracey.hazelwood@canada.ca>

Subject: COVID-19 Related: [REDACTED] EMA communication:
EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials

Dear all,

Please find below and attached an important COVID-19 related communication from the EMA advising against the use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials. Also, please note that there is an embargo on the information in this email until it is published on their website on Monday, March 22nd, 2021 at 14:00 hrs, CET.

Kindest regards,

Tanya

Tanya Srivastava

Junior Policy Analyst
Bureau of Strategic Engagement and Integrated Management Services
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Email: tanya.srivastava@canada.ca
hc.mhpdp international-dpsc international.sc@canada.ca

ATIA - 13(1)(b)

Analyste de politiques junior
Bureau de la mobilisation stratégique et des services de gestion intégrée
Direction des produits de santé commercialisés
Direction générale des produits de santé et des aliments
Santé Canada
Courriel: tanya.srivastava@canada.ca
hc.mhpd_international-dpsc_international.sc@canada.ca

Dear Colleagues,

Please find attached an EMA communication advising against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials.

The document will be published on EMA's website **on Monday, 22 March 2021, 14:00hrs, CET**. Please note that there is an embargo until such time.

Best regards,

Head of Public and Stakeholders Engagement
Stakeholders and Communication Division
European Medicines Agency

www.ema.europa.eu

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This e-mail has been scanned for all known viruses by European Medicines Agency.

From: [Durno, Laura \(HC/SC\)](#)
To: [Arnold, Sidney \(HC/SC\)](#)
Cc: [Visanuvimol, Jiravat \(HC/SC\)](#)
Subject: FW: FDA MedWatch - Why You Should Not Use Ivermectin to Treat or Prevent COVID-19: Consumer Update
Date: 2021-03-05 5:24:00 PM

FYI – thought of you Sid 😊

It's too bad Health Canada couldn't publish a similar message on our website. It might help slow down some of those letters....

Have a good weekend!

Laura

From: U.S. Food and Drug Administration <usfda@public.govdelivery.com>
Sent: 2021-03-05 4:12 PM
To: Durno, Laura (HC/SC) <laura.durno@canada.ca>
Subject: FDA MedWatch - Why You Should Not Use Ivermectin to Treat or Prevent COVID-19: Consumer Update

MedWatch Header Pharmacy



MedWatch - The FDA Safety Information and Adverse Event Reporting Program

TOPIC: Why You Should Not Use Ivermectin to Treat or Prevent COVID-19: Consumer Update

AUDIENCE: Consumer, Health Professional

ISSUE: There seems to be a growing interest in a drug called **ivermectin** to treat humans with COVID-19. The FDA has not reviewed data to support use of ivermectin in COVID-19 patients to treat or to prevent COVID-19; however, some initial research is underway.

Taking a drug for an unapproved use can be very dangerous. The FDA has received multiple reports of patients who have required medical support and been hospitalized after self-medicating with ivermectin intended for horses.

Even the levels of ivermectin for approved uses can interact with other medications, like blood-thinners. You can also overdose on ivermectin, which can cause nausea,

vomiting, diarrhea, hypotension (low blood pressure), allergic reactions (itching and hives), dizziness, ataxia (problems with balance), seizures, coma and even death.

For more information about this consumer update, click on the blue button "**Read More**" below.

BACKGROUND: Ivermectin tablets are approved by the FDA to treat people with intestinal strongyloidiasis and onchocerciasis, two conditions caused by parasitic worms. In addition, some topical (on the skin) forms of ivermectin are approved to treat external parasites like head lice and for skin conditions such as rosacea.

Some forms of ivermectin are used in animals to prevent heartworm disease and certain internal and external parasites. It's important to note that these products are different from the ones for people, and safe when used as prescribed for animals, only.

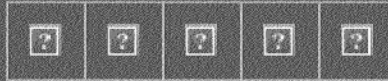
RECOMMENDATIONS:

1. FDA has not approved ivermectin for use in treating or preventing COVID-19 in humans. Ivermectin is not an anti-viral (a drug for treating viruses).
2. Taking large doses of this drug is dangerous and can cause serious harm.
3. If you have a prescription for ivermectin for an FDA-approved use, get it from a legitimate source and take it exactly as prescribed.
4. Never use medications intended for animals on yourself. Ivermectin preparations for animals are very different from those approved for humans.
5. Effective [ways to limit the spread of COVID-19](#) continue to be to wear your mask, stay at least 6 feet from others who don't live with you, wash hands frequently, and avoid crowds.

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and [submit the report online](#).
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.





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This email was sent to laura.durno@hc-sc.gc.ca using GovDelivery Communications Cloud on behalf of: U.S.
Food and Drug Administration ·
10903 New Hampshire Ave · Silver Spring, MD · 20993-0002 · 1-888-INFO-FDA

From: Duguay, David (HC/SC)
Sent: 2021-08-30 8:55 AM
To: Ferrier, Sylvie (HC/SC); Sleno, Rory (HC/SC)
Subject: FW: ivermectin - CDC health advisory

Hi Rory and Sylvie,
Thanks for the quick response on this one. We'll revisit the topic at prioritization tomorrow.
I have time today if you'd like to have a call to discuss the issue and what will be the proposal (risk communication, which type?)
David

From: Laforest, Lynda (HC/SC) <lynda.laforest@hc-sc.gc.ca>
Sent: 2021-08-30 8:52 AM
To: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>; Irfan, Nashwa (HC/SC) <nashwa.irfan@hc-sc.gc.ca>
Cc: Soltys, Kathy (HC/SC) <kathy.soltys@hc-sc.gc.ca>
Subject: RE: ivermectin - CDC health advisory

Agree
I will reschedule the meeting

From: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>
Sent: 2021-08-30 8:50 AM
To: Irfan, Nashwa (HC/SC) <nashwa.irfan@hc-sc.gc.ca>; Laforest, Lynda (HC/SC) <lynda.laforest@hc-sc.gc.ca>
Cc: Soltys, Kathy (HC/SC) <kathy.soltys@hc-sc.gc.ca>
Subject: FW: ivermectin - CDC health advisory

Hi Nashwa and Lynda,
Given the development on this topic, it would deserve an update at prioritization.
Could it be done tomorrow (I know the meeting was just cancelled, but it may be best to have a timely decision on this one...)?
Thanks,
David

From: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>
Sent: 2021-08-30 8:33 AM
To: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>
Cc: Irfan, Nashwa (HC/SC) <nashwa.irfan@hc-sc.gc.ca>; Bell, Andrea (HC/SC) <andrea.bell@hc-sc.gc.ca>; Galand, Lucye (HC/SC) <lucye.galand@hc-sc.gc.ca>
Subject: RE: ivermectin - CDC health advisory

Sounds like it's time to issue a risk comm similar to the FDA's earlier this year.

<https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals>

The information in the CBC article was what we were previously waiting for (i.e., confirmation that this was also an issue in Canada). Also timely given the FDA communicated on twitter about the topic again last week (https://twitter.com/us_fda/status/1429050070243192839).

Thanks for sharing David.

RS

Rory Sleno, PhD

Scientific Evaluator|Évaluateur Scientifique
Marketed Pharmaceuticals Bureau|Bureau des produits pharmaceutiques commercialisés
Marketed Health Product Directorate|Direction des produits de santé commercialisés
Health Canada|Santé Canada
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, K1A 0K9 - 1912B
Tel|Tél: +1(613)793-6303
Email|Courriel: rory.sleno@canada.ca

From: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>

Sent: 2021-08-30 8:27 AM

To: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>

Cc: Irfan, Nashwa (HC/SC) <nashwa.irfan@hc-sc.gc.ca>

Subject: RE: ivermectin - CDC health advisory

Hi Rory and Sylvie,

Ivermectin in the news...

Alberta feed stores inundated with calls for ivermectin over false claims livestock dewormer treats COVID

<https://www.cbc.ca/news/canada/calgary/ivermectin-alberta-covid-1.6157200>

For consideration... MPB previously looked at the information from the literature, CanadaVigilance, Poison Control Centres, VDD) when the topic was presented at prioritization in April, that was in response to public communications from other agencies. Any ongoing work in light of the more recent information such as what was included in this news article?

Thanks,
David

From: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>

Sent: 2021-08-27 11:52 AM

To: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>

sc.gc.ca>

Subject: RE: ivermectin - CDC health advisory

I think Lucye sent me that slide deck earlier today. I will provide comments on Monday.

RS

Rory Sleno, PhD

Scientific Evaluator|Évaluateur Scientifique
Marketed Pharmaceuticals Bureau|Bureau des produits pharmaceutiques commercialisés
Marketed Health Product Directorate|Direction des produits de santé commercialisés
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200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, K1A 0K9 - 1912B
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Email|Courriel: rory.sleno@canada.ca

From: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>

Sent: 2021-08-27 11:44 AM

To: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>

Subject: RE: ivermectin - CDC health advisory

That was quite the tweet!!

Doesn't seem to be evidence of similar issue in Canada right now.

Of note there is a deck being prepared on COVID-19 treatments for the ADM, from post-market perspective, and we're including a bullet on monitoring of drugs that have shown to be not effective or something along those lines which would include this one. There may be more questions on our activities, but until then I'm not sure if there is a need to poison control centers and VDD for now.

Thanks,
David

From: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>

Sent: 2021-08-27 11:40 AM

To: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>

Subject: RE: ivermectin - CDC health advisory

Hi David,

I saw the FDA tweet earlier this week: "You are not a horse. You are not a cow. Seriously, y'all. Stop it."

I just took a look at CV up to 2021-04-30 and we still don't have many case reports for 2020/2021 (8/95 cases, all for the topical formulation Rosiver).

Do either of you think we should go through the exercise with the Poison Control Centres and VDD again? Personally, I'm not expecting much just as we saw last time.

RS

Rory Sleno, PhD

Scientific Evaluator|Évaluateur Scientifique
Marketed Pharmaceuticals Bureau|Bureau des produits pharmaceutiques commercialisés
Marketed Health Product Directorate|Direction des produits de santé commercialisés
Health Canada|Santé Canada
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, K1A 0K9 - 1912B
Tel|Tél: +1(613)793-6303
Email|Courriel: rory.sleno@canada.ca

From: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>

Sent: 2021-08-27 8:18 AM

To: Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>; Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>

Subject: ivermectin - CDC health advisory

fyi

[HAN Archive - 00449](#) | [Health Alert Network \(HAN\)](#) (cdc.gov)

From: Soo, Evelyn (HC/SC)
Sent: 2021-08-30 12:27 PM
To: Kukulski, Filip (HC/SC); McLean, Martin (HC/SC)
Subject: Fwd: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19
Attachments: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200 (002)_TPDDGO.docx

Any comments?

Evelyn C Soo, PhD

Director, Health Products and Food Branch

Health Canada / Government of Canada

evelyn.soo@canada.ca / Tel: 613-941-2588 / Cel: 613-854-5378

Evelyn C Soo, PhD

Directrice, Direction générale des produits de santé et des aliments

Santé Canada / Gouvernement du Canada

evelyn.soo@canada.ca / Tél: 613-941-2588 / Tél. cell: 613-854-5378

Begin forwarded message:

From: "Mineau, Philippe (HC/SC)" <philippe.mineau@hc-sc.gc.ca>
Date: August 30, 2021 at 12:25:54 PM EDT
To: "Soo, Evelyn (HC/SC)" <evelyn.soo@hc-sc.gc.ca>
Cc: "Peate, Jaspyn (HC/SC)" <jaspyn.peate@hc-sc.gc.ca>
Subject: FW: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19

Hey there Evelyn,

For your urgent approval, please see the edits I am proposing to this PA on ivermectin, in tracked changes – just to highlight clinical trial as the appropriate route to access, and that HC would review a submission should one come in,

Let me know what you think,

P

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>

Sent: 2021-08-30 12:03 PM

To: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>

Cc: Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; MacKay, Ian (HC/SC) <ian.mackay@hc-sc.gc.ca>; Chang, Vivian (HC/SC) <vivian.chang@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>; Legare, Carole (HC/SC) <carole.legare@hc-sc.gc.ca>; Keene, Daniel (HC/SC) <daniel.keene@hc-sc.gc.ca>

Subject: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19

Importance: High

Hello All: In order to post the PA today, please see revised version for urgent approval. Please make any necessary changes directly to the document. Thanks.

From: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>

Sent: 2021-08-30 11:58 AM

To: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>

Cc: Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>; BMS ORM Risk / BSM

BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; MacKay, Ian (HC/SC) <ian.mackay@hc-sc.gc.ca>; Chang, Vivian (HC/SC) <vivian.chang@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>; Legare, Carole (HC/SC) <carole.legare@hc-sc.gc.ca>; Keene, Daniel (HC/SC) <daniel.keene@hc-sc.gc.ca>

Subject: RE: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Hey there Mimi, hey Aldege,

I just wanted to share the standard response that we have been sending Canadians who enquire about using Ivermectin for COVID-19 – it has information on the approved human uses.

I also want to flag that PHAC has prepared a scientific evidence brief on ivermectin, which is available upon request here: [Public Health Agency of Canada \(PHAC\) – Emerging Science Group \(ESG\) Evidence Reviews – CanCOVID](#), and the PAHC rapid communication on ivermectin for strongyloides infection in patients with COVID-19 ([ccdrv47i78a04-eng.pdf \(canada.ca\)](#))

Please let me know if you would like TPD to review additional versions of the PA, as I will coordinate here from DGO,

Thank you!

P

<< File: COVID - Ivermectin - Direct Reply.docx >>

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>

Sent: 2021-08-30 11:35 AM

To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>

Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Subject: RE: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Hi Aldege,

We have no reason to believe consumers have/are purchasing ivermectin for human use to treat COVID-19 as human use products require a prescription. Like the title, the messaging could be to not use any form of ivermectin to treat/prevent COVID-19. The US FDA article focuses on describing the ingredient general and then advising on how vet use products should not be used on humans.

I understand if CPAB needs to keep the focus on only Ivermectin vet products as per your process.

Will wait for TPD to chime in.

Thanks!

Mimi

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>

Sent: 2021-08-30 11:25 AM

To: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>

Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Subject: RE: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Hello All:

The US FDA and media articles are specifying veterinary version of ivermectin. Do we have reason to believe the human version is being used? I think we should keep it to the vet version but can add human version in advice to healthcare professionals.

Please advise ASAP as the PA needs to go out today.

Thanks.

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>

Sent: 2021-08-30 11:01 AM

To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>

Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Subject: RE: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Hi Aldege,

I'd added some initial comments as I feel the PA should be worded on ivermectin in general and not just that the vet version to treat COVID-19 is dangerous. I've added some preliminary thoughts.

<< File: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1015 (002) ML.docx >>

Let me know if you need a VDD contact otherwise, TPD please advise.

Thanks!

Mimi

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>

Sent: 2021-08-30 10:25 AM

To: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>

Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Subject: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Importance: High

Hello All: Attached is the first draft. This is urgent because I am told that senior management would like it out, today. Please add any missing info, as required. Cheers.

<< File: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1015.docx >>

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>

Sent: 2021-08-30 9:50 AM

To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>

Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

justin@hc-sc.gc.ca>

Subject: RE: Issue IU - Do not use ivermectin for treatment of COVID-19

Importance: High

Thanks Aldege! My advice would be to issue a similar advisory as what the US FDA did. I've copied our TPD colleagues as they would be our experts on providing advice to the public.

@TPD ORMS: Sorry for not including you in the first outreach to CPAB. In light of the articles published (US FDA and CBC) regarding consumers purchasing ivermectin to treat COVID-19, our ADM is supportive of an advisory to be issued today/tomorrow to inform the Canadian public against this use. HC has not issued any statement related to this matter. Could you please provide advice to CPAB on what the public should be made aware of and what they should do? We'd likely what to advise: what is ivermectin authorized for?, it is not authorized to treat COVID-19 and shouldn't be used in this way, what are the risks and to consult HCPs should they be seeking treatment or have questions.

I have not looped in our colleagues from VDD despite it seem like consumers are seeking the veterinary form of ivermectin as we would like to communicate on human health risk.

Thank you!

Mimi

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>

Sent: 2021-08-30 9:31 AM

To: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC)

<marilyne.nahum@hc-sc.gc.ca>

Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Subject: RE: Issue IU - Do not use ivermectin for treatment of COVID-19

Thanks, Mimi. CPAB is in agreement on issuing a PA. Please forward any info. Cheers,

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Sent: 2021-08-30 9:27 AM
To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Francis-Lamb, Laura (HC/SC) <laura.francis-lamb@hc-sc.gc.ca>
Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: Issue IU - Do not use ivermectin for treatment of COVID-19
Importance: High

Good morning Aldege,

I hope you had a fantastic weekend!! I saw you're covering for Laura today hence reaching out.

There have been multiple media articles indicating consumers may be purchasing ivermectin (veterinary version) to treat COVID-19. Ivermectin, an antiparasitic agent, is not recommended for prophylaxis or treatment of coronavirus disease 2019 (COVID-19). The idea of using ivermectin to treat COVID-19 seems to have returned and be more apparent in West Coast Canada. In addition, MHPD STARS received multiple advertising complaints on this matter.

US FDA: advising against it's use <https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>

Recent CBC Article: <https://www.cbc.ca/news/canada/calgary/ivermectin-alberta-covid-1.6157200>

Our ADM is supportive of HC issuing an article (similar to US FDA) to advise against the use of ivermectin to treat COVID-19. We would like to seek CPAB's advise on issuing an IU on this matter.

Please advise,

Mimi

Mimi Lin

(she/elle)

Senior Corporate Regulatory Compliance & Enforcement Advisor,

Health Product Compliance & Enforcement Unit / Regulatory Operations and Enforcement Branch

Health Canada / Government of Canada

Mimi.Lin@hc-sc.gc.ca / Tel: (343)573-2580

Conseillère principale ministériel de conformité et d'application de la loi,

Unité de Conformité des produits de santé et application de la loi / Direction générale des opérations réglementaires et de l'application de la loi

Santé Canada / Gouvernement du Canada

Mimi.Lin@hc-sc.gc.ca / Tél: (343)573-2580

Pinard, Mike (HC/SC)

From: Bassi, Marilena (HC/SC)
Sent: 2021-08-30 1:41 PM
To: Hollett, Linsey (HC/SC); Robinson, Kelly (HC/SC)
Subject: FW: Ivermectin Communications

FYI

From: Tatone, Elise (HC/SC) <elise.tatone@hc-sc.gc.ca>
Sent: 2021-08-30 1:28 PM
To: Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>
Subject: Ivermectin Communications

Hi,

Just wanted to add in that the CVM also issued a statement today:

[CVM Letter to Veterinarians and Retailers: Help Stop Misuse of Animal Ivermectin to Prevent or Treat COVID-19 in Humans \(govdelivery.com\)](#)

Elise

Pinard, Mike (HC/SC)

From: Sun, Rong (HC/SC)
Sent: 2021-09-23 5:55 PM
To: Genier, Anne (HC/SC); St-Amand, Carole (HC/SC); Bassi, Marilena (HC/SC)
Cc: Davis, Meggan (HC/SC); Mehrotra, Manisha (HC/SC); Burgess, Sean (HC/SC); Legault-Thivierge, Geoffroy (HC/SC); Perrier-Belanger, Stephanie (HC/SC); Beattie, Alexander (HC/SC); Tatone, Elise (HC/SC); Geduld, Jennifer (HC/SC); Hollett, Linsey (HC/SC); Rajwani, Salima (HC/SC); Pinard, Mike (HC/SC); Perrier-Belanger, Stephanie (HC/SC); Beattie, Alexander (HC/SC)
Subject: Re: FYI - Input moving through approval this morning: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Anne,

Please see MHPD DG approved input green highlighted. Note that in this case it was a third party we were dealing with, not the company/group that paid for the ad. At this point we have not released this information, given it was a third party.

Many thanks,
 RS

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of billboard advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the sponsor company displaying of these ads removed them immediately, confirmed that these ads were no longer being displayed disseminated and committed to refraining from engaging in this non-compliant act in the future.

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred. Incidents of non-compliance are prioritised and action is taken based on the risk they may pose to the general public. It is the responsibility of companies to comply with regulatory requirements and to investigate incidents of potential non-compliance, and to take appropriate action to correct non-compliance, mitigate any risk to health, and inform Health Canada as appropriate.

To report marketing that is false or misleading or does not meeting regulatory requirements, visit <https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/illegal-marketing/complaint.html>

As part of its ongoing commitment to openness and transparency, Health Canada posts health product advertising complaints addressed by the Department <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/health-product-advertising-incidents.html>.

ATIA - 19(1)

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>

Sent: Thursday, September 23, 2021 10:04 AM

To: St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>

Cc: Davis, Meggan (HC/SC) <meggan.davis@hc-sc.gc.ca>; Mehrotra, Manisha (HC/SC) <manisha.mehrotra@hc-sc.gc.ca>; Burgess, Sean (HC/SC) <sean.burgess@hc-sc.gc.ca>; Legault-Thivierge, Geoffroy (HC/SC) <geoffroy.legault-thivierge@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; Tatone, Elise (HC/SC) <elise.tatone@hc-sc.gc.ca>; Geduld, Jennifer (HC/SC) <jennifer.geduld@hc-sc.gc.ca>; Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>; Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Pinard, Mike (HC/SC) <mike.pinard@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>

Subject: FYI - Input moving through approval this morning: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Good morning,

For your awareness - since we have received input from VDD, MHPD and HPCD – I have collated all the responses and the response below will be circulating through your ADMs office later this morning.

Merci!

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

The role of Health Canada as the federal regulator is the approval of veterinary drug products. The department ensures that all veterinary drugs fully satisfy requirements under the *Food and Drug Regulations* before any drug can be marketed in Canada. Any restrictions associated with the sale of a product intended for use in livestock would be a provincial/territorial jurisdiction. Depending on the province where the drugs are sold, there may be restrictions on who is permitted to purchase products intended for use in livestock, under their jurisdiction.

While Health Canada oversees the regulation of drugs, it has no jurisdiction over how health care professionals prescribe drugs once they are approved nor how consumers choose to consume the drug outside of approved directions for use (off-label use).

While Health Canada does not regulate off-label use by consumers, following reports of the use of veterinary ivermectin drugs to prevent or treat COVID-19, Health Canada issued a public advisory to inform Canadians that Ivermectin is not authorized to prevent or treat COVID-19 and may pose serious health risks: <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the sponsor of these ads removed them immediately, confirmed that these ads were no longer being disseminated and committed to refraining from engaging in this non-compliant act in the future.

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* and/or its Regulations, it takes steps to verify that non-compliance has occurred. Incidents of non-compliance are prioritised and action is taken based on the risk they may pose to the general public. It is the responsibility of companies to investigate incidents of potential non-compliance and to take appropriate action to correct non-compliance, mitigate any risk to health, and inform Health Canada as appropriate.

Any report of marketing that is false or misleading or do not meeting with the regulatory requirements can be reported to the department by following the information available at <https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/illegal-marketing/complaint.html>.

As part of its ongoing commitment to openness and transparency, Health Canada posts a [summary of health product advertising complaints](#) addressed by the Department.

Tasked to: HPCD, MHPD, VDD

Approved by:

Marilena Bassi, DG, VDD (approved)

Kelly Robinson, DG MHPD (approved Q2)

Linsey Hollet, DG HPCD (approved)

Eric Morrisette /Mark Johnson, Chief Media Relations (pending)

Julia Cropley, DG MCD (FYI)

Pam Aung-Thin, CPAB ADM (pending)

HPFB ADM (pending)

Stefania Trombetti, ROEB ADM (pending)

DMO (pending)

Pinard, Mike (HC/SC)

From: Robinson2, Kelly (HC/SC) <kelly.robinson2@canada.ca>
Sent: 2021-03-26 7:19 PM
To: Sun, Rong (HC/SC); Sommerer, Sophie (HC/SC)
Subject: RE: FYI - off label use of ivermectin

Thanks !

From: Sun, Rong (HC/SC) <rong.sun@canada.ca>
Sent: 2021-03-26 4:20 PM
To: Robinson2, Kelly (HC/SC) <kelly.robinson2@canada.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@canada.ca>
Subject: FYI - off label use of ivermectin

FYI. Megan wants to know. MPB did a quick/excellent summary of it.

From: Ferrier, Sylvie (HC/SC) <sylvie.ferrier@canada.ca>
Sent: 2021-03-26 4:03 PM
To: Graham, Brennan (HC/SC) <brennan.graham@canada.ca>
Cc: Irfan, Nashwa (HC/SC) <nashwa.irfan@canada.ca>; Sleno, Rory (HC/SC) <rory.sleno@canada.ca>; Soltys, Kathy (HC/SC) <kathy.soltys@canada.ca>; Sun, Rong (HC/SC) <rong.sun@canada.ca>
Subject: RE: Quick q - off label use of ivermectin

Hi Brennan,

The MPB has been monitoring this situation given recent related international communications.

Through our most recent search of the Canada Vigilance database, there have been **no** adverse drug reaction (ADR) cases for oral ivermectin tablets for human use (STROMECTOL) reported in Canada for the period of 01-Jan-2020 to 4-Mar-2021.

In that same timeframe, there have been 7 non-serious ADR cases for topical ivermectin cream for human use (ROSIVER) reported to the Canada Vigilance database. None of them reported COVID-19 (or related terms) as the indication. One of these cases was coded under the Preferred Terms (PT) Drug ineffective and PT Off-label use; however there were other suspect drugs co-reported in this case and the reported indication was "Rosacea". The relevance of topical use of ivermectin in the COVID-19 setting is limited.

The MPB has also attempted to retrieve data from provincial poison control centers for ivermectin use in the context of COVID-19, as ingestion of ivermectin products for veterinary use could be reported through this channel. Six (6) cases were identified meeting this criteria, 4 of which were without detail [REDACTED] with the center citing patient confidentiality, and 2 were retrieved from [REDACTED]. The cases from [REDACTED] were described as follows: 1) A young adult female that took 1-4 "cups" of ivermectin 0.8% (brand not recorded) and was asymptomatic 60 mins after exposure. She was referred to hospital but lost to follow-up. 2) An older male who was exposed to 1.5 mL of horse ivermectin purchased online for the prevention of COVID-19 and had a mild headache. He was seen at the ER and discharged.

Please let us know if you require more information or wish to discuss further.

Kind regards,

Sylvie
(she | elle)

Scientific Evaluator / Évaluatrice scientifique
Marketed Pharmaceuticals Bureau / Bureau des produits pharmaceutiques commercialisés
Marketed Health Products Directorate / Direction des produits de santé commercialisés
HPFB – Health Canada / DGPSA – Santé Canada
613-878-4727
sylvie.ferrier@canada.ca

From: Sun, Rong (HC/SC) <rong.sun@canada.ca>
Sent: 2021-03-26 3:10 PM
To: Graham, Brennan (HC/SC) <brennan.graham@canada.ca>
Cc: Irfan, Nashwa (HC/SC) <nashwa.irfan@canada.ca>; Sleno, Rory (HC/SC) <rory.sleno@canada.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@canada.ca>
Subject: FW: Quick q - off label use of ivermectin

Hi Brennan,

I am CCing my colleagues who may be able to help with answering your question.

Best,
RS

From: Graham, Brennan (HC/SC) <brennan.graham@canada.ca>
Sent: 2021-03-26 2:59 PM
To: Sun, Rong (HC/SC) <rong.sun@canada.ca>
Subject: RE: Quick q - off label use of ivermectin

Thanks for this, Rong.

I think the question Megan is looking to answer is have there been ADRs associated with ivermectin where COVID is mentioned? And if so, how many?

Please feel free to connect me with the appropriate group, if necessary to get these sorts of details.

Thank you!
Brennan

From: Sun, Rong (HC/SC) <rong.sun@canada.ca>
Sent: 2021-03-26 2:51 PM
To: Graham, Brennan (HC/SC) <brennan.graham@canada.ca>
Subject: RE: Quick q - off label use of ivermectin

Hi Brennan,

ADR# for a product may be obtained, but whether an ADR is for on- or off-label use could not be easily distinguished, as it requires us to dig into the report on the condition it was used to treat, if available. I know folks are monitoring poisoning and I am not aware of any reports yet.

That said, I have not checked with our people on this file. Please let me know if you would like to further explore this topic, if so, I can connect you with folks on this file.

Many thanks,
RS

From: Graham, Brennan (HC/SC) <brennan.graham@canada.ca>

Sent: 2021-03-26 2:16 PM

To: Sun, Rong (HC/SC) <rong.sun@canada.ca>

Subject: Quick q - off label use of ivermectin

Hi Rong,

I have a request that I am hoping you could help answer.

Megan is asking whether we have ADR #s on off label use of ivermectin? Would you be able to double check that for me or put in me in touch with who would have this figure?

Thank you!

Brennan Graham

COVID-19 Regulatory Response Team | Équipe d'intervention réglementaire de la COVID-19
Health Products and Food Branch | Direction générale des produits de santé et des aliments
613-406-4725

From: Wootton, Richard (HC/SC)
Sent: 2021-08-30 11:18 AM
To: [REDACTED]
 [REDACTED]
 [REDACTED] Austin, Michael (HC/SC; Bernardo, Kevin
(HC/SC; Bogeljik, Bojana (HC/SC; [REDACTED] Buch, Parag
(HC/SC; [REDACTED] Carruthers-Czyzewski, Patricia (HC/SC; Dobbin, Nina
(HC/SC; [REDACTED] Lezack, Lisa (HC/SC;
 [REDACTED]
 [REDACTED] Stothart, Tonja (HC/SC; Tam,
Ron (HC/SC; [REDACTED]
Cc: hc.chemtd-dgucht.sc@canada.ca; Sleno, Rory (HC/SC); Ferrier, Sylvie (HC/SC)
Subject: Have you managed cases associated with ivermectin for the treatment of COVID-19?

Importance: High

Good morning everyone,

Hoping you are well, you may have seen this CBC article published this morning regarding the use of veterinary ivermectin to treat COVID-19 (<https://www.cbc.ca/news/canada/calgary/ivermectin-alberta-covid-1.6157200>). The Health Products and Food Branch (HPFB) is in the process of preparing a risk communication to be issued on the topic. I am wondering if you have managed cases associated with ivermectin for the treatment of COVID-19 between March and August? And if you can disclose the number of cases to Health Canada? If additional information is required by HPFB we will prepare a formal data request.

All the best,

Richard

Richard Wootton
 Team Leader / Chef d'équipe
 Surveillance and Coordination Unit (SCU) / Unité de coordination et de surveillance
 Canadian Surveillance System for Poison Information (CSSPI) Initiative /
 Initiative du Système canadien de surveillance de l'information sur les poisons (SCSIP)

Chemical Emergency Management and Toxicovigilance Division (ChEMTD) /
 Division de la gestion des urgences chimiques et de la toxicovigilance (Division GUChT)
 Environmental Health Science and Research Bureau / Bureau de la science et de la recherche en santé environnementale
 HECS Branch/DGSESC, Health Canada / Santé Canada
 Ottawa, Ontario K1A 0K9

Cell: (613) 697-4837
 E-mail/courriel: richard.wootton@hc-sc.gc.ca

From: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>
Sent: 2021-08-30 10:43 AM
To: Wootton, Richard (HC/SC) <richard.wootton@hc-sc.gc.ca>
Cc: Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>
Subject: RE: Have you managed cases associated with ivermectin for the treatment of COVID-19?

Hi Richard,

I'm following-up on a previous request to Canadian Poison Control Centres you helped me with earlier this year regrading reports of poisoning associated with ivermectin.

A CBC article was published this morning regarding the use of veterinary ivermectin to treat COVID-19 (<https://www.cbc.ca/news/canada/calgary/ivermectin-alberta-covid-1.6157200>) and HPFB is in the process of preparing a risk communication to be issued on the topic.

I'm wondering if it would be possible to request current information on cases from the Poison Control Centres? This information would support any information requests following the publication of the risk communication.

Thanks,
Rory

Rory Sleno, PhD

Scientific Evaluator|Évaluateur Scientifique
Marketed Pharmaceuticals Bureau|Bureau des produits pharmaceutiques commercialisés
Marketed Health Product Directorate|Direction des produits de santé commercialisés
Health Canada|Santé Canada
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, K1A 0K9 - 1912B
Tel|Tél: +1(613)793-6303
Email|Courriel: rory.sleno@canada.ca

From: Wootton, Richard (HC/SC) <richard.wootton@canada.ca>

Sent: 2021-03-25 3:44 PM

To:

[REDACTED]; Austin, Michael (HC/SC) <michael.austin@canada.ca>;
Bernardo, Kevin (HC/SC) <kevin.bernardo@canada.ca>; Bogeljic, Bojana (HC/SC) <bojana.bogeljic@canada.ca>;
[REDACTED] Buch, Parag (HC/SC) <parag.buch@canada.ca>; [REDACTED] Carruthers-
Czyzewski, Patricia (HC/SC) <patricia.carruthers-czyzewski@canada.ca>; Dobbin, Nina (HC/SC) <nina.dobbin@canada.ca>;
[REDACTED] Lezack, Lisa (HC/SC)
<lisa.lezack@canada.ca>; [REDACTED] MacNeill, Morgan (HC/SC) <morgan.macneill@canada.ca>;
[REDACTED]; Perwaiz, Shahid (HC/SC) <shahid.perwaiz@canada.ca>;
Stothart, Tonja (HC/SC) <tonja.stothart@canada.ca>; Tam, Ron (HC/SC) <ron.tam@canada.ca>; Weiss, Deborah (HC/SC)
<deborah.weiss@canada.ca>; Yasseen, Abdool (HC/SC) <abdool.yasseen@canada.ca>
Cc: Duguay, David (HC/SC) <david.duguay@canada.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@canada.ca>; Irfan, Nashwa
(HC/SC) <nashwa.irfan@canada.ca>; Sleno, Rory (HC/SC) <rory.sleno@canada.ca>; Regimbald-Krnel, Michele (HC/SC)
<michele.regimbald-krnel@canada.ca>; Sokolowski, Danny (HC/SC) <danny.sokolowski@canada.ca>
Subject: RE: Have you managed cases associated with ivermectin for the treatment of COVID-19?

Good afternoon,

On behalf of the Marketed Health Products Directorate I would like to pass along a thank you to all poison centres. The information that you have provided is extremely useful.

Have a wonderful day, all the best.

Richard

Richard Wootton
Team Leader / Chef d'équipe
Surveillance and Coordination Unit (SCU) / Unité de coordination et de surveillance
Canadian Surveillance System for Poison Information (CSSPI) Initiative /
Initiative du Système canadien de surveillance de l'information sur les poisons (SCSIP)

Chemical Emergency Management and Toxicovigilance Division (ChEMTD) /
Division de la gestion des urgences chimiques et de la toxicovigilance (Division GUCHT)

Environmental Health Science and Research Bureau / Bureau de la science et de la recherche en santé environnementale
HECS Branch/DGSESC, Health Canada / Santé Canada
Ottawa, Ontario K1A 0K9

Cell: (613) 697-4837

E-mail/courriel: richard.wootton@canada.ca

From: [REDACTED]
Sent: 2021-03-24 12:42 PM
To: [REDACTED] Wootton, Richard (HC/SC) <richard.wootton@canada.ca>; [REDACTED]
[REDACTED]
[REDACTED] Austin, Michael (HC/SC) <michael.austin@canada.ca>;
Bernardo, Kevin (HC/SC) <kevin.bernardo@canada.ca>; Bogeljic, Bojana (HC/SC) <bojana.bogeljic@canada.ca>;
[REDACTED] Buch, Parag (HC/SC) <parag.buch@canada.ca>; Caitlin.wolfe@dal.ca; Carruthers-
Czyzewski, Patricia (HC/SC) <patricia.carruthers-czyzewski@canada.ca>; Dobbin, Nina (HC/SC) <nina.dobbin@canada.ca>;
[REDACTED] Lezack, Lisa (HC/SC)
<lisa.lezack@canada.ca>; [REDACTED] MacNeill, Morgan (HC/SC) <morgan.macneill@canada.ca>;
[REDACTED]
[REDACTED]; Perwaiz, Shahid (HC/SC) <shahid.perwaiz@canada.ca>;
Stothart, Tonja (HC/SC) <tonja.stothart@canada.ca>; Tam, Ron (HC/SC) <ron.tam@canada.ca>; Weiss, Deborah (HC/SC)
<deborah.weiss@canada.ca>; Yasseen, Abdool (HC/SC) <abdool.yasseen@canada.ca>
Cc: Duguay, David (HC/SC) <david.duguay@canada.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@canada.ca>; Irfan, Nashwa
(HC/SC) <nashwa.irfan@canada.ca>; Sleno, Rory (HC/SC) <rory.sleno@canada.ca>
Subject: RE: Have you managed cases associated with ivermectin for the treatment of COVID-19?

Richard,

We have had at least 3 cases of people using for COVID.

[REDACTED]

Requester agreed to
Remove 3rd Party Info

From: [REDACTED]
Sent: Wednesday, March 24, 2021 5:51 AM
To: 'Wootton, Richard (HC/SC)'; [REDACTED]
[REDACTED] Austin, Michael (HC/SC); Bernardo, Kevin (HC/SC); Bogeljic, Bojana
(HC/SC); [REDACTED] Carruthers-Czyzewski, Patricia
(HC/SC); Dobbin, Nina (HC/SC); [REDACTED]
[REDACTED] MacNeill, Morgan (HC/SC);
[REDACTED]

[REDACTED] Perwaiz, Shahid (HC/SC);
Stothart, Tonja (HC/SC); Tam, Ron (HC/SC); Weiss, Deborah (HC/SC); Yasseen, Abdool (HC/SC)
Cc: Duguay, David (HC/SC); Ferrier, Sylvie (HC/SC); Irfan, Nashwa (HC/SC); Sleno, Rory (HC/SC)
Subject: RE: Have you managed cases associated with ivermectin for the treatment of COVID-19?

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Just looked through [REDACTED] have not had any cases as described below.

The last cases was an unintentional dermal exposure to Revolution for cats in December 2020.

If there is another code [REDACTED] please let me know and I will do a search

From: Wootton, Richard (HC/SC) [<mailto:richard.wootton@canada.ca>]

Sent: Tuesday, March 23, 2021 4:01 PM

To: [REDACTED]

[REDACTED] Austin, Michael (HC/SC) <michael.austin@canada.ca>;
Bernardo, Kevin (HC/SC) <kevin.bernardo@canada.ca>; Bogeljic, Bojana (HC/SC) <bojana.bogeljic@canada.ca>;
[REDACTED] Buch, Parag (HC/SC) <parag.buch@canada.ca>; [REDACTED]
[REDACTED]; Dobbin, Nina (HC/SC) <nina.dobbin@canada.ca>;
[REDACTED]
[REDACTED] Lezack, Lisa (HC/SC) <lisa.lezack@canada.ca>; [REDACTED]
MacNeill, Morgan (HC/SC) <morgan.macneill@canada.ca>; [REDACTED]

[REDACTED]; Perwaiz, Shahid (HC/SC) <shahid.perwaiz@canada.ca>; Stothart, Tonja (HC/SC) <tonja.stothart@canada.ca>; Tam, Ron (HC/SC) <ron.tam@canada.ca>; Weiss, Deborah (HC/SC) <deborah.weiss@canada.ca>; Yasseen, Abdool (HC/SC) <abdool.yasseen@canada.ca>

Cc: Duguay, David (HC/SC) <david.duguay@canada.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@canada.ca>; Irfan, Nashwa (HC/SC) <nashwa.irfan@canada.ca>; Sleno, Rory (HC/SC) <rory.sleno@canada.ca>

Subject: Have you managed cases associated with ivermectin for the treatment of COVID-19?

**** EXTERNAL EMAIL / COURRIEL EXTERNE ****

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Good afternoon,

Hoping you are well, wondering if I could ask you to have a quick look to see if you have managed cases involving ivermectin for the treatment of COVID-19?

The Marketed Health Products Directorate (MHPD) identified a risk communication issued by the FDA on 05 March 2021 recommending against the use of ivermectin (antiparasitic agent) for the treatment of COVID-19 (<https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>) . The communication noted multiple reports of patients who have required medical support and been hospitalized after self-medicating with ivermectin intended for horses. They are now trying to determine whether there is a similar risk of harm in Canada.

Requester agreed to
Remove 3rd Party Info

Also on a separate topic reference the easy to swallow acetaminophen tablets, [REDACTED] is in the process of identifying product codes and we are scheduling a call between MHPD and CAPQ to learn more about how the exposures occurred and the factors that contributed to them. Following this discussion we will set up a follow up meeting to discuss next steps with respect to this issue.

Thank you for your ongoing support, all the best.

Richard

Richard Wootton
Team Leader / Chef d'équipe
Surveillance and Coordination Unit (SCU) / Unité de coordination et de surveillance
Canadian Surveillance System for Poison Information (CSSPI) Initiative /
Initiative du Système canadien de surveillance de l'information sur les poisons (SCSIP)

Chemical Emergency Management and Toxicovigilance Division (ChEMTD) /
Division de la gestion des urgences chimiques et de la toxicovigilance (Division GUChT)
Environmental Health Science and Research Bureau / Bureau de la science et de la recherche en santé environnementale
HECS Branch/DGSESC, Health Canada / Santé Canada
Ottawa, Ontario K1A 0K9

Cell: (613) 697-4837
E-mail/courriel: richard.wootton@canada.ca

	A	B	C	D	E	F	G	H	I	J	K	L
1	PivotTable1											
2	CDH CompuScript		Calendar Month									
3			Aug 2015	Sep 2015	Oct 2015	Nov 2015	Dec 2015	Jan 2016	Feb 2016	Mar 2016	Apr 2016	May 2016
4	Molecule	Product Full Name										
5	IVERMECTIN	ROSIVER : GLD : 07/15	1,338	1,757	2,246	1,855	1,741	1,718	2,034	2,174	2,479	2,748
6		STROMECTOL : M-F : 11/18	-	-	-	-	-	-	-	-	-	-
7	IVERMECTIN Subtotal		1,338	1,757	2,246	1,855	1,741	1,718	2,034	2,174	2,479	2,748
8	Grand Total		1,338	1,757	2,246	1,855	1,741	1,718	2,034	2,174	2,479	2,748
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ROSIVER

Series1 Series2

	M	N	O	P	Q	R	S	T	U	V	W	X	Y
1													
2											Calendar Month		
3	Jun 2016	Jul 2016	Aug 2016	Sep 2016	Oct 2016	Nov 2016	Dec 2016	Jan 2017	Feb 2017	Mar 2017	Apr 2017	May 2017	Jun 2017
4													
5	2,692	2,402	2,416	2,442	2,662	2,927	2,898	2,755	2,782	3,228	3,221	3,577	3,467
6	-	-	-	-	-	-	-	-	-	-	-	-	-
7	2,692	2,402	2,416	2,442	2,662	2,927	2,898	2,755	2,782	3,228	3,221	3,577	3,467
8	2,692	2,402	2,416	2,442	2,662	2,927	2,898	2,755	2,782	3,228	3,221	3,577	3,467
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STROMECTOL

Month	Sales (Series1)
Nov 2018	100
Dec 2018	250
Jan 2019	350
Feb 2019	250
Mar 2019	250
Apr 2019	450
May 2019	500
Jun 2019	450
Jul 2019	550
Aug 2019	950
Sep 2019	650
Oct 2019	750
Nov 2019	950
Dec 2019	500
Jan 2020	450
Feb 2020	450
Mar 2020	650
Apr 2020	550
May 2020	550
Jun 2020	550
Jul 2020	550
Aug 2020	550
Sep 2020	550
Oct 2020	550
Nov 2020	750
Dec 2020	1050
Jan 2021	1400
Feb 2021	1000
Mar 2021	1300
Apr 2021	1200
May 2021	800
Jun 2021	900
Jul 2021	800

	Z	AA	AB	AC	AD	AE	AF	AG	AH	AI	AJ	AK	AL	AM	AN	AO	AP	AQ
1																		
2	Calendar Mon																	
3	Jul 2017	Aug 2017	Sep 2017	Oct 2017	Nov 2017	Dec 2017	Jan 2018	Feb 2018	Mar 2018	Apr 2018	May 2018	Jun 2018	Jul 2018	Aug 2018	Sep 2018	Oct 2018	Nov 2018	Dec 2018
4																		
5	2,951	3,184	3,314	3,622	3,768	3,705	3,721	3,722	4,444	4,223	4,454	4,270	3,889	3,757	3,805	4,534	4,645	4,437
6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	91	248
7	2,951	3,184	3,314	3,622	3,768	3,705	3,721	3,722	4,444	4,223	4,454	4,270	3,889	3,757	3,805	4,534	4,736	4,685
8	2,951	3,184	3,314	3,622	3,768	3,705	3,721	3,722	4,444	4,223	4,454	4,270	3,889	3,757	3,805	4,534	4,736	4,685
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2	th																	
3	Jan 2019	Feb 2019	Mar 2019	Apr 2019	May 2019	Jun 2019	Jul 2019	Aug 2019	Sep 2019	Oct 2019	Nov 2019	Dec 2019	Jan 2020	Feb 2020	Mar 2020	Apr 2020	May 2020	Jun 2020
4																		
5	4,584	4,457	5,179	5,315	5,730	5,080	5,114	4,572	4,775	5,409	5,591	5,491	5,333	5,333	5,928	4,804	4,713	4,888
6	345	254	269	440	493	414	526	947	618	705	931	473	440	458	625	495	540	502
7	4,929	4,711	5,448	5,755	6,223	5,494	5,640	5,519	5,393	6,114	6,522	5,964	5,773	5,791	6,553	5,299	5,253	5,390
8	4,929	4,711	5,448	5,755	6,223	5,494	5,640	5,519	5,393	6,114	6,522	5,964	5,773	5,791	6,553	5,299	5,253	5,390
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1														
2	Calendar Month													
3	Jul 2020	Aug 2020	Sep 2020	Oct 2020	Nov 2020	Dec 2020	Jan 2021	Feb 2021	Mar 2021	Apr 2021	May 2021	Jun 2021	Jul 2021	Grand Total
4														
5	4,452	4,092	4,556	4,945	4,902	5,289	4,825	4,768	5,838	5,502	5,527	5,281	4,582	284,859
6	547	506	502	572	736	1,072	1,393	978	1,277	1,171	760	884	773	20,985
7	4,999	4,598	5,058	5,517	5,638	6,361	6,218	5,746	7,115	6,673	6,287	6,165	5,355	305,844
8	4,999	4,598	5,058	5,517	5,638	6,361	6,218	5,746	7,115	6,673	6,287	6,165	5,355	305,844
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1	PivotTable1							
2	CDH CompuScript		Calendar Quarter					
3			CQTR 2018/03	CQTR 2018/06	CQTR 2018/09	CQTR 2018/12	CQTR 2019/03	CQTR 2019/06
4	Molecule	Product Full Name	Total Prescriptions	Total Prescriptions	Total Prescriptions	Total Prescriptions	Total Prescriptions	Total Prescriptions
5	IVERMECTIN	ROSIVER : GLD : 07/15	11,887	12,947	11,451	13,616	14,220	16,125
6		STROMECTOL : M-F : 11/18	-	-	-	339	868	1,347
7	IVERMECTIN Subtotal		11,887	12,947	11,451	13,955	15,088	17,472
8	Grand Total		11,887	12,947	11,451	13,955	15,088	17,472

	I	J	K	L	M	N	O	P
1								
2								
3	CQTR 2019/09	CQTR 2019/12	CQTR 2020/03	CQTR 2020/06	CQTR 2020/09	CQTR 2020/12	CQTR 2021/03*	Grand Total
4	Total Prescriptions	Total Prescriptions	Total Prescriptions	Total Prescriptions	Total Prescriptions	Total Prescriptions	Total Prescriptions	Total Prescriptions
5	14,461	16,491	16,594	14,405	13,100	15,136	4,825	175,258
6	2,091	2,109	1,523	1,537	1,555	2,380	1,393	15,142
7	16,552	18,600	18,117	15,942	14,655	17,516	6,218	190,400
8	16,552	18,600	18,117	15,942	14,655	17,516	6,218	190,400

PivotTable1

CDH CompuScript		Calendar Year							
		YEAR 2015*	YEAR 2016	YEAR 2017	YEAR 2018	YEAR 2019	YEAR 2020	YEAR 2021*	Grand Total
Molecule	Product Full Name	Total Prescriptions	Total Prescriptions	Total Prescriptions	Total Prescriptions	Total Prescriptions	Total Prescriptions	Total Prescriptions	Total Prescriptions
IVERMECTIN	ROSIVER : GLD : 07/15	8,937	29,592	39,574	49,901	61,297	59,235	36,323	284,859
	STROMEKTOL : M-F : 11/18	-	-	-	339	6,415	6,995	7,236	20,985
IVERMECTIN Subtotal		8,937	29,592	39,574	50,240	67,712	66,230	43,559	305,844
Grand Total		8,937	29,592	39,574	50,240	67,712	66,230	43,559	305,844

From: Truong, Jenny (HC/SC)
Sent: 2021-09-15 3:39 PM
To: Badenduck, Lucas (HC/SC); Chang, Vivian (HC/SC); Corrin, Raymond (HC/SC); Dinakaran, Deborah (HC/SC); Djelouah, Ilhemme (HC/SC); Keene, Daniel (HC/SC); Kurichh, Alka I (HC/SC); Lacroix, Jeremie (HC/SC); Lefebvre, Larissa (HC/SC); Legare, Carole (HC/SC); Leonard, Michael (HC/SC); Long, Trisha (HC/SC); MacKay, Ian (HC/SC); Pham, Co (HC/SC); Piecha, Maryanne (HC/SC); Tang, Jessica (HC/SC); Tang, Marianne (HC/SC); Zhou, Jennifer (HC/SC)
Subject: Issues: September 15, 2021
Attachments: Issues Summary 2021-09-15.pdf

Good afternoon,

Please see this week's SAP Issues meeting report attached.

Regards,

Jenny

- 1) The evidence available continues to be quite limited due to methodological issues. To date, there are approximately 18 RCTs conducted including about 2100 participants, most are small in size and are of limited quality (high risk of bias). There is a recent Cochrane systemic review that summarizes this information. Conclusions reliable evidence available does not support the use of ivermectin for treatment or prevention of COVID-19 outside of well-designed randomized trials.
- 2) The ivermectin literature is in flux. A few of the early studies have been recently scrutinized and retracted and/or are being revised due to fraud allegations. Debate is ongoing regarding inclusion/correction of these studies in meta-analyses.
- 3) To date, studies generally do not report any safety concerns beyond those related to COVID-19 progression.
- 4) There are no completed or ongoing Canadian clinical trials for ivermectin in COVID-19.
- 5) There are several ongoing trials worldwide. Large PRINCIPLE (5000) and TOGETHER (1500) trials include the study of ivermectin. The Cochrane systemic review (July 28, 2021) identified nearly 50 studies that were ongoing, requiring clarification or publication.

More to come in terms of data, but again, these studies are mainly focusing on the investigation of ivermectin to prevent or treat COVID-19; for our purposes, there is no strong focus on safety at this point beyond COVID-19 progression. These studies are not relevant to the risk of self-directed use of large concentrations/veterinary formulations (e.g., overdosage).

Social media. Emily Lawrence. BSEIMS.

Pinard, Mike (HC/SC)

From: Robinson, Kelly (HC/SC)
Sent: 2021-09-02 6:44 PM
To: Bombardier, Manon (HC/SC)
Subject: FW: Ivermectin - Advisory

Good evening Manon,

As discussed, in addition to the targeted distribution by VDD and CPAB, the Ivermectin PA was distributed via our medeffect list serve - which goes out to over 29,000 subscribers.

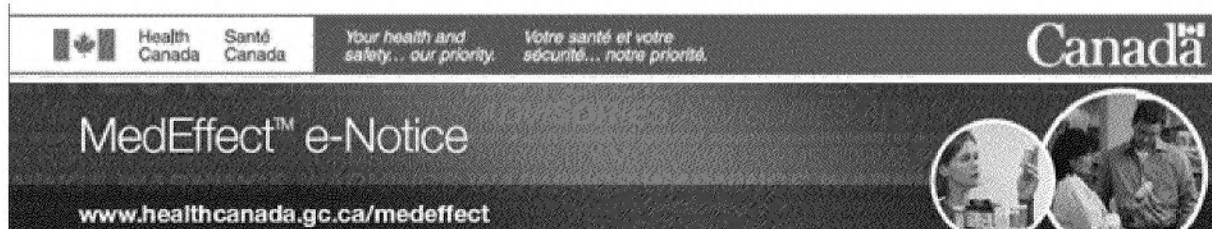
I note that the advisory was picked up by Ottawa Public Health -
<https://mobile.twitter.com/OttawaHealth/status/1432854427652743168>
(the phrase we discussed - You are not a horse. You are not a cow.- comes from the FDA's tweet on this issue
https://mobile.twitter.com/US_FDA/status/1429050070243192839)

I will follow up with our team to see if we have any previous safety reviews on ivermectin.

I will also ask the team to reach out to poison control centres to see if they have received any reports related to use of ivermectin to treat or prevent COVID-19.

Thanks, Kelly

From: medeffect-notice_avis-medeffet@hc-sc.gc.ca <medeffect-notice_avis-medeffet@hc-sc.gc.ca>
Sent: 2021-08-31 7:50 PM
To: MEDEFFECT@LIST.HC-SC.GC.CA
Subject: Ivermectin - Advisory



As a subscriber to Health Canada's MedEffect™ e-Notice, you are being informed of the latest Advisory.
<http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>

Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems

Health Canada has received concerning reports of the use of veterinary ivermectin to prevent or treat COVID-19. Canadians should never consume health products intended for animals because of the potential serious health dangers posed by them.

In this light, Health Canada is advising Canadians not to use either the veterinary or human drug versions

of Ivermectin to prevent or treat COVID-19. There is no evidence that ivermectin in either formulation is safe or effective when used for those purposes. The human version of ivermectin is authorized for sale in Canada only for the treatment of parasitic worm infections in people.

You can report any suspected adverse reactions to drugs and other health products to the Canada Vigilance Program by visiting the [Adverse Reaction and Medical Device Problem Reporting](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) page.
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

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Pinard, Mike (HC/SC)

From: Irfan, Nashwa (HC/SC)
Sent: 2021-09-02 8:52 PM
To: Robinson, Kelly (HC/SC)
Cc: Derry, Mélanie (HC/SC); Sommerer, Sophie (HC/SC)
Subject: RE: Ivermectin - Advisory
Attachments: Ivermectin and COVID-19_2021-08-31.docx

Hi Kelly,

Please find the summary document attached as well as some high level bullets below. Please let us know if you need any additional information..

Thanks
Nash

- CBC published 2 articles on 30 August 2021 reporting on increased demand for veterinary ivermectin in Albert and BC for the treatment of COVID-19. In response to this trigger, Health Canada published a PA on 31 August 2021 to educate on the lack of evidence supporting effectiveness/safety of ivermectin for the treatment of COVID-19 and warning about the danger of using veterinary ivermectin in humans (ROEB lead).
 - MPB was following this issue since early 2021 following communications advising against the use of ivermectin for COVID-19 outside of clinical trials by the FDA, EMA, WHO, and Merck (MAH of Stromectol, oral tablet for human use). At the time there was limited evidence that this was an issue in Canada.
- In March 2021, MPB reached out to Canadian Poison Control Centres to identify possible cases in Canada (6 cases identified with veterinary products from the Centres covering [REDACTED]). For the cases that provided some detailed information, the outcomes were non-serious (mild-headache reported in 1 case).
 - A follow-up on 30 August 2021 with the Centres for data since March 2021 identified 11 cases in [REDACTED] associated with ivermectin but details on reason for exposure (i.e., to treat COVID-19) and about the product (human vs. veterinary) were not provided. Responses have been received for [REDACTED] - still awaiting responses from the remaining Centres.
- A search of the Canada Vigilance database up to 29 August 2021 identified 94 case reports. Of these cases, 8 were received in 2020 and 2021 (4 each year). All 8 cases were associated with Rosiver (a topical formulation for humans) and the indication was reported as rosacea for all except 1 case (product used for unknown indication). The PTs reported for the single case not noting a rosacea indication were PT Rosacea and PT condition aggravated.
- IQVIA prescription data for human ivermectin products up to July 2021 did not identify a clear trend for increased prescription during 2020/2021 compared to before the pandemic.

From: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Sent: 2021-09-02 8:04 PM

To: Irfan, Nashwa (HC/SC) <nashwa.irfan@hc-sc.gc.ca>

Cc: Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>

Subject: RE: Ivermectin - Advisory

Thanks Nash, Kelly

From: Irfan, Nashwa (HC/SC) <nashwa.irfan@hc-sc.gc.ca>

Sent: 2021-09-02 7:04 PM

To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>

Cc: Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>

Subject: Re: Ivermectin - Advisory

Hi Kelly,

Yes will do. Our folks did a screening on this some time ago and have kept a running document. They had also followed up with the Poison Control Centres. I will ask them to provide the document as well as some high level bullets.

Thanks

Nash

Sent from my iPhone

On Sep 2, 2021, at 6:46 PM, Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca> wrote:

Hi team,

Please see my email to Manon below - can we follow up on the highlighted items? Thanks, Kelly

From: Robinson, Kelly (HC/SC)

Sent: 2021-09-02 6:44 PM

To: Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>

Subject: FW: Ivermectin - Advisory

Good evening Manon,

As discussed, in addition to the targeted distribution by VDD and CPAB, the Ivermectin PA was distributed via our medeffect list serve - which goes out to over 29,000 subscribers.

I note that the advisory was picked up by Ottawa Public Health -

<https://mobile.twitter.com/OttawaHealth/status/1432854427652743168>

(the phrase we discussed - You are not a horse. You are not a cow.- comes from the FDA's tweet on this issue https://mobile.twitter.com/US_FDA/status/1429050070243192839)

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I will also ask the team to reach out to poison control centres to see if they have received any reports related to use of ivermectin to treat or prevent COVID-19.

Thanks, Kelly

From: medeffect-notice_avis-medeffet@hc-sc.gc.ca <medeffect-notice_avis-medeffet@hc-sc.gc.ca>
Sent: 2021-08-31 7:50 PM
To: MEDEFFECT@LIST.HC-SC.GC.CA
Subject: Ivermectin - Advisory

<19539764.jpg>

As a subscriber to Health Canada's MedEffect™ e-Notice, you are being informed of the latest Advisory.

<http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>

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In this light, Health Canada is advising Canadians not to use either the veterinary or human drug versions of Ivermectin to prevent or treat COVID-19. There is no evidence that ivermectin in either formulation is safe or effective when used for those purposes. The human version of ivermectin is authorized for sale in Canada only for the treatment of parasitic worm infections in people.

You can report any suspected adverse reactions to drugs and other health products to the Canada Vigilance Program by visiting the [Adverse Reaction and Medical Device Problem Reporting](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) page.
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 March 2021
EMA/153588/2021

**EMBARGO – DO NOT PUBLISH BEFORE
MONDAY, 22 MARCH 2021, 14:00 HRS CET**

EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials

EMA has reviewed the latest evidence on the use of ivermectin for the prevention and treatment of COVID-19 and concluded that the available data do not support its use for COVID-19 outside well-designed clinical trials.

In the EU, ivermectin tablets are approved for treating some parasitic worm infestations while ivermectin skin preparations are approved for treating skin conditions such as rosacea. Ivermectin is also authorised for veterinary use for a wide range of animal species for internal and external parasites.

Ivermectin medicines are not authorised for use in COVID-19 in the EU, and EMA has not received any application for such use.¹

Following recent media reports and publications on the use of ivermectin, EMA reviewed the latest published evidence from laboratory studies, observational studies, clinical trials and meta-analyses. Laboratory studies found that ivermectin could block replication of SARS-CoV-2 (the virus that causes COVID-19), but at much higher ivermectin concentrations than those achieved with the currently authorised doses. Results from clinical studies were varied, with some studies showing no benefit and others reporting a potential benefit. Most studies EMA reviewed were small and had additional limitations, including different dosing regimens and use of concomitant medications. EMA therefore concluded that the currently available evidence is not sufficient to support the use of ivermectin in COVID-19 outside clinical trials.

Although ivermectin is generally well tolerated at doses authorised for other indications, side effects could increase with the much higher doses that would be needed to obtain concentrations of ivermectin in the lungs that are effective against the virus. Toxicity when ivermectin is used at higher than approved doses therefore cannot be excluded.

¹ Czechia and Slovakia, have allowed the temporary use of the medicine for COVID-19 within the remit of their national legislation.



EMA therefore concluded that use of ivermectin for prevention or treatment of COVID-19 cannot currently be recommended outside controlled clinical trials. Further well-designed, randomised studies are needed to draw conclusions as to whether the product is effective and safe in the prevention and treatment of COVID-19.

This EMA public health statement has been endorsed by the [COVID-19 EMA pandemic Task Force](#) (COVID-ETF), in light of the ongoing discussions on the use of ivermectin in the prevention and treatment of COVID-19.

References

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Pinard, Mike (HC/SC)

From: Robinson, Kelly (HC/SC)
Sent: 2021-09-03 4:45 PM
To: Superle, Tamy (HC/SC)
Cc: Smith, Melissa (HC/SC); Derry, Mélanie (HC/SC)
Subject: RE: ivermectin

Hi Tammy, just to confirm, I am only commenting on the MHPD info - some small tweaks suggested here.
I will reach out if/when I get an update on the billboard advert. Thanks, Kelly

- MHPD is continuing to monitor this issue, including scanning literature, requesting data from Canadian Poison Control Centres and monitoring the Canada Vigilance database, to inform additional measures as required.

From: Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>
Sent: 2021-09-03 4:18 PM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Cc: Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>
Subject: ivermectin

Hi Kelly,

I have pulled together some updates for Manon to send to the AsDM. Can you please review as soon as you're able to ensure that I've accurately represented what you've done and are doing on ivermectin. Thanks!

Actions to date:

- Follow-up meeting was held today between CPAB and HFPB to updated and discuss further outreach measures.
- CFIA have retweeted HC's message.
- MHPD is monitoring this issue, including working with Canadian Poison Control Centres and searching the Canada Vigilance database to inform additional measures as required.
- CFIA and VDD met with the Council of Chief Veterinary Officers (CCVO) on Sept 3. The meeting had good jurisdictional representation and members expressed that they were using and sharing the PA widely to a diverse group of stakeholders, including retail stores. There were no requests for additional GoC support made.
- The metrics on the public advisory and the tweet are very good indicating that the message is being seem and shared.

Next steps:

- CPAB is developing a robust social media messages on this issue.
- Exploring how CPHO social media could be leveraged.
- CVMA will be sending a letter (authored by HC) to their members regarding the risks of ivermectin use the week of September 6. CVMA will also including information about the PA in their e-newsletter.
- CPAB is engaging with the FPT Public Health Network Comms Working Group to possibly put this item on their next weekly meeting (scheduled from Wednesday September 8th) for additional P/T engagement and amplifying of messages.

- In response to Ivermectin being advertised as a treatment/prevention for COVID-19 on a billboard in Manitoba, ROEB is working with HPFB to send a regulatory letter to the advertiser to direct that all non-compliant signage be removed. Additional action will be taken should the advertiser not comply.

Tamy Superle, PhD

A/Senior Advisor | Conseillère principale par intérim
Office of the Assistant Deputy Minister | Bureau du sous-ministre adjoint
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
Tamy.superle@hc-sc.gc.ca | 343-553-1415

From: MacKay, Ian (HC/SC)
Sent: 2021-07-17 10:55 PM
To: Legare, Carole (HC/SC)
Cc: Keene, Daniel (HC/SC)
Subject: Ivermectin

Follow Up Flag: Follow up
Flag Status: Flagged

<https://www.theguardian.com/science/2021/jul/16/huge-study-supporting-ivermectin-as-covid-treatment-withdrawn-over-ethical-concerns>

Sent from my iPhone

Pinard, Mike (HC/SC)

From: Robinson, Kelly (HC/SC)
Sent: 2021-09-04 8:17 AM
To: Berg, Jason (HC/SC)
Cc: Musende, Alain (HC/SC); Derry, Mélanie (HC/SC); Sommerer, Sophie (HC/SC); Rahim, Hamida (HC/SC)
Subject: Re: ivermectin ad / billboard

Thank you Jason and team. Best, Kelly

Kelly Robinson
 MHPD

On Sep 3, 2021, at 8:21 PM, Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca> wrote:

Hi Kelly,
 I got the following updates from STARS on the Ivermectin signage concern:

- We carried out a compliance assessment of the Ivermectin case and we determined that it constitutes advertising of a health product to the public for the treatment of a Schedule A disease, in contravention of the *Food & Drugs Act*.
- Alain called [REDACTED] for Magnetsigns in Winkler, Manitoba on August 27, 2021 to discuss the case, inform them of Health Canada's position, request to immediately remove all signs with the contravening information and inform them that we are in the process of sending them a regulatory letter. Magnetsigns [REDACTED]
- We sent a regulatory letter to the representative for Magnetsigns in Winkler, Manitoba on August 31, 2021 requesting that Magnetsigns immediately acknowledges receipt of our correspondence and cease any advertising of Ivermectin or any other product in all media for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.
- Furthermore, we reached out to ROEB to discuss this case and checked if they can confirm whether the billboards in Winkler and area have been removed and they agreed to keep us posted.

I can ask the team about following up with ROEB next week and we'll let you know what we hear about the regional office checking into this.

Jason

From: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Sent: 2021-09-03 4:37 PM
To: Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca>; Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Cc: Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>; Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>
Subject: ivermectin ad / billboard

Hi, just wondering if I can get an update on the ivermectin billboard ad, and where we are with that?

Thanks, Kelly

Kelly Robinson

Director General Marketed Health Products Directorate / Directrice générale Direction des produits de santé commercialisés

kelly.robinson@hc-sc.gc.ca

PROTECTED B

March 26, 2021

Health Canada

Health Products and Food Branch

Ivermectin and COVID-19

- Ivermectin (brand name STROMEKTOL) is an antiparasitic drug approved by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMEKTOL has been marketed in Canada since 2018.
- Health Canada is monitoring all potential therapeutic treatments and vaccines in development in Canada and abroad, including products such as ivermectin that are being use outside of their authorized indication (off-label use), as potential treatments for COVID-19.
- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Health Canada has no jurisdiction over how health care professionals prescribe drugs once they are approved.
- Healthcare practitioners may prescribe drugs, including ivermectin, outside of their authorized indications (off-label use), based on other sources of information such as medical literature. Off-label use falls under the practice of medicine and is regulated at the provincial and territorial level.
- To date, Health Canada has not received any clinical trial application for studying the safety and efficacy of ivermectin for the prevention or treatment of COVID-19, and no ivermectin manufacturer has made an application for this drug to be approved for the treatment or prevention of COVID-19.
- On March 22, 2021, the European Medicines Agency issued a [statement](#) advising against the use of ivermectin for treatment or prevention of COVID-19 outside of clinical trials.
- The US FDA has also issued a similar [advisory](#) against the use of ivermectin
- Unusually, Merck, the manufacturer of STROMEKTAL, has also issued a [statement](#) discouraging use of their product for COVID-19, stating that there is:
 - “No scientific basis for a potential therapeutic effect against COVID-19 from pre-clinical studies;
 - No meaningful evidence for clinical activity or clinical efficacy in patients with COVID-19 disease, and;
 - A concerning lack of safety data in the majority of studies.”

Ivermectin for COVID-19 (human and veterinary product use in humans)

Trigger

Alberta CBC - <https://www.cbc.ca/news/canada/calgary/ivermectin-alberta-covid-1.6157200>

BC CBC - <https://www.cbc.ca/news/canada/british-columbia/b-c-feed-stores-see-increased-demand-for-livestock-dewormer-falsely-touted-as-covid-19-treatment-1.6158624>

A PA is being led by ROEB. A first draft was shared with MHPD at the end of the day yesterday and David provided comments that have gone up to DGO.

*This topic was previously discussed at the 13 April 2021 SP meeting following multiple communications in the media, by foreign regulators, and Merck. No further action was recommended at that time, as there was little evidence of the issue in Canada.

Foreign regulator communications

FDA

05 March 2021 – Why You Should Not Use Ivermectin to Treat or Prevent COVID-19

<https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>

26 April 2021 – FAQ: COVID-19 and Ivermectin Intended for Animals

<https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals>

21 August 2021 – Tweet “You are not a horse. You are not a cow. Seriously, y'all. Stop it.”

https://twitter.com/us_fda/status/1429050070243192839

EMA

22 March 2021 – EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials

<https://www.ema.europa.eu/en/news/ema-advises-against-use-ivermectin-prevention-treatment-covid-19-outside-randomised-clinical-trials>

TGA

23 August 2021 – Risks of importing Ivermectin for treatment of COVID-19/Ivermectin is not approved for the treatment of COVID-19/Beware of buying medicines from questionable websites

<https://www.tga.gov.au/media-release/risks-importing-ivermectin-treatment-covid-19>

MAH communications

Merck (Stromectol), 04 February 2021

- No scientific basis for a potential therapeutic effect against COVID-19 from pre-clinical studies;
- No meaningful evidence for clinical activity or clinical efficacy in patients with COVID-19 disease, and;
- A concerning lack of safety data in the majority of studies.

<https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/>

WHO communication

31 March 2021 - WHO advises that ivermectin only be used to treat COVID-19 within clinical trials

<https://www.who.int/news-room/feature-stories/detail/who-advises-that-ivermectin-only-be-used-to-treat-covid-19-within-clinical-trials>

Canadian Poison Control Centres

Six (6) cases were identified for veterinary ivermectin use in the context of COVID-19, 4 of which were without detail [REDACTED] with the center citing patient confidentiality, and 2 were retrieved from [REDACTED]. The cases from [REDACTED] were described as follows: 1) A young adult female that took 1-4 "cups" of ivermectin 0.8% (brand not recorded) and was asymptomatic 60 mins after exposure. She was referred to hospital but lost to follow-up. 2) An older male who was exposed to 1.5 mL of horse ivermectin purchased online for the prevention of COVID-19 and had a mild headache. He was seen at the ER and discharged.

Call for updated information from the PCCs went out 30 August 2021

- [REDACTED] replied on 30 August 2021 with no identified cases
- [REDACTED] replied on 31 August 2021 with 11 cases identified between 01 March and 30 August 2021
- [REDACTED] replied on 31 August 2021 with no identified cases

Requester agreed to
Remove 3rd Party Info



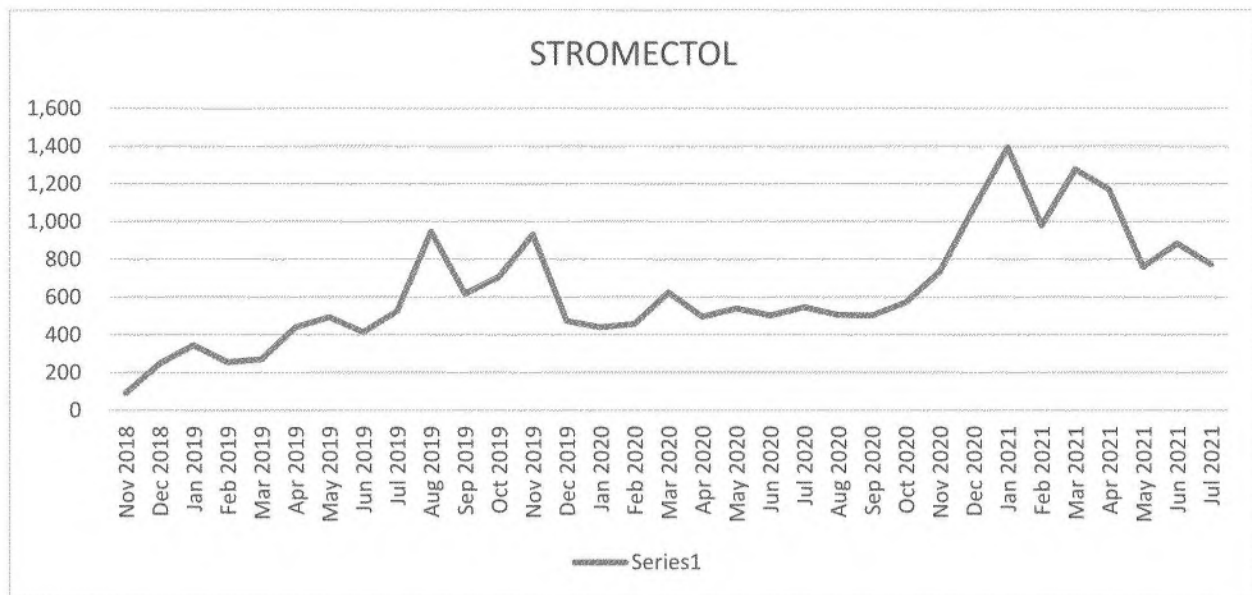
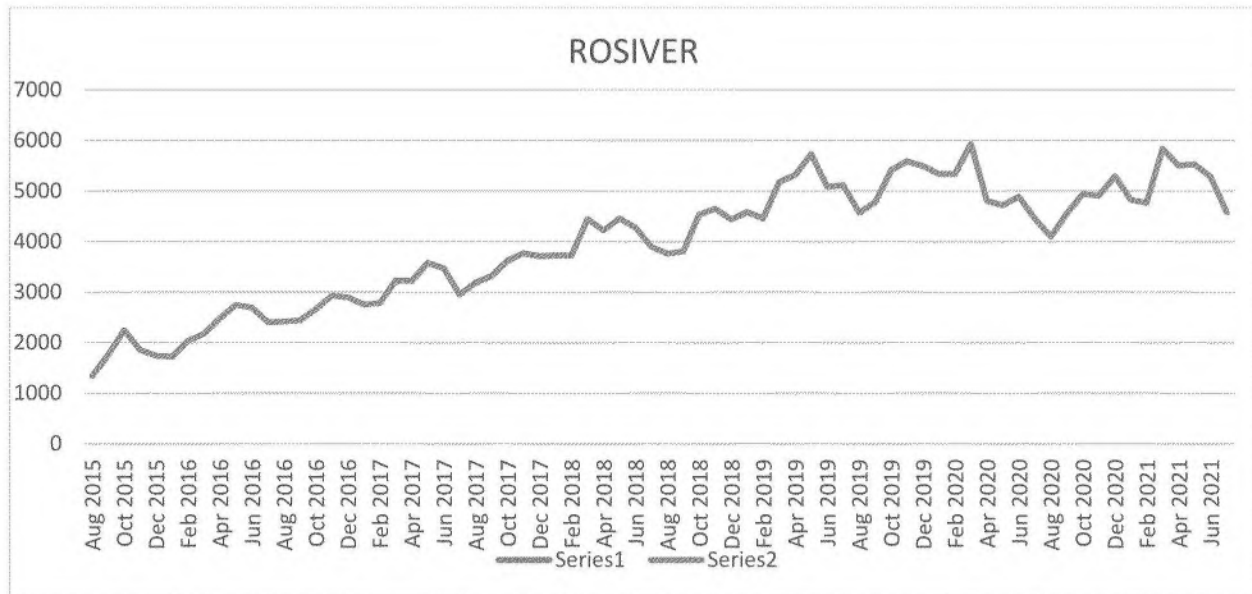
CV

HPSEB identified 94 case reports in CV for ivermectin up to 29 August 2021. Of these cases, 8 cases were received in 2020 and 2021 (4 each year). All cases were associated with Rosiver and the indication was reported as rosacea for all except 1 case (product used for unknown indication). The PTs reported for the single case not noting a rosacea indication were PT Rosacea and PT condition aggravated.

Of note, there were 2 cases in CV associated with EQVALAN ORAL PASTE FOR HORSES but they were from 1996 and 2001. Just to say, veterinary products may be captured in CV.

UPDATE 2021-10-07 for Canada Vigilance: A search of the CV database from 29 August 2021 to 07 October 2021 identified 1 case report. The case was associated with exposure to Stromectol (oral formulation of ivermectin for human use indicated for the treatment of intestinal strongyloidiasis and onchocerciasis) used for the reported off-label indication of infection parasitic. Review of the case narrative did not identify any reason to suspect ivermectin was used to treat COVID-19.

IQVIA



Anticipatory media lines
Ivermectin and treatment of COVID-19
23 March 2021

Risk communications were issued by the FDA¹ (05 March 2021) and the EMA² (22 March 2021) recommending against the use of ivermectin for the treatment of COVID-19. Both communications noted that there is currently an absence of robust scientific evidence supporting the use of ivermectin for the treatment of COVID-19 and that there are theoretical safety concerns associated with doses larger than those used for approved indications and that would be needed to obtain concentrations of ivermectin in the lungs that are effective against the virus. In addition, the FDA communication noted multiple reports of patients who have required medical support and been hospitalized after self-medicating with ivermectin intended for horses.

Ivermectin is marketed as 2 products for human use in Canada:

- Rosiver – topical cream indicated for rosacea
 - ~60,000 prescriptions in Canada in 2020
- Stromectol – oral tablet indicated for the treatment of parasitic infections
 - ~7,000 prescriptions in Canada in 2020

Additionally, there are currently 17 marketed veterinary products containing ivermectin listed on the Drug Product Database (3 prescription/14 OTC).

At this time, Health Canada is not aware of any cases of ivermectin poisoning associated with treatment of COVID-19 for products authorized for human or veterinary use in Canada.

Review of studies investigating the use of ivermectin for the treatment of COVID-19 are generally of low quality and there is limited information pertaining to safety.

¹ <https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>

² <https://www.ema.europa.eu/en/news/ema-advises-against-use-ivermectin-prevention-treatment-covid-19-outside-randomised-clinical-trials>

Ivermectin and treatment of COVID-19 13 April 2021

Risk communications were issued by the FDA¹ (05 March 2021), the EMA² (22 March 2021), and WHO³ (31 March 2021) recommending against the use of ivermectin for the treatment of COVID-19. All communications noted that there is currently an absence of robust scientific evidence supporting the use of ivermectin for the treatment of COVID-19 and that there are theoretical safety concerns associated with doses larger than those used for approved indications. Such high doses would be needed to obtain concentrations of ivermectin in the lungs that are effective against the virus. In addition, the FDA communication noted multiple reports of patients who have required medical support and been hospitalized after self-medicating with ivermectin intended for horses.

Ivermectin is marketed as 2 prescription products for human use in Canada:

- Rosiver – topical cream indicated for rosacea
 - ~60,000 prescriptions in Canada in 2020
- Stromectol – oral tablet indicated for the treatment of parasitic infections
 - ~7,000 prescriptions in Canada in 2020
 - Merck risk communication⁴ on 04 February 2021 for Stromectol and COVID-19

A request to VDD noted that there are three companies representing 18 veterinary drug products, containing ivermectin, marketed in Canada. Of these products, 3 are prescription and 15 OTC in a variety of dosage forms, indicated for horses, cattle, pigs, sheep, and dogs. Each company replied that there have been no adverse reactions reported for their products, apart from one report of a confirmed asymptomatic ingestion (accidental) of a small quantity of Panomec® Paste for Horses (Ivermectin 1.87%).

A search of the Canada Vigilance database, identified no adverse drug reaction (ADR) cases for oral ivermectin tablets for human use (STROMECTOL) reported in Canada for the period of 01-Jan-2020 to 4-Mar-2021.

In that same timeframe, there have been 7 non-serious ADR cases for topical ivermectin cream for human use (ROSIVER) reported to the Canada Vigilance database. None of them reported COVID-19 (or related terms) as the indication. One of these cases was coded under the Preferred Terms (PT) Drug ineffective and PT Off-label use; however there were other suspect drugs co-reported in this case and the reported indication was "Rosacea". The relevance of topical use of ivermectin in the COVID-19 setting is limited.

The MPB has also attempted to retrieve data from provincial poison control centers for ivermectin use in the context of COVID-19, as ingestion of ivermectin products for veterinary use could be reported through this channel. Six (6) cases were identified meeting this criteria, 4 of which were without detail [REDACTED], with the center citing patient confidentiality, and 2 were retrieved from [REDACTED]. The cases from [REDACTED] were described as follows: 1) A young adult female that took 1-4 "cups" of

¹ <https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>

² <https://www.ema.europa.eu/en/news/ema-advises-against-use-ivermectin-prevention-treatment-covid-19-outside-randomised-clinical-trials>

³ <https://www.who.int/news-room/feature-stories/detail/who-advises-that-ivermectin-only-be-used-to-treat-covid-19-within-clinical-trials>

⁴ <https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/>

ivermectin 0.8% (brand not recorded) and was asymptomatic 60 mins after exposure. She was referred to hospital but lost to follow-up. 2) An older male who was exposed to 1.5 mL of horse ivermectin purchased online for the prevention of COVID-19 and had a mild headache. He was seen at the ER and discharged.

Review of studies investigating the use of ivermectin for the treatment of COVID-19 are generally of low quality and there is limited information pertaining to safety.

From: Corrin, Raymond (HC/SC)
Sent: 2021-09-15 12:30 PM
To: Truong, Jenny (HC/SC); MacKay, Ian (HC/SC)
Subject: Ivermectin for Covid, DYK text

#nicht ivermectin
or
#rien d'ivermectin

Health Canada has not approved ivermectin for the treatment or prevention of COVID-19 in people or animals. Ivermectin has not been shown to be safe or effective for this indication. Much misinformation is circulating. Several regulators including Health Canada, FDA and EMA have issued warnings that it should be restricted to clinical trial use only. The Special Access Program will not be authorizing any requests.

21-000-893-877

HPFB INPUT

Standard response regarding the potential effectiveness of Ivermectin (brand name STROMECTOL), for the treatment of COVID-19 patients.

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug approved by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECTOL has been marketed in Canada since 2018.
- Health Canada is closely monitoring all potential therapeutic treatments and vaccines in development in Canada and abroad, including products such as ivermectin that are being used outside of their authorized indication (off-label use), as potential treatments for COVID-19.
- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Health Canada has no jurisdiction over how health care professionals prescribe drugs once they are approved.
- Healthcare practitioners may prescribe drugs, including ivermectin, outside of their authorized indications (off-label use), based on other sources of information such as medical literature. Off-label use falls under the practice of medicine and is regulated at the provincial and territorial level.
- However, at this time, no ivermectin manufacturer has made an application for this drug to be approved for the treatment or prevention of COVID-19. Therefore, the effectiveness of ivermectin as a therapeutic option for COVID-19 has not been evaluated by Health Canada.
- For drugs that have potential to be helpful in treating COVID-19, Health Canada encourages drug manufacturers to conduct clinical trials. This would provide an opportunity for the healthcare community to collect information on the effectiveness of the treatment and its associated risks. Evidence from well-designed studies is needed to determine whether ivermectin might be helpful in preventing or treating COVID-19.
- A list of all clinical trials approved for the prevention or treatment of COVID-19 can be found on Health Canada's website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-clinical-trials/list-authorized->

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trials.html

- In Canada, clinical trials for COVID-19 are facilitated under an Interim Order, which was signed by the Minister of Health on May 23, 2020:
<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/notice-interim-order.html>
- Clinical trials can be pursued by a range of sponsors, such as a drug manufacturer, an academic institution or research centre, or a physician. It should be noted that Health Canada does not actively conduct the research. For more information on how to submit a COVID-19 Clinical Trial, please refer to the following link: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/drug-guidance.html>
- To date, Health Canada has not received any clinical trial application for studying the safety and efficacy of ivermectin for the prevention or treatment of COVID-19. However, Health Canada is aware that such clinical trials may be planned or underway internationally.
- Following the clinical trial stage, companies can choose between two different authorization pathways for COVID-19-related drugs and vaccines: existing regulatory pathways outlined in the *Food and Drug Regulations* or the Interim Order pathway for COVID-19-related drugs and vaccines, which was signed by the Minister of Health and came into effect on September 16, 2020:
<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs/note.html>
- This interim order facilitates timely access for Canadians to drugs and vaccines that have demonstrated the ability to diagnose, prevent, treat or cure COVID-19. It introduces temporary regulations to expedite the authorization for importing, selling and advertising COVID-19-related drugs without compromising patient safety.
- Health Canada's position on ivermectin is aligned with that of other regulators. Ivermectin has not been approved by the U.S. Food and Drug Administration or the European Medicines Agency for the prevention or treatment of COVID-19.

Potential effectiveness of Ivermectin (brand name STROMEKTOL), for the treatment of COVID-19 patients.

RESPONSE

- Under the *Food and Drugs Act* and its regulations, every product sold or marketed in Canada and making a therapeutic claim must be approved by Health Canada as either a drug, a medical device or a natural health product. The drug authorization process is initiated when a manufacturer submits an application to Health Canada for review. Every drug submission is then reviewed by scientists to assess the product's safety, efficacy and quality. All drug products approved for sale in Canada are listed on the Drug Product Database, available at: <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>.
- Ivermectin (brand name STROMEKTOL) is an antiparasitic drug approved by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMEKTOL has been marketed in Canada since 2018.
- At this time, no ivermectin manufacturer has made an application for this drug to be approved for the treatment or prevention of COVID-19. Therefore, the effectiveness of ivermectin as a therapeutic option for COVID-19 has not been evaluated by Health Canada.
- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it has no jurisdiction over how health care professionals prescribe drugs once they are approved.
- Healthcare practitioners may prescribe drugs, including ivermectin, outside of their authorized indications (off-label use), based on other sources of information such as medical literature. Off-label use falls under the practice of medicine and is regulated at the provincial and territorial level.
- For drugs that have potential to be helpful in treating COVID-19, Health Canada encourages drug manufacturers to conduct clinical trials. This would provide an opportunity for the healthcare community to collect information on the effectiveness of the treatment and its associated risks.
- A list of all clinical trials approved for the prevention or treatment of COVID-19 can be found on Health Canada's website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-clinical-trials/list-authorized-trials.html>

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- In Canada, clinical trials for COVID-19 are facilitated under an Interim Order. Clinical trials can be pursued by a range of sponsors, such as a drug manufacturer, an academic institution or research centre, or a physician. It should be noted that Health Canada does not actively conduct the research. For more information on how to submit a COVID-19 Clinical Trials, please refer to the following link. <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/drug-guidance.html>

Pinard, Mike (HC/SC)

From: Robinson, Kelly (HC/SC)
Sent: 2021-09-03 7:13 AM
To: Bombardier, Manon (HC/SC)
Cc: Bassi, Marilena (HC/SC); Sommerer, Sophie (HC/SC)
Subject: RE: Ivermectin update

Good morning Manon,

The team has drafted some bullets below based on the MHPD work with Ivermectin. We do not have any specific safety reviews, but have been monitoring the information available in Canada. As we get additional responses from the poison control centers or any new relevant data in Canada Vigilance we will share this with Marilena.

Best, Kelly

- CBC published 2 articles on 30 August 2021 reporting on increased demand for veterinary ivermectin in Albert and BC for the treatment of COVID-19. In response to this trigger, Health Canada published a PA on 31 August 2021 to educate on the lack of evidence supporting effectiveness/safety of ivermectin for the treatment of COVID-19 and warning about the danger of using veterinary ivermectin in humans (ROEB lead).
- MHPD was following this issue since early 2021 following communications advising against the use of ivermectin for COVID-19 outside of clinical trials by the FDA, EMA, WHO, and Merck (MAH of Stromectol, oral tablet for human use). At the time there was limited evidence that this was an issue in Canada.
- In March 2021, MPB reached out to Canadian Poison Control Centres to identify possible cases in Canada (6 cases identified with veterinary products from the Centres covering [REDACTED]). For the cases that provided some detailed information, the outcomes were non-serious (mild-headache reported in 1 case).
- A follow-up on 30 August 2021 with the Centres for data since March 2021 identified 11 cases in [REDACTED] associated with ivermectin but details on reason for exposure (i.e., to treat COVID-19) and about the product (human vs. veterinary) were not provided. Responses have been received for [REDACTED] – still awaiting responses from the remaining Centres.
- A search of the Canada Vigilance database up to 29 August 2021 identified 94 case reports. Of these cases, 8 were received in 2020 and 2021 (4 each year). All 8 cases were associated with Rosiver (a topical formulation for humans) and the indication was reported as rosacea for 7. The remaining case also suggests use to treat rosacea.
- Prescription data for human ivermectin products up to July 2021 did not identify a clear trend for increased prescription during 2020/2021 compared to before the pandemic.

From: Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>
Sent: 2021-09-02 11:15 PM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Subject: FW: Ivermectin update

Apologies Kelly, forgot to cc you on this. Thanks again for the call and for following up with your team as discussed.

Manon Bombardier

A/Associate Assistant Deputy Minister | Sous ministre adjointe déléguée par intérim

Health Products and Food Branch | Direction générale des produits de santé et des aliments

Health Canada | Santé Canada

From: Bombardier, Manon (HC/SC)

Sent: 2021-09-02 11:13 PM

To: Kochhar, Harpreet (HC/SC) <harpreet.kochhar@canada.ca>

Cc: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@canada.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>;

Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>; Murseli, Lissa (HC/SC) <lissa.murseli@hc-sc.gc.ca>

Subject: Ivermectin update

Bonsoir Harpreet, here is a summary of the outreach undertaken since the release of the public advisory on Ivermectin, and proposed next steps to further amplify our message.

Actions to date:

- Upon release of the PA on Aug 31, a targeted email was sent to key vet health professional organizations/partners to make them aware and solicit their assistance in maximizing the outreach on this issue. The list of recipients included several producer associations, the chief vet officers across the country, the PT registrars, the CVMA, NAPRA, and 2 main industry associations.
- The PA was also distributed via our medeffect list serve - which goes out to over 29,000 subscribers. It was picked up by Ottawa Public Health - <https://mobile.twitter.com/OttawaHealth/status/1432854427652743168>
- CFIA was also informed and asked to distribute the PA to their stakeholders.
- Meeting was held today between CPAB and HFPB to discuss additional outreach measures that could be taken.

Next steps:

- Further tailored outreach is being considered, including to Livestock Medicine Outlets and those most likely to be buying ivermectin.
- CPAB is developing social media messages on this issue.
- In collaboration with CFIA, engage P/Ts to explore on measures that they could take to manage the sale of veterinary ivermectin. A meeting with the Council of Chief Veterinary Officers (CCVO) is scheduled for tomorrow.
- CFIA is exploring options to amplify HC's message with their stakeholders.
- VDD will connect with CVMA tomorrow regarding a letter (authored by HC) to send to CVMA members regarding the risks of ivermectin use.
- MHPD will reach out to poison control centres to see if they have received any reports related to use of ivermectin to treat or prevent COVID-19. This will help inform additional measures, as required.

Please let me know if you have any questions or wish to discuss. Thanks.

Manon Bombardier

A/Associate Assistant Deputy Minister | Sous ministre adjointe déléguée par intérim

Health Products and Food Branch | Direction générale des produits de santé et des aliments

Health Canada | Santé Canada

Marketed Health Products Directorate
Direction des produits de santé commercialisés

Health Products and Foods Branch
Direction générale des produits de santé et des aliments



Health
Canada

Santé
Canada

Canada Vigilance Program

Adverse Reaction Search Request Form Internal to Health Canada

Email to CanadaVigilance@hc-sc.gc.ca

Date 2021-08-30

Reason for search request:

In preparation for a risk communication

Therapeutic product:

-Please fill in **EITHER** the trade name **OR** the active ingredient (**NOT BOTH**)

-If not otherwise specified, only the therapeutic product with a suspect role will be included in this search

Brand name/Trade name(s): *[Only this trade name will be searched]*

OR

Active ingredient/generic name: *[All products containing the active ingredient will be searched.]*

ivermectin

Adverse reaction(s):



All ARs



All ARs for the System Organ Class(es): _____



All ARs for the Standardised MedDRA Queries (SMQs):



Search only the following ARs: _____

Time period:

Years of data required: _____

If time period is not specified, the search will cover the entire database.

Urgency:

Urgency of this request:



1-2 week



3-4 weeks



Urgent (24 to 48 hrs) - *Rationale for Urgent request: Risk comm to be issued*

today

Date after which the data would no longer be useful: _____

Is a search of the WHO database required?



Yes



No

Requester information

Name: Rory Sleno

Bureau/Organization: MPB

Phone number: 613-793-6303

Email address: rory.sleno@canada.ca

Marketed Pharmaceuticals Bureau

Summary of Safety Literature Scanning: Ivermectin

Key Messages:

- The evidence available to support the safety and efficacy of ivermectin for the prevention or treatment of COVID-19 continues to be restricted by methodological limitations. Most randomized clinical trials conducted to date are small in size and are of low quality. Large ongoing international trials are expected to provide more robust conclusions.
- Published studies generally do not report any new safety concerns beyond those known and labelled for ivermectin or related to COVID-19 progression in situations of lack of efficacy. The studies identified to date are clinical investigations, and generally do not report on the safety of self-directed use of veterinary/high concentration formulations.
- The MHPD Pharmaceutical Safety Literature Scanning Working Group will be continuing to scan relevant literature and will be maintaining an evergreen summary of this information.

April 2021

- 1) The MHPD Pharmaceutical Safety Literature Scanning Working Group (PSLS WG) scanned the studies cited in the EMA publication in March 2021 (<https://www.ema.europa.eu/en/news/ema-advises-against-use-ivermectin-prevention-treatment-covid-19-outside-randomised-clinical-trials>) :
 - Very low quality of evidence. Significant methodological issues (open design, no controls, single centers, small sample sizes) for most studies. Many are pre-publication and not peer reviewed. A handful of in vitro/in vivo/reviews were included in the list of references. There were a few studies that were not designed to study ivermectin alone (e.g., triple combination vs placebo), limiting the conclusions on drug-relatedness of the AEs.
 - Studies were conducted throughout the world (Iraq, Bangladesh, Mexico, Egypt, Lagos, Peru, India). Unclear if this is related to the clinical use/availability of ivermectin in those regions.
 - Most studies reporting on the "safety and efficacy" of ivermectin use interpret COVID-related patient outcomes (e.g., mortality, ICU status, hospitalization, recovery) as a safety issue. Per the inclusion criteria that I defined in the excel sheet (attached), I was looking for studies that reported safety concerns (e.g., AEs), potentially with high doses or inappropriate/off-label use of ivermectin.
 - A few studies report high doses of ivermectin (400 mcg/kg for 4-9 days, 48 mg x 2 seven days apart, 600 mcg/kg for 5 days, 200 mcg/kg for 5 days). No articles described intentional or accidental use of "veterinary" ivermectin in COVID-19 patients. Most studies described a dose of 200 mcg/kg (roughly 12 mg for a 60kg adult) either as a

single or two doses given a few days apart. The PM for STROMEKTOL recommends the use of a single dose adjusted to 200 mcg/kg, that can be given again 3 months later or a year later.

- Most studies did not discuss adverse events; only 4 studies presented AEs for the ivermectin group. Most reported known/labelled or mild AEs. Krolewiecki et al. (Lancet pre-print) that gave 600 mcg/kg for 5 days reported a serious adverse event of hyponatremia, but did not definitively attribute this to ivermectin use (potentially confounded by COVID-19).
- Based on this brief scanning, the EMA statement "... *side effects could increase with the much higher doses that would be needed to obtain concentrations of ivermectin in the lungs that are effective against the virus*" is a theoretical safety concern and not drawn from this list of publications. The PM for STROMEKTOL includes information on the symptoms of accidental intoxication or overdosage.

August 2021

1) To date, there are approximately 18 RCTs conducted including about 2100 participants, most are small in size and are of low quality (high risk of bias). A recent Cochrane systemic review (July 2021, <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD015017.pub2/full?cookiesEnabled>) concluded: *reliable evidence available does not support the use of ivermectin for treatment or prevention of COVID-19 outside of well-designed randomized trials.*

2) The body of ivermectin literature is currently in flux. A few of the early studies have been recently scrutinized and retracted and/or are being revised due to fraud allegations [REDACTED]
[REDACTED] Debate is ongoing regarding inclusion/correction of these studies in meta-analyses.

3) To date, studies generally do not report any new safety concerns beyond those labelled for ivermectin or related to COVID-19 progression in situations of lack of efficacy.

4) There are no completed or ongoing Canadian clinical trials for ivermectin in COVID-19.

5) There are several ongoing trials worldwide. Large PRINCIPLE (5000) and TOGETHER (1500) trials include the study of ivermectin. The Cochrane systemic review (July 2021) identified nearly 50 studies that were ongoing, requiring clarification or publication.

6) These studies are mainly focusing on the investigation of ivermectin to prevent or treat COVID-19; for our purposes, these studies are not relevant to the risk of self-directed use of large concentrations/veterinary formulations (e.g., overdosage).

Literature

August 2021

Pedroso C, Vaz S, Netto EM, et al. Self-prescribed Ivermectin use is associated with a lower rate of seroconversion in health care workers diagnosed with COVID, in a dose-dependent response [published online ahead of print, 2021 Aug 12]. *Braz J Infect Dis.* 2021;25(4):101603. doi:10.1016/j.bjid.2021.101603

This cross-sectional study aimed to evaluate the effect of ivermectin use on (1) the production of antibodies against SARSCoV-2, (2) the production of Th1/Th2 cytokines and (3) seroconversion in health care workers diagnosed with COVID-19. The study included 45 individuals stratified according to use of ivermectin (≤ 1 dose vs. multiple doses) for treatment of COVID-19. Ivermectin was used by 19 individuals (8 used a single dose, 11 used multiple doses). Mean elapsed time between diagnosis of COVID-19 and study tests was 109 days.

The authors state that disease severity was similar across groups. Neutralizing antibodies were detected less frequently in those who had taken multiple doses (70%) vs. ≤ 1 dose (97%) $p = 0.02$. Peripheral blood mononuclear cells of patients in the multiple dose group were less likely to produce antibodies against SARS-CoV-2 following in vitro compared to patients having taken ≤ 1 dose ($p < 0.001$). The production of Th1/Th2 cytokines was similar between groups. Seroconversion rates were lower in the ivermectin group. Abdominal pain, diarrhea and dysgeusia were more frequently reported by participants that used multiple doses.

Considerations:

- The exposure to ivermectin is not clearly defined. Patients completed a questionnaire indicating "ivermectin dosages used during disease", with a dose being equivalent to 6 mg by mouth. The timeline of treatment initiation with respect to disease onset, duration of treatment and frequency of dosing was not defined. As such, there are significant limitations in characterizing exposure.*
- The product monograph for STOMECTOL is labelled for abdominal pain and diarrhea under clinical trial adverse drug reactions. Taste disturbance is not labelled. However, it is unclear when adverse event data were collected or when these events occurred in relation to drug exposure. These results could be subjected to significant recall bias.*
- Use of ivermectin was not associated with more severe disease and the clinical impact of the results from the immunological assays is not evident.*
- Baseline characteristics of patient groups not well defined.*

Conclusion: based on the significant limitations of this study, this article is proposed for dismissal.

September 2021

PSLS became aware of media reports of a study published in 2011 that reported reduced sperm count, and sperm motility as well as an increase in abnormal sperm morphology (e.g., large heads, two tails, etc).

Idonije O.B., et al. Effects of Ivermectin therapy on the sperm functions of Nigerian onchocerciasis patients. *Archives of Applied Science Research.* 2011, 3(3):533-543.

The study identified 385 patients diagnosed with onchocerciasis, otherwise known as river blindness (this is an authorized indication for ivermectin in Canada). Of the 385 patients diagnosed with onchocerciasis, only 37 were found to be eligible for the study as their sperm variables were considered normal (per WHO

standard) at baseline. The subjects' ages ranged between 28 and 57 years old. No additional patient characteristics (e.g., concomitant medications, comorbidities) were described in the study.

The authors indicated that patients were treated with "*150 mcg/kg body weight of ivermectin for eleven months*". No additional information is provided on the treatment regimen (frequency of dosing) in the publication. According to the STROMEKTOL PM, the recommended posology for ivermectin for onchocerciasis is a single dose of 150 mcg/kg body weight of ivermectin, which can be given again at 3 months and/or at 12 months.

The study did not include a control group to account for time-related differences in sperm variables. The study did not perform any statistical analysis on any of the findings. The study did not discuss strength and limitations. The study did not provide any plausible explanation or biological mechanism for the observed effect.

The widely-circulated media claim that "85% of men who take ivermectin become sterilized" is cited in this 2011 study from a 2002 paper (Asika E.C. Okhiai O. Awemu G.A. *Journal of Biomedical investigation*; 2002: 3(1) 41-43). The 2002 paper is not available online or in Pubmed; a search of the archives of the Journal of Biomedical investigation only goes back to 2003. The 2011 study is published in a journal that requires payments for publication, and its peer-review process has not been reviewed by organizations that index journals, such as Clarivate. A high-level search for similar studies conducted in humans did not identify any new evidence since 2011.

The current PMs for STROMEKTOL and ROSIVER do not list any information related to a risk of spermatogenesis/semen disorders. The ROSIVER PM indicates that "*(i)vermectin was found to have no effect on the fertility of male and female rats at oral doses up to 9 mg/kg/day (animal:human AUC ratio ~ 484)*".

A spokesperson for the US FDA said that it continues monitor reports of all adverse events with ivermectin, and infertility in men is not a known side effect of it and, as such, is not included as a side effect in U.S. labeling. Ivermectin was also shown to have no adverse effects on the fertility in rats in studies at repeated doses of up to three times the maximum recommended human dose, the FDA added (<https://www.snopes.com/fact-check/ivermectin-sterility-in-men/>).

A search of the UMC Vigilyze database for reports of ivermectin with a Preferred Term (PT) linked to the HLT Sexual function and fertility disorders and/or HLT Spermatogenesis and semen disorders was performed on 9-Sept-2021. The search identified one (1) 2011 report of PT Haemospermia (IC: 1.2, IC025: -2.6) in a 35 year old male from the country Togo (TG-CNPV DPLET-2011-00005, completeness score 0.34).

A search of the online CVP database was performed for ivermectin and SOC Reproductive system and breast disorders. No reports were retrieved matching the search criteria.

Key messages:

- The study published in 2011 lacks scientific rigour and may not meet publication standards for peer-reviewed journals;

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- The current PMs for STROMECTOL and ROSIVER do not list any information related to a risk of spermatogenesis/semen disorders. The ROSIVER PM indicates that *“(i)vermectin was found to have no effect on the fertility of male and female rats at oral doses up to 9 mg/kg/day”*;
- At this time, there is no credible evidence to support a risk of infertility or sperm disorders in patients taking ivermectin.

Cain, Francoise (HC/SC)

From: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Sent: 2021-03-26 11:03 AM
To: Soo, Evelyn (HC/SC)
Subject: FW: Ivermectin lines
Attachments: 21-000893-877.pdf; 21-000893-877 - TPD Input - Ivermectin.docx

Hi Evelyn,

These are our standard Ivermectin lines. We can add that Merck has issued a press release saying there isn't evidence to support it's use. Not sure there is much else from our side frankly.

Thoughts?

B

From: Randall, Bruce (HC/SC)
Sent: 2021-02-05 11:34 AM
To: Bettel, Megan (HC/SC) <megan.bettel@canada.ca>; Lehman, Kelly (HC/SC) <kelly.lehman@canada.ca>
Subject: Ivermectin lines

Hi there,

Attached are the standard lines we have been using for Ivermectin. We still get some correspondence, mostly dated sent to PMO, around HCQ with very similar type response.

B

Pinard, Mike (HC/SC)

From: Sun, Rong (HC/SC)
Sent: 2021-09-08 12:21 PM
To: Robinson, Kelly (HC/SC)
Cc: HC.F MHPD Action Requests F.SC
Subject: Re: Kelly by noon: Social Media Plan – Ivermectin
Attachments: HPFB_SM_Ivermectin_2021-09-08_MHPD.docx

Hi Kelly,
Now fixed two more places that say "in animals".

If you are OK with it, I will send the document back with the following comments:

General comment: Ivermectin is authorized as an antiparasitic drug in humans and animals. Suggest that some of the wording around it only being a vet drug be nuanced.

Some specific comments have been included in the document.

Many thanks,
rs

From: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Sent: Wednesday, September 8, 2021 11:56 AM
To: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: RE: Kelly by noon: Social Media Plan – Ivermectin

Thanks, the only other point I would add it that ivermectin is authorized for people as an antiparasitic drug - so some of the wording around it only being a vet drug needs to be nuanced. Thanks, Kelly

From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Sent: 2021-09-08 11:51 AM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: Kelly by noon: Social Media Plan – Ivermectin

Hi Kelly,

This plan now has Louise's input, mainly on page 5. I removed "in animals", as it's for both humans and animals. 😊

For your review by noon.

Many thanks,
RS

From: Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>
Sent: Wednesday, September 8, 2021 11:39 AM
To: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Subject: RE: Louise asap: For Review: Social Media Plan – Ivermectin

Hi Rong,

Thanks for sharing with me. Attached are a few comments in track changes. When I review a text, given I'm not the product specialist, I review the flow and impact for the target audience. Once a specialist (ie: you) tell me the facts are good, then I can read the text and focus more on the message. In this case, I also looked at the proposed images, which I think are all great. Let me know if you have any questions. One point I noticed was that we use "may" instead of "can" cause serious health problems. May is a bit less definitive than can – if we could change to something more direct, I would prefer using "can", but if the scientists prefer "may", I have no problems.

I also removed the word unsupervised because at the end of the day, we don't want people to use it at all. To me, if we add unsupervised, we could be signalling that if someone takes it under supervision, it might be OK, which it's not at this time.

Let me know if you have any questions.

Thank you.

Louise Payette
(she/elle)
Cell : 613-462-2059

From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Sent: 2021-09-08 11:19 AM
To: Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>
Subject: Louise asap: For Review: Social Media Plan – Ivermectin

Hi Louise,

Wondering if you could take a look at the attached social media plan for Ivermectin?

Ivermectin is approved as an antiparasitic drug in both animals and humans, but not approved for COVID in humans. Some people take the vet drug as they can get it without prescription.

Kelly and I would like to know if you have any comments or thoughts about this plan? Our scientists do not have concerns.

A question from me: I normally look at the facts of the text - is there anything else you would look at when reviewing these social media plans? Appreciated!

This plan is due back to CPAB by noon today, would appreciate a quick turnaround if possible. .

Many thanks,
RS

From: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>
Sent: Wednesday, September 8, 2021 9:59 AM
To: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>
Subject: RE: Action MPB asap: For Review: Social Media Plan – Ivermectin

Hi Rong,

Information is factual in relation to ivermectin at this time. The messaging is in line with the content of the Public Advisory of August 31, 2021 (Canadians should never consume health products intended for animals because of the potential serious health dangers posed by them).

However some large studies that are assessing the efficacy and safety of ivermectin for COVID-19 are ongoing and results may become available in several months (no actual dates available at this point). These studies are not relevant to the risk of self-directed use of large concentrations/veterinary formulations. MHPD is aware of the PRINCIPLE (n=5000) and TOGETHER (n=1500) trials that are investigating ivermectin to prevent or treat COVID-19. TPD may have further input on this topic.

If possible, the messaging should include a qualifier that it is the status of the science at this time.

Thanks,
David

From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Sent: 2021-09-08 9:28 AM
To: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>; Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: Action MPB asap: For Review: Social Media Plan – Ivermectin

Hi David,
As discussed, please review this plan asap. Can we please have it back to DGO by 10:45 please?
Many thanks,
RS

From: Legault-Thivierge, Geoffroy (HC/SC) <geoffroy.legault-thivierge@hc-sc.gc.ca>
Sent: Wednesday, September 8, 2021 9:18 AM

To: Mehrotra, Manisha (HC/SC) <manisha.mehrotra@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@hc-sc.gc.ca>
Cc: Li, Xianzhi (HC/SC) <xianzhi.li@hc-sc.gc.ca>
Subject: RE: For Review: Social Media Plan – Ivermectin

Bonjour Rong, Philippe et Isabel,

Attached is a social media plan on ivermectin, at the Associate DM's request.

Could you please review the attached and flag any concerns **by 12:00 p.m. today (September 8)?**

Apologies for the rush, we are hoping to post as soon as possible.

Please let me know if you have any questions.

Merci beaucoup,
Geoffroy

From: Legault-Thivierge, Geoffroy (HC/SC)
Sent: 2021-09-07 4:21 PM
To: Mehrotra, Manisha (HC/SC) <manisha.mehrotra@hc-sc.gc.ca>
Cc: Li, Xianzhi (HC/SC) <xianzhi.li@hc-sc.gc.ca>
Subject: For Approval: Social Media Plan – Ivermectin
Importance: High

Bonjour Manisha,

Attached is the social media plan on ivermectin (see background down below).

Could you please approve the attached **by 10:00 a.m. tomorrow (September 8)?**

Apologies for the rush, we are hoping to post on Thursday and we need to seek numerous approvals before then.

Please let me know if you have any questions.

Merci beaucoup,

Geoffroy Legault-Thivierge
(he, him | il, lui)

Communications Advisor, Communications and Public Affairs Branch
Health Canada, Government of Canada
Geoffroy.Legault-Thivierge@hc-sc.gc.ca / Tel.: 613-790-5718

Conseiller en communications, Direction générale des communications et des affaires publiques
Santé Canada, Gouvernement du Canada
Geoffroy.Legault-Thivierge@hc-sc.gc.ca / Tél. : 613-790-5718

Please do not hesitate to reply in the official language of your choice. / N'hésitez pas à répondre dans la langue officielle de votre choix.

From: Legault-Thivierge, Geoffroy (HC/SC)
Sent: 2021-09-03 9:06 AM
To: Li, Xianzhi (HC/SC) <xianzhi.li@hc-sc.gc.ca>
Subject: Heads Up: Social Media Plan – Ivermectin

Good morning!

My name is Geoffroy and I work in Strat Comms, more specifically on food files but also veterinary drugs.

Just sending a heads up your way in Manisha's absence.

The Associate DM has requested that we do more outreach on the issue mentioned in this [advisory](#) about ivermectin (previously tweeted about [here](#)).

As such, I will be developing a social media plan on the topic, which will make its way to you for DG approval.

Please let me know if you have any questions.

Merci et bonne journée!

Geoffroy Legault-Thivierge
(he, him | il, lui)

Communications Advisor, Communications and Public Affairs Branch
Health Canada, Government of Canada
Geoffroy.Legault-Thivierge@hc-sc.gc.ca / Tel.: 613-790-5718

Conseiller en communications, Direction générale des communications et des affaires publiques
Santé Canada, Gouvernement du Canada
Geoffroy.Legault-Thivierge@hc-sc.gc.ca / Tél. : 613-790-5718

Please do not hesitate to reply in the official language of your choice. / N'hésitez pas à répondre dans la langue officielle de votre choix.

Pinard, Mike (HC/SC)

From: Sun, Rong (HC/SC)
Sent: 2021-09-08 4:41 PM
To: Sommerer, Sophie (HC/SC); Robinson, Kelly (HC/SC)
Cc: HC.F MHPD Action Requests F.SC
Subject: Re: Kelly COB today: Media Query: Toronto Star [REDACTED] Use of Ivermectin to treat COVID-19 + incident report

Thanks Sophie. Will share with CPAB our input with your edits. 😊

From: Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Sent: Wednesday, September 8, 2021 4:08 PM
To: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: RE: Kelly COB today: Media Query: Toronto Star [REDACTED] Use of Ivermectin to treat COVID-19 + incident report

Hi Rong,

It seems strange to refer the reporter to the PCCs. I'm suggesting striking that line. The rest looks good!

Thanks,
 Sophie

From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Sent: 2021-09-08 3:46 PM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Subject: Kelly COB today: Media Query: Toronto Star [REDACTED] Use of Ivermectin to treat COVID-19 + incident report

Hi Kelly,

Looks like Ivermectin is getting media attention. We have been asked to provide input to the Toronto Star question:

Q1. I'm writing about ivermectin and its rise in popularity as a COVID-19 treatment despite it being unauthorized for such use. The advisory posted last week notes that Health Canada has received reports of people using ivermectin for COVID-19 purposes; does Health Canada have numbers on how many reports have been made and where these reports are coming from?

We have asked CPAB to reach out to ROEB and VDD as well, and ROEB should lead. TPD did not have any.

MHPD proposed input, for your review today:

ATIA - 19(1)

ATIA - 21(1)(a)

ATIA-14(a)

Ivermectin is an antiparasitic agent approved for use in humans and animals. There are concerns about consumers purchasing veterinary Ivermectin to prevent or treat COVID-19. On August 31, 2021, Health Canada published a Public Advisory (<https://healthykanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>) informing the public that Ivermectin is not authorized to prevent or treat COVID-19 and using it for such purposes can cause serious health problems. This advisory noted that the Department has received concerning reports of the use of veterinary ivermectin to prevent or treat COVID-19. This is in reference to reports of patients in the U.S. as stated in the advisory. (CPAB, please check with VDD/ROEB to confirm)

At this time, Health Canada has not received reports of adverse events associated with the use of ivermectin-containing products in humans for COVID-19 purposes. [REDACTED]

Many thanks,
RS

From: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>
Sent: Wednesday, September 8, 2021 3:09 PM
To: Thin, Sophea (HC/SC) <sophea.thin@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; HC.F MHPD MPB ASSISTANTS F.SC <hc.mhpdmpbassistants.sc@hc-sc.gc.ca>; HC.F MHPD HPSEB Assistants F.SC <hc.mhpdhpsebassistants.sc@hc-sc.gc.ca>; Irfan, Nashwa (HC/SC) <nashwa.irfan@hc-sc.gc.ca>; Soltys, Kathy (HC/SC) <kathy.soltys@hc-sc.gc.ca>; Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>
Subject: RE: MPB lead with input from HPSEB - FW: For HPFB-TBD input: Media Query: Toronto Star [REDACTED]
Use of Ivermectin to treat COVID-19 + incident report

Hi Sophea and Rong,

We had requested information from HPSEB last week on this topic and we are including that information in the response below.

Kathy and Nashwa are away today, and I am acting for them. This is the response from MPB:

The advisory issued by Health Canada noted that the Department has received concerning reports of the use of veterinary ivermectin to prevent or treat COVID-19. This is in reference to reports of patients in the U.S. as stated in the advisory. (for VDD/ROEB to confirm)

At this time, Health Canada has not received reports of adverse events associated with the use of ivermectin-containing products for human use for COVID-19 purposes. [REDACTED]

Thanks,
David

From: Thin, Sophea (HC/SC) <sophea.thin@hc-sc.gc.ca>
Sent: 2021-09-08 2:18 PM
To: HC.F MHPD MPB ASSISTANTS F.SC <hc.mhpdmpbassistants.sc@hc-sc.gc.ca>; HC.F MHPD HPSEB Assistants F.SC <hc.mhpdhpsebassistants.sc@hc-sc.gc.ca>
Cc: HC.F MHPD MPB MANAGEMENT F.SC <hc.mhpdmpbmanagement.sc@hc-sc.gc.ca>; HC.F MHPD

ATIA - 19(1)

HPSEB Management / DPSC BSPSE Gestionnaires F.SC <hc.mhpdhpsebmanagement@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>

Subject: MPB lead with input from HPSEB - FW: For HPFB-TBD input: Media Query: Toronto Star [REDACTED]
[REDACTED] Use of Ivermectin to treat COVID-19 + incident report

Hi MPB/HPSEB,

For your action. CPAB is requesting an extension from the reporter, I will keep you posted.

LEAD BUREAU	MPB lead with input from HPSEB
RESPONSE TO BE SENT TO	MHPD Action Requests
MECS NUMBER	Nil
DUE IN DGO BY	TBD
CONSULTATIONS	The "lead" bureau is responsible to include and incorporate all relevant information and approvals in the final response being submitted to DGO.
	Please indicate (via email or MECS) whom your bureau has consulted with: (i.e. other MHPD Bureaux, a Directorate, Legal Services, ROEB, SPB, etc.)

Please consult directly with other bureaus if necessary prior to submission to DGO

From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>

Sent: 2021-09-08 2:01 PM

To: Thin, Sophea (HC/SC) <sophea.thin@hc-sc.gc.ca>

Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>

Subject: Re: Rong pls advise - FW: For HPFB-TBD input: Media Query: Toronto Star [REDACTED] Use of Ivermectin to treat COVID-19 + incident report

Hi Sophia, Please advise CPAB to seek input from ROEB, they should be the lead, and VDD should be approached too.

We can provide input as well. Please ask MPB to lead with input fro HPSEB.. Also, the 2pm timeline is not feasible ask for COB or tomorrow please.

Many thanks,

Rong Sun, Ph.D.
Health Canada/Santé Canada
New! rong.sun@hc-sc.gc.ca

On Sep 8, 2021, at 1:47 PM, Thin, Sophea (HC/SC) <sophea.thin@hc-sc.gc.ca> wrote:

Hi Rong,

[REDACTED] Is this something that MHPD has input for? I see that you are working on a similar one that is with Kelly right now.
Can you let me know if this need to be assigned out asap.

From: Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>
Sent: 2021-09-08 1:42 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; HC.F TPD Media Requests F.SC <tpd_media_requests@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Cc: Aboueid, Suzane (HC/SC) <suzane.aboueid@hc-sc.gc.ca>; Francis-Lamb, Laura (HC/SC) <laura.francis-lamb@hc-sc.gc.ca>; Zaman, Muhammad (HC/SC) <muhammad.zaman@hc-sc.gc.ca>
Subject: RE: For HPFB-TBD input: Media Query: Toronto Star [REDACTED] Use of Ivermectin to treat COVID-19 + incident report

You may want to try ROEB as they initiated the PA. Otherwise, VDD. My understanding from MHPD is that we are not seeing an increase in the prescribing of ivermectin – the concern seems to be more about the use of the veterinary form.

From: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Sent: 2021-09-08 1:31 PM
To: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; HC.F TPD Media Requests F.SC <tpd_media_requests@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Cc: Aboueid, Suzane (HC/SC) <suzane.aboueid@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; Francis-Lamb, Laura (HC/SC) <laura.francis-lamb@hc-sc.gc.ca>; Zaman, Muhammad (HC/SC) <muhammad.zaman@hc-sc.gc.ca>
Subject: RE: For HPFB-TBD input: Media Query: Toronto Star [REDACTED] Use of Ivermectin to treat COVID-19 + incident report

Hi there Anne,

TPD has no reports of ivermectin use – maybe MHPD has these? However, I believe the “reports” mentioned in the advisory, with regards to veterinary ivermectin use, were media reports, i.e. news articles.

P

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>
Sent: 2021-09-08 12:05 PM
To: HC.F TPD Media Requests F.SC <tpd_media_requests@hc-sc.gc.ca>
Cc: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Aboueid, Suzane (HC/SC) <suzane.aboueid@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; Francis-Lamb, Laura (HC/SC) <laura.francis-lamb@hc-sc.gc.ca>; Zaman, Muhammad (HC/SC) <muhammad.zaman@hc-sc.gc.ca>
Subject: For HPFB-TBD input: Media Query: Toronto Star [REDACTED] Use of Ivermectin to treat COVID-19 + incident report

Good day HPFB,

We have received a media query asking the # of reports received on the use of ivermectin to treat COVID-19 (as stated in the recall last week Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems - Recalls and safety alerts (healthycanadians.gc.ca))

Is this information we can provide to the reporter? Note the tight deadline (2 pm today)– I will manage the reporter's expectations.

Your input would be greatly appreciated.

Thank you.

Anne

Media/Reporter: Toronto Star [REDACTED]

Deadline to reporter: September 8 / 2 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. I'm writing about ivermectin and its rise in popularity as a COVID-19 treatment despite it being unauthorized for such use. The advisory posted last week notes that Health Canada has received reports of people using ivermectin for COVID-19 purposes; does Health Canada have numbers on how many reports have been made and where these reports are coming from?

Tasked to:
Approved by:

Anne Génier

Senior Media Relations Advisor, Communication and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Conseillère principale des relations avec les médias, Direction générale des communications et des affaires publiques
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967
- - -

Media | Média T: [613-957-2983](tel:613-957-2983), E/CE: media@hc-sc.gc.ca

Pinard, Mike (HC/SC)

From: Robinson, Kelly (HC/SC)
Sent: 2021-09-22 3:24 PM
To: Sun, Rong (HC/SC)
Cc: Sommerer, Sophie (HC/SC); HC.F MHPD Action Requests F.SC
Subject: Re: Kelly/Sophie today Sept 22: Media Query: Winnipeg Free Press [REDACTED]
 Regulations of agricultural ivermectin

Hi, are we sure the ivermectin billboard was for human product?

Kelly Robinson
 MHPD

On Sep 22, 2021, at 3:21 PM, Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca> wrote:

Hi Kelly/Sophie,

This media request is about veterinary Ivermectin, our input on its advertising was requested. Just so you know that the request also went to ROEB and VDD.

The wording in the question is vague which could cover both human and veterinary versions of this drug. We became aware of incidents of non-compliant advertising for human Ivermectin, no veterinary incidents have come to our attention.

The proposed MHPD input for your review **today**:

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of incidents ~~eases of~~ human Ivermectin advertising for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, ~~that the sponsor of these ads removes them immediately.~~ the sponsor confirmed that these ads were no longer being disseminated and committed to refrain from engaging in this non-compliant act in the future.

Many thanks,
 RS

From: Pinard, Mike (HC/SC) <mike.pinard@hc-sc.gc.ca>
Sent: Wednesday, September 22, 2021 3:03 PM
To: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: Rong: OPRAA for action - Sept 22 by 3pm - FW: For MHPD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Rong,

Media response is with you for review. Due back to CPAB by end of day today.

Thanks!

Mike

From: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>
Sent: 2021-09-22 2:56 PM
To: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Subject: FW: OPRAA for action - Sept 22 by 3pm - FW: For MHPD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Good afternoon,

Please see director approved response below.

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of cases of Ivermectin advertising for the treatment of COVID-19 in Manitoba this past summer. Health Canada requested that the sponsor of these ads removes them immediately. The sponsor confirmed that these ads were no longer being disseminated and committed to refrain from engaging in this non-compliant act in the future.

Thanks,
 Martin

From: Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>
Sent: 2021-09-22 2:48 PM
To: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>; Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca>; Murray, Jennifer (HC/SC) <jennifer.murray@hc-sc.gc.ca>
Subject: RE: OPRAA for action - Sept 22 by 3pm - FW: For MHPD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Great thanks – Alain.
 Approved

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Sent: 2021-09-22 1:06 PM
To: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>; Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>; Roy,

Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimirad@hc-sc.gc.ca>; Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca>; Murray, Jennifer (HC/SC) <jennifer.murray@hc-sc.gc.ca>
Subject: RE: OPRAA for action - Sept 22 by 3pm - FW: For MHPD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Hamida,

Here is our proposed response, in blue, to this media request. Please note the following:

- Q1 is ROEB's lead.
- Q2 involves advertising and sale. We have addressed the advertising component and ROEB should address the sale aspect.
- The sponsor confirmed that these ads were removed but we are still working with ROEB to verify whether these physical billboards are indeed no longer there.

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of cases of Ivermectin advertising for the treatment of COVID-19 in Manitoba this past summer. Health Canada requested that the sponsor of these ads removes them immediately. The sponsor confirmed that these ads were no longer being disseminated and committed to refrain from engaging in this non-compliant act in the future.

Thanks,

Alain G. Musende, PhD
 Manager, Section for Transparency and Advertising Regulatory Surveillance/
 Section de la surveillance réglementaire en matière de transparence et publicité
 Marketed Health Products Directorate/
 Direction des produits de santé commercialisés
 Government of Canada | Gouvernement du Canada
alain.musende@canada.ca
 Tel: Cell: (613) 302-4856 / Office:: Cell: (613) 954-6780
 200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
 Ottawa, Canada K1A 0K9

From: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>
Sent: 2021-09-22 11:05 AM
To: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimirad@hc-sc.gc.ca>; Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Subject: FW: OPRAA for action - Sept 22 by 3pm - FW: For MHPD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Good morning all,

Please see action request below, due by 3:00 pm today.

Thanks,
Martin

From: Thin, Sophea (HC/SC) <sophea.thin@hc-sc.gc.ca>
Sent: 2021-09-22 11:03 AM
To: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>;
HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: OPRAA for action - Sept 22 by 3pm - FW: For MHPD input: Media Query: Winnipeg
Free Press [REDACTED] Regulations of agricultural ivermectin

LEAD BUREAU	OPRAA
RESPONSE TO BE SENT TO	MHPD Action Requests
MECS NUMBER	Nil
DUE IN DGO BY	Sept 22 by 3pm
CONSULTATIONS	The "lead" bureau is responsible to include and incorporate all relevant information and approvals in the final response being submitted to DGO.
	Please indicate (via email or MECS) whom your bureau has consulted with: (i.e. other MHPD Bureaux, a Directorate, Legal Services, ROEB, SPB, etc.)

Please consult directly with other bureaus if necessary prior to submission to DGO

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>
Sent: 2021-09-22 10:53 AM
To: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Cc: Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@canada.ca>; Keeping, Elizabeth (HC/SC) <elizabeth.keeping@canada.ca>; Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Subject: For MHPD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Good morning MHPD colleagues,

We have received a media query on agricultural ivermectin. Initially, this query was sent to CFIA but they confirmed that HC may have a role to play.

We have sent the request to HPCD but they have advised that your team may be able to provide input for **Q2**.

Your input by end of day would be greatly appreciated.

Thank you,

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Tasked to:

Approved by:

Anne Génier

Senior Media Relations Advisor, Communication and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Conseillère principale des relations avec les médias, Direction générale des communications et des affaires publiques
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Media | Média T: [613-957-2983](tel:613-957-2983), E/CE: media@hc-sc.gc.ca

Pinard, Mike (HC/SC)

From: Robinson, Kelly (HC/SC)
Sent: 2021-09-23 5:45 PM
To: Sun, Rong (HC/SC); Sommerer, Sophie (HC/SC)
Cc: HC.F MHPD Action Requests F.SC
Subject: RE: Kelly/Sophie (ASAP) // Ivermectin Media Query: Winnipeg Free Press [REDACTED]
 Regulations of agricultural ivermectin

I would not include this text - given this is a third party and not the company/group that paid for the ad. We can let RMOd ADMO know that at this point we have not released this information, given it was a third party.

From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Sent: 2021-09-23 5:34 PM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: Re: Kelly/Sophie (ASAP) // Ivermectin Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Thank you Kelly.

I don't think we need the entire green para, but may want to keep sentence about the billboard company, as this is what RMOD ADMO is asking for:

So the input would look like this, sounds good?

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of billboard advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the sponsor company displaying of these ads removed them immediately, confirmed that these ads were no longer being displayed disseminated and committed to refraining from engaging in this non-compliant act in the future.

Health Canada have been in contact with dealing with the billboard company involved: [REDACTED]
 based in Alberta during the process [REDACTED]

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred. Incidents of non-compliance are prioritised and action is taken based on the risk they may pose to the general public. It is the responsibility of companies to comply with regulatory requirements and to investigate incidents of potential non-compliance, and to take appropriate action to correct non-compliance, mitigate any risk to health, and inform Health Canada as appropriate.

To report marketing that is false or misleading or does not meeting regulatory requirements, visit <https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/illegal-marketing/complaint.html>

ATIA - 19(1)

As part of its ongoing commitment to openness and transparency, Health Canada posts ~~on par 5 an~~ health product advertising complaints addressed by the Department <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/health-product-advertising-incidents.html>.

From: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Sent: Thursday, September 23, 2021 5:27 PM
To: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: RE: Kelly/Sophie (ASAP) // Ivermectin Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

I think we need to revised the first para, given we spoke to the billboard company, not the sponsor- and if it is a billboard, the ad was not being disseminated How does this work? - also, please confirm we will be making the name of the billboard company public and when (if possible)

Health Canada became aware of billboard advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the ~~sponsor~~ company displaying of these ads removed them immediately, confirmed that these ads were no longer being displayed ~~disseminated~~ and committed to refraining from engaging in this non-compliant act in the future

And do we need this para - I think it is already addressed in the bottom para

~~Non-compliant COVID-19 advertising information is provided proactively through the table of advertising incident for COVID-19 table of advertising incident for COVID-19, which updated weekly. We do not know the sponsor of the ad but we know and- In this case Health Canada have been was in contact with dealing with the billboard company involved: Magnet Signs based in Alberta during the process. Magnet Signs~~

From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Sent: 2021-09-23 5:11 PM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: Kelly/Sophie (ASAP) // Ivermectin Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Kelly/Sophie,

The Invermectin media query came back with ROEB ADMO's request for more information yellow highlighted.

ATIA - 19(1)

- Note the table of advertising incident for COVID-19 is usually updated weekly, but this case has not been included (will be in the next two weeks), therefore changing it to "regularly." I have adjusted the wording at the end for this reason too.

See our inputs in green and my edits in orange. For your review by COB today.

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the sponsor of these ads removed them immediately, confirmed that these ads were no longer being disseminated and committed to refraining from engaging in this non-compliant act in the future. [I think we can expect the reporter to ask for more details regarding this case, including who the sponsor of the ad was. Is there any reason why we can't provide this info proactively? Will the case be published in the online list of advertising complaints?]

Non-compliant COVID-19 advertising information is provided proactively through the table of advertising incident for COVID-19, which is updated weekly. In this case Health Canada have been in contact with dealing with the billboard company involved during the process.

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred. Incidents of non-compliance are prioritised and action is taken based on the risk they may pose to the general public. It is the responsibility of companies to comply with regulatory requirements and to investigate incidents of potential non-compliance, and to take appropriate action to correct non-compliance, mitigate any risk to health, and inform Health Canada as appropriate.

To report marketing that is false or misleading or does not meeting regulatory requirements, visit <https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/illegal-marketing/complaint.html>.

As part of its ongoing commitment to openness and transparency, Health Canada posts COVID-19 health product advertising complaints addressed by the Department through this link <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/health-product-advertising-incidents.html>. This case is expected to be posted online in the coming weeks. [Can we also include the link to the summary of advertising complaints specific to COVID-19?]:

From: Pinard, Mike (HC/SC) <mike.pinard@hc-sc.gc.ca>

Sent: Thursday, September 23, 2021 4:19 PM

To: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>

Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>

Subject: Rong: OPRAA (ASAP) // For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press Regulations of agricultural ivermectin

Hi Rong,

ATIA - 19(1)

The ivermectin media response is now with you for review.

Thanks!

Mike

From: Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>

Sent: 2021-09-23 4:17 PM

To: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>

Cc: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>

Subject: FW: OPRAA (ASAP) // For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press
[REDACTED] Regulations of agricultural ivermectin

I made a small edit other than that good to go to DGO
Hamida

From: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>

Sent: 2021-09-23 4:08 PM

To: Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>

Subject: FW: OPRAA (ASAP) // For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press
[REDACTED] Regulations of agricultural ivermectin

Hi Hamida,

For your approval, further explanation was required for this media request. Alain's response is in green.

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the sponsor of these ads removed them immediately, confirmed that these ads were no longer being disseminated and committed to refraining from engaging in this non-compliant act in the future. [I think we can expect the reporter to ask for more details regarding this case, including who the sponsor of the ad was. Is there any reason why we can't provide this info proactively? Will the case be published in the online list of advertising complaints?]

This information is provided proactively through the table of advertising incident for COVID-19, which is updated weekly. [REDACTED] Health Canada have been in contact with [REDACTED] dealing with the billboard company involved. [REDACTED] during the process. Magnet Signs [REDACTED]

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred. Incidents of non-compliance are prioritised and action is taken based on the risk they may pose to the general public. It is the responsibility of companies to comply with regulatory requirements and to investigate incidents of potential non-compliance, and to take appropriate action to correct non-compliance, mitigate any risk to health, and inform Health Canada as appropriate.

To report marketing that is false or misleading or does not meeting regulatory requirements, visit <https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/illegal-marketing/complaint.html>.

As part of its ongoing commitment to openness and transparency, Health Canada posts COVID-19 health product advertising complaints through this link and this case can be found under the resolved. a summary of health product advertising complaints addressed by the Department. [Can we also include the link to the summary of advertising complaints specific to COVID-19?]: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/health-product-advertising-incidents.html>

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>

Sent: 2021-09-23 12:51 PM

To: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>

Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>

Subject: RE: OPRAA (ASAP) // For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press
[REDACTED] Regulations of agricultural ivermectin

Salut Martin,

Please see my responses in **green** highlights below.

Thanks,

Alain G. Musende, PhD

Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca

Tel: Cell: (613) 302-4856 / Office:: Cell: (613) 954-6780

200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D

Ottawa, Canada K1A 0K9

From: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>

Sent: 2021-09-23 12:23 PM

To: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>

Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>

Subject: FW: OPRAA (ASAP) // For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press
[REDACTED] Regulations of agricultural ivermectin

Hello STARS,

Please see follow-up to this media request, due ASAP please.

ATIA - 19(1)

Thanks,
Martin

From: Pinard, Mike (HC/SC) <mike.pinard@hc-sc.gc.ca>
Sent: 2021-09-23 12:22 PM
To: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: OPRAA (ASAP) // For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press [REDACTED]
[REDACTED] Regulations of agricultural ivermectin

Hi OPRAA,

ROEB has proposed edits for this media response that require more input from us. Please review and provide a Director approved response back up to DGO. CPAB did not provide a specific deadline but we can assume they will want our DG approved response before COB today. Thanks!

LEAD BUREAU	OPRAA
RESPONSE TO BE SENT TO	MHPD Action Requests
MECS NUMBER	Nil
DUE IN DGO BY	ASAP
CONSULTATIONS	The "lead" bureau is responsible to include and incorporate all relevant information and approvals in the final response being submitted to DGO.
	Please indicate (via email or MECS) whom your bureau has consulted with: (i.e. other MHPD Bureaux, a Directorate, Legal Services, ROEB, SPB, etc.)

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>
Sent: 2021-09-23 12:15 PM
To: St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>
Cc: Davis, Meggan (HC/SC) <meggan.davis@hc-sc.gc.ca>; Mehrotra, Manisha (HC/SC) <manisha.mehrotra@hc-sc.gc.ca>; Burgess, Sean (HC/SC) <sean.burgess@hc-sc.gc.ca>; Legault-Thivierge, Geoffroy (HC/SC) <geoffroy.legault-thivierge@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; Tatone, Elise (HC/SC) <elise.tatone@hc-sc.gc.ca>; Geduld, Jennifer (HC/SC) <jennifer.geduld@hc-sc.gc.ca>; Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>; Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Pinard, Mike (HC/SC) <mike.pinard@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; HC.F RORB HPC Media F.SC <rorb_hpc_media@hc-sc.gc.ca>
Subject: For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Carole / Rong / Marilena,

ATIA - 19(1)

ROEB ADMO is proposing changes to the response and is asking a few things to be addressed (highlighted in yellow). Can you take a look at the response below?

Merci beaucoup!

Anne

From: Genier, Anne (HC/SC)

Sent: 2021-09-23 10:04 AM

To: St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>

Cc: Davis, Meggan (HC/SC) <meggan.davis@hc-sc.gc.ca>; Mehrotra, Manisha (HC/SC) <manisha.mehrotra@hc-sc.gc.ca>; Burgess, Sean (HC/SC) <sean.burgess@hc-sc.gc.ca>; Legault-Thivierge, Geoffroy (HC/SC) <geoffroy.legault-thivierge@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; Tatone, Elise (HC/SC) <elise.tatone@hc-sc.gc.ca>; Geduld, Jennifer (HC/SC) <jennifer.geduld@hc-sc.gc.ca>; Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>; Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Pinard, Mike (HC/SC) <mike.pinard@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>

Subject: FYI - Input moving through approval this morning: Media Query: Winnipeg Free Press [REDACTED]
Regulations of agricultural ivermectin

Good morning,

For your awareness - since we have received input from VDD, MHPD and HPCD – I have collated all the responses and the response below will be circulating through your ADMs office later this morning.

Merci!

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

One of ~~The role of~~ Health Canada's roles, as the federal regulator, is the approval of veterinary drug products. [should also say something here about HC's role re: compliance and enforcement to ensure that regulated products are not being advertised or sold for indications that are not authorized] The Department helps ensure that all veterinary drugs fully satisfy requirements under the *Food and Drug Regulations* before they can be marketed in Canada. Restrictions associated with the sale of a product intended for use in livestock would be of provincial or territorial jurisdiction

[please confirm accuracy. Isn't any drug subject to FDR and FDA requirements related to advertising and sale? I think we should provide more info here to clarify that HC doesn't have jurisdiction over how a product is ultimately used but we do regulate the sale and advertising of drugs and take action when a product is being advertised or sold outside the terms of its market authorization]. Depending on the province or territory where the drugs are sold, there may be restrictions on who is permitted to purchase products intended for use in livestock-

Following reports of the use of veterinary ivermectin drugs outside of approved directions for use (off-label use), Health Canada issued a public advisory to inform Canadians that Ivermectin is not authorized to prevent or treat COVID-19 and may pose serious health risks: <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the sponsor of these ads removed them immediately, confirmed that these ads were no longer being disseminated and committed to refraining from engaging in this non-compliant act in the future. [I think we can expect the reporter to ask for more details regarding this case, including who the sponsor of the ad was. Is there any reason why we can't provide this info proactively? Will the case be published in the online list of advertising complaints?]

We can provide the information proactively since we'll post it on the table of advertising incident for COVID-19. [REDACTED] we know and have been dealing with the billboard company involved: Magnet Signs based in Alberta. Magnet Signs [REDACTED]

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred. Incidents of non-compliance are prioritised and action is taken based on the risk they may pose to the general public. It is the responsibility of companies to comply with regulatory requirements and to investigate incidents of potential non-compliance, and to take appropriate action to correct non-compliance, mitigate any risk to health, and inform Health Canada as appropriate.

To report marketing that is false or misleading or does not meeting regulatory requirements, visit <https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/illegal-marketing/complaint.html>.

As part of its ongoing commitment to openness and transparency, Health Canada posts a summary of health product advertising complaints addressed by the Department. [Can we also include the link to the summary of advertising complaints specific to COVID-19?]: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/health-product-advertising-incidents.html>

Requester agreed to
Remove 3rd Party Info

Tasked to: HPCD, MHPD, VDD

Approved by:

Marilena Bassi, DG, VDD (approved)

Kelly Robinson, DG MHPD (approved Q2)

Linsey Hollet, DG HPCD (approved)

Eric Morrisette /Mark Johnson, Chief Media Relations (pending)

Julia Cropley, DG MCD (FYI)

Pam Aung-Thin, CPAB ADM (pending)

HPFB ADM (pending)
Stefania Trombetti, ROEB ADM (pending)
DMO (pending)

Pinard, Mike (HC/SC)

From: Robinson, Kelly (HC/SC)
Sent: 2021-09-27 12:28 PM
To: Sun, Rong (HC/SC); Sommerer, Sophie (HC/SC)
Cc: HC.F MHPD Action Requests F.SC
Subject: RE: Kelly/Sophie asap: Media Query: Follow-up: Winnipeg Free Press [REDACTED]
 Regulations of agricultural ivermectin

Approved with changes below - thanks, Kelly

From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Sent: 2021-09-27 12:07 PM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: Kelly/Sophie asap: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Kelly/Sophie,

We have received some follow-up questions from the reporter wanting to know more about the false advertising incident involving ivermectin and its sponsors. Louise saw this as well. I made small edits. For your review **asap**.

Q1. Do you have more information on the false advertising in Manitoba?

R1. ~~No. We provided all the information explaining Health Canada's handling of this issue.~~
 Additional information is provided below.

Q2. How many billboards were there and where were they located?

R2. ~~We Health Canada~~ received complaints about billboards in the Winkler area. We cannot confirm how many billboards were in the area at that time, however the company has confirmed that all billboards with these claims have been removed.

Q3. Were they claiming ivermectin cures COVID-19?

R3. ~~No,~~ They were all advertising Ivermectin for the treatment of COVID-19.

Q4. Was the company fined?

R4. [REDACTED] Health Canada issued a regulatory letter requesting that the sponsor of these ads to removes them immediately. The sponsor has confirmed that these ads are no longer being displayed and committed to refrain from engaging in this non-compliant act in the future.

Many thanks,
 RS

Requester agreed to
 Remove 3rd Party Info

From: Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>
Sent: Monday, September 27, 2021 11:55 AM

ATIA - 19(1)

To: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>

Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>

Subject: RE: Louise asap - W: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

I have nothing to add. This is pretty straightforward. Thanks.

Louise Payette

(she/elle)

Cell : 613-462-2059

From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>

Sent: 2021-09-27 11:51 AM

To: Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>

Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>

Subject: Louise asap - W: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

As discussed. Many thanks! 😊

From: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>

Sent: Monday, September 27, 2021 11:22 AM

To: Thin, Sophea (HC/SC) <sophea.thin@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>

Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>

Subject: FW: OPRAA for action Due Sept 27 by 11am - FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Good morning,

Please see director approved response:

Q1. Do you have more information on the false advertising in Manitoba?

R1. No. We provided all the information explaining Health Canada's handling of this issue.

Q2. How many billboards were there and where were they located?

R2. We received complaints about billboards in the Winkler area. We cannot confirm how many billboards were in the area at this time, however the company has confirmed that all billboards with these claims have been removed.

Q3. Were they claiming ivermectin cures COVID-19?

R3. No, they were all advertising Ivermectin for the treatment of COVID-19.

Q4. Was the company fined?

R4. No the company was not fined; however, we have issued a regulatory letter requesting that the sponsor of these ads removes them immediately. The sponsor has confirmed that these ads are no longer being disseminated and committed to refrain from engaging in this non-compliant act in the future.

Thanks,
Martin

From: Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>
Sent: 2021-09-27 11:13 AM
To: Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>
Cc: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>; Murray, Jennifer (HC/SC) <jennifer.murray@hc-sc.gc.ca>
Subject: RE: OPRAA for action Due Sept 27 by 11am - FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Martin – I have made changes. Approved with my changes and please forward to DGO.
Hamida

From: Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>
Sent: 2021-09-27 11:08 AM
To: Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>
Cc: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>; Murray, Jennifer (HC/SC) <jennifer.murray@hc-sc.gc.ca>
Subject: FW: OPRAA for action Due Sept 27 by 11am - FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

From: Lejmi Mrad, Rim (HC/SC)
Sent: 2021-09-27 11:07 AM
To: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Subject: RE: OPRAA for action Due Sept 27 by 11am - FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Hamida and Martin,

Please see my proposed responses below in green.

Thanks,

Rim

From: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>
Sent: 2021-09-27 10:40 AM
To: Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Subject: FW: OPRAA for action Due Sept 27 by 11am - FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Bonjour Rim,

Please see Hamida's comments in red below.

Thanks,
Martin

From: Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>
Sent: 2021-09-27 10:33 AM
To: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Subject: RE: OPRAA for action Due Sept 27 by 11am - FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Please see comments below

From: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>
Sent: 2021-09-27 10:05 AM
To: Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Subject: FW: OPRAA for action Due Sept 27 by 11am - FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Hamida,

Due by 11:00 am, please see STARS' answers to the follow-up media request questions.

Thanks,
Martin

From: Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>
Sent: 2021-09-27 9:54 AM
To: Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>; Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>; Murray, Jennifer (HC/SC) <jennifer.murray@hc-sc.gc.ca>; Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca>
Subject: RE: OPRAA for action Due Sept 27 by 11am - FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Hamida and Martin,

Please find our proposed response, in blue, to this media request.

Thanks,

Rim

From: Thin, Sophea (HC/SC) <sophea.thin@hc-sc.gc.ca>
Sent: 2021-09-27 8:53 AM
To: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: OPRAA for action Due Sept 27 by 11am - FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query:

ATIA - 19(1)

Follow-up: Winnipeg Free Press () Regulations of agricultural ivermectin

Importance: High

LEAD BUREAU	OPRAA
RESPONSE TO BE SENT TO	MHPD Action Requests
MECS NUMBER	Nil
DUE IN DGO BY	Today by 11am
CONSULTATIONS	The "lead" bureau is responsible to include and incorporate all relevant information and approvals in the final response being submitted to DGO.
	Please indicate (via email or MECS) whom your bureau has consulted with: (i.e. other MHPD Bureaux, a Directorate, Legal Services, ROEB, SPB, etc.)

Please consult directly with other bureaus if necessary prior to submission to DGO

From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>

Sent: 2021-09-24 5:18 PM

To: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; HC.F RORB HPC Media F.SC <rorb_hpc_media@hc-sc.gc.ca>

Cc: Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>

Subject: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press () Regulations of agricultural ivermectin

Hi Team, These are follow-up questions about the billboard ad. To OPRAA if not already tasked. Many thanks,
RS

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>

Sent: Friday, September 24, 2021 4:17 PM

To: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; HC.F RORB HPC Media F.SC <rorb_hpc_media@hc-sc.gc.ca>

Cc: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>

Subject: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press () Regulations of agricultural ivermectin

Hi MHPD,

As expected the reporter is asking for more details on the case in Manitoba.

Rong- you said that in this case, it was a third party we were dealing with, not the company/group that paid for the ad. At this point we have not released this information, given it was a third party. Can we put that as a response?

Carole – I believe Q5 falls under HPCD.

Input by noon on Monday would be greatly appreciated.

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 27

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Do you have more information on the false advertising in Manitoba?

Q2. How many billboards were there and where were they located?

Q3. Were they claiming ivermectin cures COVID-19?

Q4. Was the company fined?

Q5. And can businesses be fined for selling ivermectin if they know it won't be used for its intended purpose? (HPCD)

Response previously provided:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

One of Health Canada's roles, as the federal regulator, is the approval of veterinary drug products. The Department helps ensure that all veterinary drugs fully satisfy requirements under the Food and Drug Regulations before they can be marketed. Health Canada is also responsible for compliance monitoring and enforcement activities related to veterinary drugs in Canada, including verifying that they are marketed in a manner that is consistent with their terms of market authorization and federal legislation and are not advertised in a false, misleading or deceptive manner. Depending on the province or territory where the drugs are sold, there may be restrictions on who is permitted to purchase products intended for use in livestock. Health Canada does not have jurisdiction over how a product is ultimately used.

Following reports of the use of veterinary ivermectin drugs outside of approved directions for use (off-label use), Health Canada issued a public advisory to inform Canadians that Ivermectin is not authorized to prevent or treat COVID-19 and may pose serious health risks: <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of billboard advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the company displaying these ads removed them immediately, confirmed that these ads were no longer being displayed and committed to refraining from engaging in this non-compliant act in the future.

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred. Incidents of non-compliance are prioritised and

action is taken based on the risk they may pose to the general public. It is the responsibility of companies to comply with regulatory requirements and to investigate incidents of potential non-compliance, take appropriate action to correct non-compliance, mitigate any risk to health, and inform Health Canada as appropriate.

To report marketing that is false or misleading or does not meet regulatory requirements, visit <https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/illegal-marketing/complaint.html>.

As part of its ongoing commitment to openness and transparency, Health Canada posts a [summary of health product advertising complaints](#) as well as [health product advertising incidents related to COVID-19](#) addressed by the Department. This case is expected to be posted online in the coming weeks.

Tasked to:
Approved by:

Anne Génier

Senior Media Relations Advisor, Communication and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Conseillère principale des relations avec les médias, Direction générale des communications et des affaires publiques
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Media | Média T: [613-957-2983](tel:613-957-2983), E/CE: media@hc-sc.gc.ca

Pinard, Mike (HC/SC)

From: Robinson, Kelly (HC/SC)
Sent: 2021-09-22 4:15 PM
To: Sun, Rong (HC/SC); Sommerer, Sophie (HC/SC)
Cc: HC.F MHPD Action Requests F.SC
Subject: RE: Kelly/Sophie today Sept 22: Media Query: Winnipeg Free Press [REDACTED]
Regulations of agricultural ivermectin

Thanks, some tweaks here, approved, Kelly

Health Canada became aware of incidents ~~cases of human~~ Ivermectin advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, ~~that~~ the sponsor of these ads removed them immediately-, ~~the sponsor~~ confirmed that these ads were no longer being disseminated and committed to refraining from engaging in this non-compliant act in the future.

From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Sent: 2021-09-22 3:22 PM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhp_d_action_requests@hc-sc.gc.ca>
Subject: Kelly/Sophie today Sept 22: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Kelly/Sophie,

This media request is about veterinary Ivermectin, our input on its advertising was requested. Just so you know that the request also went to ROEB and VDD.

The wording in the question is vague which could cover both human and veterinary versions of this drug. We became aware of incidents of non-compliant advertising for human Ivermectin, no veterinary incidents have come to our attention.

The proposed MHPD input for your review **today**:

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of incidents ~~eases of human~~ Ivermectin advertising for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, ~~that the sponsor of these ads removes them immediately-~~ the sponsor confirmed that these ads were no longer being disseminated and committed to refrain from engaging in this non-compliant act in the future.

Many thanks,
RS

From: Pinard, Mike (HC/SC) <mike.pinard@hc-sc.gc.ca>
Sent: Wednesday, September 22, 2021 3:03 PM
To: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>

ATIA - 19(1)

Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>

Subject: Rong: OPRAA for action - Sept 22 by 3pm - FW: For MHPD input: Media Query: Winnipeg Free Press
Regulations of agricultural ivermectin

Hi Rong,

Media response is with you for review. Due back to CPAB by end of day today.

Thanks!

Mike

From: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>

Sent: 2021-09-22 2:56 PM

To: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>

Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>

Subject: FW: OPRAA for action - Sept 22 by 3pm - FW: For MHPD input: Media Query: Winnipeg Free Press
Regulations of agricultural ivermectin

Good afternoon,

Please see director approved response below.

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of cases of Ivermectin advertising for the treatment of COVID-19 in Manitoba this past summer. Health Canada requested that the sponsor of these ads removes them immediately. The sponsor confirmed that these ads were no longer being disseminated and committed to refrain from engaging in this non-compliant act in the future.

Thanks,
Martin

From: Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>

Sent: 2021-09-22 2:48 PM

To: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>; Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>

Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca>; Murray, Jennifer (HC/SC) <jennifer.murray@hc-sc.gc.ca>

Subject: RE: OPRAA for action - Sept 22 by 3pm - FW: For MHPD input: Media Query: Winnipeg Free Press
Regulations of agricultural ivermectin

Great thanks – Alain.
Approved

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>

Sent: 2021-09-22 1:06 PM

To: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>; Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>

Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca>; Murray, Jennifer (HC/SC) <jennifer.murray@hc-sc.gc.ca>

Subject: RE: OPRAA for action - Sept 22 by 3pm - FW: For MHPD input: Media Query: Winnipeg Free Press
[REDACTED] Regulations of agricultural ivermectin

Hi Hamida,

Here is our proposed response, in blue, to this media request. Please note the following:

- Q1 is ROEB's lead.
- Q2 involves advertising and sale. We have addressed the advertising component and ROEB should address the sale aspect.
- The sponsor confirmed that these ads were removed but we are still working with ROEB to verify whether these physical billboards are indeed no longer there.

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of cases of Ivermectin advertising for the treatment of COVID-19 in Manitoba this past summer. Health Canada requested that the sponsor of these ads removes them immediately. The sponsor confirmed that these ads were no longer being disseminated and committed to refrain from engaging in this non-compliant act in the future.

Thanks,

Alain G. Musende, PhD

Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/

Direction des produits de santé commercialisés

Government of Canada | Gouvernement du Canada

alain.musende@canada.ca

Tel: Cell: (613) 302-4856 / Office:: Cell: (613) 954-6780

200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D

Ottawa, Canada K1A 0K9

From: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>

Sent: 2021-09-22 11:05 AM

To: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca>

Cc: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>

Subject: FW: OPRAA for action - Sept 22 by 3pm - FW: For MHPD input: Media Query: Winnipeg Free Press
[REDACTED] Regulations of agricultural ivermectin

Good morning all,

ATIA - 19(1)

Please see action request below, due by 3:00 pm today.

Thanks,
Martin

From: Thin, Sophea (HC/SC) <sophea.thin@hc-sc.gc.ca>
Sent: 2021-09-22 11:03 AM
To: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: OPRAA for action - Sept 22 by 3pm - FW: For MHPD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

LEAD BUREAU	OPRAA
RESPONSE TO BE SENT TO	MHPD Action Requests
MECS NUMBER	Nil
DUE IN DGO BY	Sept 22 by 3pm
CONSULTATIONS	The "lead" bureau is responsible to include and incorporate all relevant information and approvals in the final response being submitted to DGO.
	Please indicate (via email or MECS) whom your bureau has consulted with: (i.e. other MHPD Bureaux, a Directorate, Legal Services, ROEB, SPB, etc.)

Please consult directly with other bureaus if necessary prior to submission to DGO

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>
Sent: 2021-09-22 10:53 AM
To: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Cc: Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC <aldege.bellefeuille@canada.ca>; Keeping, Elizabeth (HC/SC <elizabeth.keeping@canada.ca>; Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Subject: For MHPD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Good morning MHPD colleagues,

We have received a media query on agricultural ivermectin. Initially, this query was sent to CFIA but they confirmed that HC may have a role to play.

We have sent the request to HPCD but they have advised that your team may be able to provide input for **Q2**.

Your input by end of day would be greatly appreciated.

Thank you,

ATIA - 19(1)

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Tasked to:

Approved by:

Anne Génier

Senior Media Relations Advisor, Communication and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Conseillère principale des relations avec les médias, Direction générale des communications et des affaires publiques
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Media | Média T: [613-957-2983](tel:613-957-2983), E/CE: media@hc-sc.gc.ca

From: Ferrier, Sylvie (HC/SC)
Sent: 2021-09-09 2:52 PM
To: Duguay, David (HC/SC); Sleno, Rory (HC/SC)
Subject: Literature update - Ivermectin
Attachments: Ivermectin_PSL5_Summary_9-Sept-2021_SF.docx

Follow Up Flag: Follow up
Flag Status: Completed

Hi David and Rory,

As discussed, I've updated the ivermectin literature summary to include the 2011 study (re: sperm effects) as well as some key limitations/messages.

Please let me know if you have any questions,

Sylvie
(she | elle)

Scientific Evaluator, Health Products and Food Branch
Health Canada and Public Health Agency of Canada, Government of Canada
sylvie.ferrier@canada.ca / Tel : 613-878-4727

Évaluatrice scientifique, Direction générale des produits de santé et des aliments
Santé Canada et Agence de la santé publique du Canada, Gouvernement du Canada
sylvie.ferrier@canada.ca / Tél : 613-878-4727

Pinard, Mike (HC/SC)

From: Pinard, Mike (HC/SC)
Sent: 2021-09-08 4:26 PM
To: Genier, Anne (HC/SC)
Cc: HC.F MHPD Action Requests F.SC
Subject: MHPD approved: Media Query: Toronto Star [REDACTED] Use of Ivermectin to treat COVID-19 + incident report

Hi Anne,

Please see MHPD's approved input noted below.

Thanks!

Mike

From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Sent: 2021-09-08 3:46 PM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Subject: Kelly COB today: Media Query: Toronto Star [REDACTED] Use of Ivermectin to treat COVID-19 + incident report

Hi Kelly,

Looks like Ivermectin is getting media attention. We have been asked to provide input to the Toronto Star question:

Q1. I'm writing about ivermectin and its rise in popularity as a COVID-19 treatment despite it being unauthorized for such use. The advisory posted last week notes that Health Canada has received reports of people using ivermectin for COVID-19 purposes; does Health Canada have numbers on how many reports have been made and where these reports are coming from?

We have asked CPAB to reach out to ROEB and VDD as well, and ROEB should lead. TPD did not have any.

MHPD proposed input, for your review today:

Ivermectin is an antiparasitic agent approved for use in humans and animals. There are concerns about consumers purchasing veterinary Ivermectin to prevent or treat COVID-19. On August 31, 2021, Health Canada published a Public Advisory (<https://healthykanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>) informing the public that Ivermectin is not authorized to prevent or treat COVID-19 and using it for such purposes can cause serious health problems. This advisory noted that the Department has received concerning reports of the use of veterinary ivermectin to prevent or treat COVID-19. This is in reference to reports of patients in the U.S. as stated in the advisory. (**CPAB**, please check with VDD/ROEB to confirm)

ATIA-14(b)

ATIA - 19(1)

At this time, Health Canada has not received reports of adverse events associated with the use of ivermectin-containing products in humans for COVID-19 purposes. [REDACTED]

From: Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>
Sent: 2021-09-08 1:42 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; HC.F TPD Media Requests F.SC <tpd_media_requests@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Cc: Aboueid, Suzane (HC/SC) <suzane.aboueid@hc-sc.gc.ca>; Francis-Lamb, Laura (HC/SC) <laura.francis-lamb@hc-sc.gc.ca>; Zaman, Muhammad (HC/SC) <muhammad.zaman@hc-sc.gc.ca>
Subject: RE: For HPFB-TBD input: Media Query: Toronto Star [REDACTED] Use of Ivermectin to treat COVID-19 + incident report

You may want to try ROEB as they initiated the PA. Otherwise, VDD. My understanding from MHPD is that we are not seeing an increase in the prescribing of ivermectin – the concern seems to be more about the use of the veterinary form.

From: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Sent: 2021-09-08 1:31 PM
To: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; HC.F TPD Media Requests F.SC <tpd_media_requests@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Cc: Aboueid, Suzane (HC/SC) <suzane.aboueid@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; Francis-Lamb, Laura (HC/SC) <laura.francis-lamb@hc-sc.gc.ca>; Zaman, Muhammad (HC/SC) <muhammad.zaman@hc-sc.gc.ca>
Subject: RE: For HPFB-TBD input: Media Query: Toronto Star [REDACTED] Use of Ivermectin to treat COVID-19 + incident report

Hi there Anne,

TPD has no reports of ivermectin use – maybe MHPD has these? However, I believe the “reports” mentioned in the advisory, with regards to veterinary ivermectin use, were media reports, i.e. news articles.

P

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>
Sent: 2021-09-08 12:05 PM
To: HC.F TPD Media Requests F.SC <tpd_media_requests@hc-sc.gc.ca>
Cc: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Aboueid, Suzane (HC/SC) <suzane.aboueid@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; Francis-Lamb, Laura (HC/SC) <laura.francis-lamb@hc-sc.gc.ca>; Zaman, Muhammad (HC/SC) <muhammad.zaman@hc-sc.gc.ca>
Subject: For HPFB-TBD input: Media Query: Toronto Star ([REDACTED]) Use of Ivermectin to treat COVID-19 + incident report

Good day HPFB,

We have received a media query asking the # of reports received on the use of ivermectin to treat COVID-19 (as stated in the recall last week Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems - Recalls and safety alerts (healthycanadians.gc.ca))

Is this information we can provide to the reporter? Note the tight deadline (2 pm today)– I will manage the reporter's expectations.

Your input would be greatly appreciated.

Thank you.

Anne

Media/Reporter: Toronto Star [REDACTED]

Deadline to reporter: September 8 / 2 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. I'm writing about ivermectin and its rise in popularity as a COVID-19 treatment despite it being unauthorized for such use. The advisory posted last week notes that Health Canada has received reports of people using ivermectin for COVID-19 purposes; does Health Canada have numbers on how many reports have been made and where these reports are coming from?

Tasked to:
Approved by:

Anne Génier

Senior Media Relations Advisor, Communication and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Conseillère principale des relations avec les médias, Direction générale des communications et des affaires publiques
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967
- - -

Media | Média T: [613-957-2983](tel:613-957-2983), E/CE: media@hc-sc.gc.ca

Pinard, Mike (HC/SC)

From: Pinard, Mike (HC/SC)
Sent: 2021-09-27 12:41 PM
To: Genier, Anne (HC/SC)
Cc: HC.F MHPD Action Requests F.SC
Subject: MHPD DG Approved: Media Query: Follow-up: Winnipeg Free Press [REDACTED]
 Regulations of agricultural ivermectin

Hi Anne,

Please see MHPD's DG approved responses below.

Thanks!

Mike

From: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Sent: 2021-09-27 12:28 PM
To: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: RE: Kelly/Sophie asap: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Approved with changes below - thanks, Kelly

Q1. Do you have more information on the false advertising in Manitoba?

R1. ~~We provided all the information explaining Health Canada's handling of this issue.~~
 Additional information is provided below.

Q2. How many billboards were there and where were they located?

R2. ~~We~~ Health Canada received complaints about billboards in the Winkler area. We cannot confirm how many billboards were in the area at that time, however the company has confirmed that all billboards with these claims have been removed.

Q3. Were they claiming ivermectin cures COVID-19?

R3. ~~No,~~ They were all advertising Ivermectin for the treatment of COVID-19.

Q4. Was the company fined?

R4. [REDACTED] we Health Canada issued a regulatory letter requesting that the sponsor of these ads to removes them immediately. The sponsor has confirmed that these ads are no longer being displayed and committed to refrain from engaging in this non-compliant act in the future.

Requester agreed to
Remove 3rd Party Info

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>
Sent: Friday, September 24, 2021 4:17 PM
To: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; HC.F RORB HPC Media F.SC

ATIA - 19(1)

<rorb_hpc_media@hc-sc.gc.ca>

Cc: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>

Subject: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi MHPD,

As expected the reporter is asking for more details on the case in Manitoba.

Rong- you said that in this case, it was a third party we were dealing with, not the company/group that paid for the ad. At this point we have not released this information, given it was a third party. Can we put that as a response?

Carole – I believe Q5 falls under HPCD.

Input by noon on Monday would be greatly appreciated.

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 27

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Do you have more information on the false advertising in Manitoba?

Q2. How many billboards were there and where were they located?

Q3. Were they claiming ivermectin cures COVID-19?

Q4. Was the company fined?

Q5. And can businesses be fined for selling ivermectin if they know it won't be used for its intended purpose? (HPCD)

.

Response previously provided:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

One of Health Canada's roles, as the federal regulator, is the approval of veterinary drug products. The Department helps ensure that all veterinary drugs fully satisfy requirements under the Food and Drug Regulations before they can be marketed. Health Canada is also responsible for compliance monitoring and enforcement activities related to veterinary drugs in Canada, including verifying that they are marketed in a manner that is consistent with their terms of market authorization and federal legislation and are not advertised in a false, misleading or deceptive manner. Depending on the province or territory where the drugs are sold,

there may be restrictions on who is permitted to purchase products intended for use in livestock. Health Canada does not have jurisdiction over how a product is ultimately used.

Following reports of the use of veterinary ivermectin drugs outside of approved directions for use (off-label use), Health Canada issued a public advisory to inform Canadians that Ivermectin is not authorized to prevent or treat COVID-19 and may pose serious health risks: <https://healthykanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of billboard advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the company displaying these ads removed them immediately, confirmed that these ads were no longer being displayed and committed to refraining from engaging in this non-compliant act in the future.

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred. Incidents of non-compliance are prioritised and action is taken based on the risk they may pose to the general public. It is the responsibility of companies to comply with regulatory requirements and to investigate incidents of potential non-compliance, take appropriate action to correct non-compliance, mitigate any risk to health, and inform Health Canada as appropriate.

To report marketing that is false or misleading or does not meet regulatory requirements, visit <https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/illegal-marketing/complaint.html>.

As part of its ongoing commitment to openness and transparency, Health Canada posts a [summary of health product advertising complaints](#) as well as [health product advertising incidents related to COVID-19](#) addressed by the Department. This case is expected to be posted online in the coming weeks.

Tasked to:
Approved by:

Anne Génier

Senior Media Relations Advisor, Communication and Public Affairs Branch
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anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

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Media | Média T: [613-957-2983](tel:613-957-2983), E/CE: media@hc-sc.gc.ca

Pinard, Mike (HC/SC)

From: Pinard, Mike (HC/SC)
Sent: 2021-09-22 4:29 PM
To: Genier, Anne (HC/SC)
Cc: Bellefeuille, Aldege (HC/SC); Keeping, Elizabeth (HC/SC); HC.F MHPD Action Requests F.SC
Subject: MHPD DG Approved: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Anne,

Our DG approved response to Q2 is pasted below.

Thanks!

Mike

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>
Sent: 2021-09-22 10:53 AM
To: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Cc: Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@canada.ca>; Keeping, Elizabeth (HC/SC) <elizabeth.keeping@canada.ca>; Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Subject: For MHPD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Good morning MHPD colleagues,

We have received a media query on agricultural ivermectin. Initially, this query was sent to CFIA but they confirmed that HC may have a role to play.

We have sent the request to HPCD but they have advised that your team may be able to provide input for Q2.

Your input by end of day would be greatly appreciated.

Thank you,

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the sponsor of these ads removed them immediately, confirmed that these ads were no longer being disseminated and committed to refraining from engaging in this non-compliant act in the future.

Tasked to:

Approved by:

Anne Génier

Senior Media Relations Advisor, Communication and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

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Media | Média T: [613-957-2983](tel:613-957-2983), E/CE: media@hc-sc.gc.ca

Pinard, Mike (HC/SC)

From: Sommerer, Sophie (HC/SC)
Sent: 2021-09-13 12:16 PM
To: Robinson, Kelly (HC/SC); Rahim, Hamida (HC/SC)
Cc: Sun, Rong (HC/SC)
Subject: RE: new advertising issue?

Re. the ivermectin incident, I was just wondering if there would be any follow-up by HC with the organization that sponsored the ad or is it always directed at the publisher?

From: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Sent: 2021-09-13 11:43 AM
To: Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Cc: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Subject: RE: new advertising issue?

Thanks for the follow up on Ivermectin.
Regarding Parvulan - please let us know if the team has seen any such advertising. Thank you, Kelly

From: Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>
Sent: 2021-09-13 11:35 AM
To: Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>; Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Cc: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Subject: RE: new advertising issue?

Hi Sophie and Kelly,

The team did carry out a compliance assessment of the Ivermectin case and we determined that it constitutes advertising of a health product to the public for the treatment of a Schedule A disease, in contravention of the *Food & Drugs Act*.

Alain called [REDACTED] the representative for Magnetsigns in Winkler, Manitoba on August 27, 2021 to discuss the case, inform them of Health Canada's position, request to immediately remove all signs with the contravening information and inform them that we are in the process of sending them a regulatory letter. Magnetsigns [REDACTED]
[REDACTED]

We sent a regulatory letter to the representative for Magnetsigns in Winkler, Manitoba on August 31, 2021 requesting that Magnetsigns immediately acknowledges receipt of our correspondence and ceases any advertising of Ivermectin or any other product in all media for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Furthermore, we reach out to ROEB to discuss this case and check if they can confirm whether the billboards in Winkler and area have been removed and they agreed to keep us posted.

The team is currently following up with ROEB now to see if the billboards have in fact been removed in the specific area identified above. I will get back to you once we have confirmed.

Thanks
Hamida

From: Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Sent: 2021-09-13 11:22 AM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>
Cc: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Subject: RE: new advertising issue?

Hi Kelly, Hamida,

Here's what I found in the GPHIN article that they refer to below:

- **Italy:** Italy's medicines agency IFA has warned officials of a high number of requests to import Parvulan, an antiviral drug used as treatment for Herpes Zoster, which is not authorized in Italy but legally registered and marketed in Brazil. IFA indicated that requests from customers in Italy showed that Parvulan is being proposed off-label as a treatment for the prevention of COVID-19, in alternative to licensed vaccines. ([National Post](#))

I don't know if Parvulan is authorized in Canada.

Sophie

From: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Sent: 2021-09-13 11:13 AM
To: Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>
Cc: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Subject: FW: new advertising issue?

Hi Hamida,

Please see the email below - wondering if you or the team are aware of any "new" products being advertised for COVID treatments. Thanks, Kelly

From: Lourenco, Celia (HC/SC) <celia.lourenco@hc-sc.gc.ca>
Sent: 2021-09-13 11:07 AM
To: Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>; Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Subject: RE: HPEC Sept 13

Hi Marilyne, I'm not aware of which drug she may be referring to other than ivermectin. I'm copying Kelly in case she is aware based on MHPD surveillance of false advertising claims. Thanks, Celia

From: Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>
Sent: 2021-09-13 10:56 AM
To: Lourenco, Celia (HC/SC) <celia.lourenco@hc-sc.gc.ca>; Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>
Subject: FW: HPEC Sept 13
Importance: High

Hi Celia and Pat,

CPHO has flagged that some people are using an unauthorized treatment other than ivermectin. Are you aware of what drug they may be talking about it? In the meantime, I've shared this generic messaging with PHAC comms:

- Every drug or health product making a therapeutic claim sold or marketed in Canada needs to be approved by Health Canada for safety, efficacy and quality.
- For drugs that show an early promise in treating COVID-19, the best way to access therapies is through clinical trials.
- Health Canada encourages health care professionals prescribing or using experimental therapies for COVID-19 patients to contact the Department to initiate a clinical trial.
- Health Canada is working closely with other international regulators and the World Health Organisation to share information about potential COVID-19 treatments.

Thanks

From: Fraser, Holly (HC/SC) <holly.fraser@hc-sc.gc.ca>
Sent: 2021-09-13 10:49 AM
To: Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>
Subject: FW: HPEC Sept 13
Importance: High

Good morning Marilyne,

CPHO flagged at HPEG that people are using another unauthorized COVID treatment – do you have any info or messaging on this item?

Thanks,

Holly

From: McLachlan, Kailey (HC/SC) <kailey.mclachlan@hc-sc.gc.ca>
Sent: 2021-09-13 10:09 AM
To: Earley, Jaimie (HC/SC) <jaimie.earley@hc-sc.gc.ca>; Allison, Catherine (HC/SC) <catherine.allison@hc-sc.gc.ca>; Sousa, Marcella (HC/SC) <marcella.sousa@hc-sc.gc.ca>; Magee, Heather (HC/SC) <heather.magee@hc-sc.gc.ca>; Russo, Laura (HC/SC) <laura.russo@hc-sc.gc.ca>; Hinds, Chris (HC/SC) <chris.hinds@hc-sc.gc.ca>; Gearey, Jennifer (HC/SC) <jennifer.gearey@hc-sc.gc.ca>; Ward, Jonathan (HC/SC) <jonathan.ward@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>
Cc: Manick, Alexis (HC/SC) <alexis.manick@hc-sc.gc.ca>; Burke, Suzanne (HC/SC) <suzanne.burke@hc-sc.gc.ca>
Subject: HPEC Sept 13
Importance: High

Good morning,

Lisa is back tomorrow so this is your last set of HPEG notes from me for now! Have a great day ☺

Kailey

HPEG:

Dr Tam:

- People are ordering another strange covid treatment product (didn't catch the name) – saw on GPHN this morning – will monitor and flag if we need to communicate on this.
 - o Comms – dust off lines on COVID treatment in case w need them

Pinard, Mike (HC/SC)

From: Pinard, Mike (HC/SC)
Sent: 2021-08-25 12:15 PM
To: Barre, Martin (HC/SC)
Cc: HC.F MHPD Action Requests F.SC; HC.F MHPD OPRAA Assistants F.SC; Berg, Jason (HC/SC); Musende, Alain (HC/SC)
Subject: FW: OPRAA for action due ASAP [REDACTED] - Ivermectin signage concern [REDACTED]

Hi Martin,

DGO is advising that OPRAA can deal with this in house in the normal manner used to process general advertising complaints. I will remove this from the DGO tracking.

Thanks!

Mike

From: Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>
Sent: 2021-08-25 11:57 AM
To: Pinard, Mike (HC/SC) <mike.pinard@hc-sc.gc.ca>
Subject: RE: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage concern [REDACTED]

Ok great, so as long as there is no direct response to the complainant from us, then let's please advise OPRAA to go ahead as per usual processes.

Thanks everyone!
Mel.

From: Pinard, Mike (HC/SC) <mike.pinard@hc-sc.gc.ca>
Sent: 2021-08-25 11:55 AM
To: Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: RE: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage concern [REDACTED]

Hi Mel,

In my experience DGO does not usually review advertising related actions. In this case, because the letter came from TPD as a re-direct to our DGO, I had classified it as a general OOB when it should've been classified as an advertising complaint instead. I think it makes more sense for OPRAA to treat this the same as any other advertising complaint and move forward with it as per their normal process (ie, forward to their counterparts in ROEB for action).

Thanks

Mike

From: Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>
Sent: 2021-08-25 11:39 AM

To: Pinard, Mike (HC/SC) <mike.pinard@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: RE: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage concern [REDACTED]

Thanks team. I have some procedural questions before I proceed.

(I see Jason was wondering what DGO was expecting; and we were expecting this would be treated as a regular advertising complaint.)

- Does OPRAA normally respond to the complainant directly when we re-direct to ROEB? I'm guessing not based on the email below, in which we are only recommending a redirect to ROEB. **If yes**, I will send to Kelly for review due to caretaker considerations.
- Does DGO usually review advertising-related actions? I don't think I've seen one before, but it's possible they've all been going to Rong until now. If not, and **only if we aren't planning to respond directly to the complainant**, OPRAA can go ahead as per usual.

Thanks! And thanks to OPRAA for keeping us in the loop.
Mel.

From: Pinard, Mike (HC/SC) <mike.pinard@hc-sc.gc.ca>
Sent: 2021-08-25 11:30 AM
To: Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>
Cc: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: Mel: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage concern [REDACTED]

Hi Mel,

OPRAA suggests re-directing this OOB to ROEB. With you for review.

Thanks

Mike

From: Barre, Martin (HC/SC) <martin.barre@hc-sc.gc.ca>
Sent: 2021-08-25 11:27 AM
To: Morgan, Haylee (HC/SC) <haylee.morgan@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: FW: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage concern [REDACTED]

Good morning,

Apologies for the delay, this response has been sitting in my drafts rather than being sent out. Please see director approved response below with the recommendation that it be redirected to ROEB.

Thanks,
Martin

From: Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca>
Sent: 2021-08-23 3:23 PM
To: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>; Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>

Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>; HC.F MHPD
OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>

Subject: RE: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage
concern [REDACTED]

Great. Thanks

@ Martin. Please respond to DGO as Alain suggests below and include the following:

We have reviewed this message and it indeed constitutes advertising of a health product to the public for the treatment of a Schedule A disease, and would also constitute an off-label advertising, both in contravention of the *FOOD & Drugs Act*. Although [REDACTED]

OPRAA will refer the case to ROEB for dispatching a regional inspector to determine the advertiser, probably via the billboard rental company and request required corrective actions.

Thanks
Jason

Requester agreed to
Remove 3rd Party Info

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>

Sent: 2021-08-23 3:03 PM

To: Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca>; Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>

Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>; HC.F MHPD
OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>

Subject: RE: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage
concern [REDACTED]

Yes, this is a good approach as well. Martin could inform DGO that we are referring it to ROEB with the explanation below and I am referring it now to Toufic, the manager at HPCD, and his supervisors.

Thanks,

Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca
Tel: Office : (613) 954-6780 / Cell : (613) 302-4856
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

From: Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca>

Sent: 2021-08-23 2:59 PM

To: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>; Rahim, Hamida (HC/SC)
<hamida.rahim@hc-sc.gc.ca>

Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>; HC.F MHPD

OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>

Subject: RE: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage concern [REDACTED]

Thanks, Alain. It's not clear to me from the action request what DGO was looking for. Can we just signal to them that we have reviewed it and will refer the matter to ROEB for further action? I would include the summary below.

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>

Sent: 2021-08-23 2:46 PM

To: Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca>; Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>

Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>; HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>

Subject: RE: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage concern [REDACTED]

Hello Jason,

Requester agreed to
Remove 3rd Party Info

Here is our proposed response to this action request, for your review/approval:

We have reviewed this message and it indeed constitutes advertising of a health product to the public for the treatment of a Schedule A disease, and would also constitute an off-label advertising, both in contravention of the *FOOD & Drugs Act*. Although the [REDACTED]

[REDACTED]

As such, we propose as a course action that the case be referred to ROEB for dispatching a regional inspector to determine the advertiser, probably via the billboard rental company and request required corrective actions.

Thanks,

Alain G. Musende, PhD

Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité

Marketed Health Products Directorate/

Direction des produits de santé commercialisés

Government of Canada | Gouvernement du Canada

alain.musende@canada.ca

Tel: Office : (613) 954-6780 / Cell : (613) 302-4856

200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D

Ottawa, Canada K1A 0K9

From: Morgan, Haylee (HC/SC) <haylee.morgan@hc-sc.gc.ca>

Sent: 2021-08-23 8:26 AM

To: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>

Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>

Subject: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage concern [REDACTED]

LEAD BUREAU	OPRAA
RESPONSE TO BE SENT TO	MHPD Action Requests
MECS NUMBER	Nil
DUE IN DGO BY	ASAP
CONSULTATIONS	The "lead" bureau is responsible to include and incorporate all relevant information and approvals in the final response being submitted to DGO.
	Please indicate (via email or MECS) whom your bureau has consulted with: (i.e. other MHPD Bureaux, a Directorate, Legal Services, ROEB, SPB, etc.)

Please consult directly with other bureaus if necessary prior to submission to DGO

From: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>

Sent: 2021-08-23 7:52 AM

To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>

Cc: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>

Subject: FW: [REDACTED] - Ivermectin signage concern [REDACTED]

Hi Kelly

As this compliant involves what appears to be inappropriate advertising of an approved health product I am forwarding this onto for MHPD's assessment. I have cc'd Linsey Hollet as well.

If you are okay with it, I will respond back to [REDACTED] indicating receipt of the email and that I have forwarded it onto to MHPD for action.

Thanks.

Pat

Dr. J. Patrick Stewart, MD, CCFP(EM)
Director General/ Directeur général
Therapeutic Products Directorate/ Direction des produits thérapeutiques
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
613-859-2433 (cell)

From: Rani Chatterjee-Mehta <rchatterjee-mehta@cphm.ca>

Sent: 2021-08-20 6:44 PM

To: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>

Cc: prescription.drug.enquiries / renseignements.drogue.ordonnance (HC/SC) <prescription.drug.enquiries-renseignements.drogue.ordonnance@hc-sc.gc.ca>; Susan Lessard-Friesen <slessard-friesen@cphm.ca>

Subject: College of Pharmacists of Manitoba - Ivermectin signage concern [REDACTED]

Dear Dr. Stewart,

ATIA - 19(1)

I am writing to you on behalf of [REDACTED] regarding a concern that had been brought to our attention recently involving the advertisement of the use of Ivermectin in treating Covid-19.

[REDACTED]

[REDACTED] has recently received notification from two rural pharmacists about a sign along a rural highway in Manitoba that reads "Ivermectin treats COVID-19 [REDACTED]". I have attached a picture for your review as well. These pharmacists have expressed great concern about this apparent misinformation, placed in a region with extremely poor/low vaccination uptake, combined with the potentially lower educational levels of some residents of the particular area.

[REDACTED]

[REDACTED] The information was originally shared with the provincial College of Physicians and Surgeons of Manitoba (CPSM) for their review and considerations for further action. Unfortunately, none of the HCPs fall under the jurisdiction of the CPSM [REDACTED]

The TPD may already be aware of this inaccurate/non-compliant advertising, and I'm forwarding to you for your consideration on how best to address and manage. Perhaps the TPD may consider direct communication to [REDACTED] to remove all non-compliant advertisements regarding Ivermectin use in Covid-19. Is there anything further that the TPD can do about this advertising considering this drug is not approved for use in Covid-19 in Canada?

For your reference, I have also brought this to the attention of our provincial Vaccine Implementation Task Force (VITF) Medical Team Leads for their consideration of addressing provincially as well.

[REDACTED] is very open to any direction you may wish to provide on this, and would be agreeable to any further discussions as well. Please feel welcome to contact me should you wish to discuss further and I will ensure arrangements are made.

I look forward to hearing from you.

Kind regards,

Requester agreed to
Remove 3rd Party Info

	A	B	C	D	E
1		EMA Paper (Refer to Public Health Communication)	Included (Y/N)	Comments	Safety concern
2	1	Elgazzar, A., et al., <i>Efficacy and safety of ivermectin for treatment and prophylaxis of COVID-19 pandemic</i> . Research Square, 2020.	N	No description of Aes, low quality study, pre-peer review, 4-9 days of consecutive use (400 mcg/kg bw)	None
3	2	Ahmed, S., et al., <i>A five-day course of ivermectin for the treatment of COVID-19 may reduce the duration of illness</i> . Int J Infect Dis, 2021. 103: p. 214-216.	N	"There were no severe adverse events recorded in the study", 12 mg once daily for 5 days	None
4	3	Alam, M.T., et al., <i>Ivermectin as pre-exposure prophylaxis for COVID-19 among healthcare providers in a selected tertiary hospital in Dhaka – an observational study</i> . European Journal of Medical Health and Sciences, 2020.	N	No description of AES, Low quality study, Oral monthly dose of 12mg for 4 months.	None
5	4	Arévalo, A.P., et al., <i>Ivermectin reduces coronavirus infection in vivo: a mouse experimental model</i> . Biorxiv, 2020.	N	In vivo	N/A
6	5	Babalola, O.E., et al., <i>Ivermectin shows clinical benefits in mild to moderate COVID19: a randomised controlled double-blind, dose-response study in Lagos</i> . QJM, 2021.	N	Low quality study, "No adverse effects of ivermectin was reported in response to questioning or spontaneous report"	None
7	6	Behera, P., et al., <i>Prophylactic role of ivermectin in SARS-CoV-2 infection among healthcare workers</i> . Research Square, 2021.	Y	Low quality study, Updake of 2 doses of ivermectin (300 mcg/kg separated by 72hrs). Only 1.8% of the participants reported adverse events, which were mild and self-limiting.	Adverse events were-headache, diarrhoea, nausea, itching, rashes, fatigue, vomiting, dizziness, and abdominal pain.
8	7	Bray, M., et al., <i>Ivermectin and COVID-19: a report in antiviral research, widespread interest, an FDA warning, two letters to the editor and the authors' responses</i> . Antiviral Res, 2020. 178: p. 104805.	N	Previously dismissed by PSLS	None
9	8	Caly, L., et al., <i>The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro</i> . Antiviral Res, 2020. 178: p. 104787.	N	In vitro	N/A
10	9	Camprubí, D., et al., <i>Lack of efficacy of standard doses of ivermectin in severe COVID-19 patients</i> . PLoS One, 2020. 15(11): p. e0242184.	N	Previously dismissed by PSLS	None
11	10	Carvalho, H., et al., <i>Safety and efficacy of the combined use of ivermectin, dexamethasone, enoxaparin and aspirin against COVID 19</i> . MedRxiv, 2020.	N	Low quality study, "No adverse effects of ivermectin was reported in response to questioning or spontaneous report"	None
12	11	Carvalho, H., et al., <i>Study of the efficacy and safety of topical ivermectin + iota-carrageenan in the prophylaxis against COVID-19 in health personnel</i> . Journal of Biomedical Research and Clinical Investigation, 2020.	N	Low quality study, 24-48 mg given 7 days apart, in combination with DEX and aspirin.	Only one patient suffered from a serious adverse event. It was a patient who had previous history of gastric ulcer and contracted one during treatment, probably caused by Dexamethasone
13	12	Castañeda-Sabogal, A., et al., <i>Outcomes of ivermectin in the treatment of COVID-19: a systematic review and meta-analysis</i> . Medrxiv, 2021.	N	High risk of bias, very low certainty of evidence. MA did not report on safety (efficacy only).	None
14	13	Chaccour, C., et al., <i>Nebulized ivermectin for COVID-19 and other respiratory diseases, a proof of concept, dose-ranging study in rats</i> . Sci Rep, 2020. 10(1): p. 17073.	N	In vivo	N/A

	A	B	C	D	E
14		Chaccour, C., et al., <i>The effect of early treatment with ivermectin on viral load, symptoms and humoral response in patients with non-severe COVID-19: a pilot, double-blind, placebo-controlled, randomized clinical trial</i> . EClinicalMedicine, 2021: p. 100720.	Y	Low quality study, small sample size, 400 mcg/kg single dose vs placebo	There were no differences in the reported patient-days between the ivermectin and the placebo group for confusion (1 vs 0), drowsiness (0 vs 0), or pruritus (0 vs 3). Patients in the ivermectin group reported more patient-days of dizziness (7 vs 1) and blurred vision (24 vs 1), with this last value driven by a single patient in the ivermectin group reporting blurred vision on days 2— 28, further evaluation suggested previously undiagnosed presbyopia.
15					
16	15	Chachar, A.Z.K., et al., <i>Effectiveness of ivermectin in SARS-CoV-2/COVID-19 patients</i> . International Journal of Sciences, 2020. 9(09): p. 31-35.	N	Low quality study, no discussion of Aes or safety	None
17	16	Chowdhury, A.T.M.M., et al., <i>A randomized trial of ivermectin-doxycycline and hydroxychloroquine-azithromycin therapy on COVID19 patients</i> . Research Square, 2020.	N	Low quality study, 200 mcg/kg single dose + doxycycline BID for 10 days. Not designed to isolate the safety of ivermectin alone.	Group A patients had symptoms that could have been caused by the medication in 31.67% of patients, including lethargy in 14(23.3%), nausea in 11(18.3%), and occasional vertigo in 7(11.66%) of patients. Not included as there is no control to isolate ivermectin use.
18	17	de Melo, G.D., et al., <i>Anti-COVID-19 efficacy of ivermectin in the golden hamster</i> . BioRxiv, 2020.	N	In vivo	N/A
19	18	Elalfy, H., et al., <i>Effect of a combination of nitazoxanide, ribavirin, and ivermectin plus zinc supplement (MANS.NRIZ study) on the clearance of mild COVID-19</i> . J Med Virol, 2021.	N	Triple combination of ivermectin, nitazoxanide and ribavirin. Not designed to isolate the safety of ivermectin alone.	N/A
20	19	Errecalde, J., et al., <i>Safety and pharmacokinetic assessments of a novel ivermectin nasal spray formulation in a pig model</i> . J Pharm Sci, 2021.	N	In vivo	N/A
21	20	Espitia-Hern, G., et al., <i>Effects of ivermectin-azithromycin-cholecalciferol combined therapy on COVID-19 infected patients: A proof of concept study</i> . Biomedical Research, 2020.	N	Triple combination of ivermectin-azithromycin-cholecalciferol. Not designed to isolate the safety of ivermectin alone.	Transient and mild adverse reactions like diarrhea and nausea have been reported in 3 (10.7%) patients in the combination group.
22	21	Formiga, F.R., et al., <i>Ivermectin: an award-winning drug with expected antiviral activity against COVID-19</i> . J Control Release, 2020.	N	Review paper.	N/A
23	22	Gonzalez, J.L.B., et al., <i>Efficacy and safety of ivermectin and hydroxychloroquine in patients with severe COVID-19. A randomized controlled trial</i> . Medrxiv, 2021.	N	Low quality study, single dose of 12mg or 18 mg based on patient weight. No Aes discussed.	None
24	23	Gorial, F.I., et al., <i>Effectiveness of ivermectin as add-on therapy in COVID-19 management (pilot trial)</i> . Medrxiv, 2020.	N	Low quality study, 200 mcg/kg IVM + HCQ and AZT, compared to HCQ and AZT. "No adverse events were observed"	None
25	24	Hashim, H.A., et al., <i>Controlled randomized clinical trial on using ivermectin with doxycycline for treating COVID-19 patients in Baghdad, Iraq</i> . Medrxiv, 2020.	N	200 mcg/kg PO per day for 2-3 days + doxycycline vs standard therapy. Not designed to isolate the safety of ivermectin alone. No discussion of Aes.	None

	A	B	C	D	E
26	25	Hellwig, M.D., and Maia, A., <i>A COVID-19 prophylaxis? Lower incidence associated with prophylactic administration of ivermectin.</i> Int J Antimicrob Agents, 2021. 57(1): p. 106248.	N	Low quality study (overlapping covid cases with ivermectin exposure).No discussion of safety or Aes.	None
27	26	Hill, A., et al., <i>Meta-analysis of randomized trials of ivermectin to treat SARS-CoV-2 infection.</i> Research Square, 2021.	N	High heterogeneity of evidence. No discussion of safety outcomes.	None
28	27	Jermain, B., et al., <i>Development of a minimal physiologically-based pharmacokinetic model to simulate lung exposure in humans following oral administration of ivermectin for COVID-19 drug repurposing.</i> J Pharm Sci, 2020. 109(12): p. 3574-3584.	N	PK modeling using population model.	N/A
29	28	Kalfas, S., et al., <i>The therapeutic potential of ivermectin for covid-19: a systematic review of mechanisms and evidence.</i> Medrxiv, 2020.	N	Systematic review (no M-A)	N/A
30	29	Khan, M.S.I., et al., <i>Ivermectin treatment may improve the prognosis of patients with COVID-19.</i> Arch Bronconeumol, 2020. 56(12): p. 828-830.	N	Low quality study, published as "letter to editor". "The treatment did not produce any aberrant symptoms related to ivermectin use. "	None
31	30	Kim, M.S., et al., <i>Comparative efficacy and safety of pharmacological interventions for the treatment of COVID-19: a systematic review and network meta-analysis.</i> PLoS Med, 2020. 17(12): p. e1003501.	N	Large M-A for all COVID-19 treatments, comparing efficacy outcomes. Ivermectin AEs not discussed.	None
32	31	Kory, P., et al., <i>Review of the emerging evidence demonstrating the efficacy of ivermectin in the prophylaxis and treatment of COVID-19.</i> FICCC.net, 2021.	N	Systematic review (no M-A)	N/A
33	32	Krolewiecki, A., <i>Antiviral effect of high-dose ivermectin in adults with COVID-19: a pilot randomised, controlled, open label, multicentre trial.</i> Lancet preprint, 2020.	Y	Low study quality. Open label, small sample size (30 in ivermectin, 15 controls). 600 mcg/kg per day for 5 days.	Adverse events were reported in 18 (40%) of the 45 patients included in the safety analysis, which by the design of the study was unblinded; 13 (43%) in the IVM group and 5 (33%) in the control group (table 2). The most frequent adverse event and the only experienced by more than 1 case in the IVM group was rash in 3 (10%) cases (all mild, self-limited and lasting approximately 24 h); in the control group, single events of abdominal pain, dizziness, anxiety, anguish, and hyperglycemia (all mild) were reported. A single serious adverse event (SAE) was reported in the trial in a patient in the IVM group with hyponatremia, which has been recently recognized in case series of COVID-19 cases and has not been reported in association to IVM use. A relationship between IVM systemic concentration and adverse events failed to reveal a link between these variables.
34	33	Lehrer, S., and Rheinstein, P.H., <i>Ivermectin docks to the SARS-CoV-2 spike receptor-binding domain attached to ACE2.</i> In Vivo, 2020. 34(5): p. 3023-3026.	N	In vitro/in vivo	N/A

	A	B	C	D	E
35	34	Lima-Morales, R., et al., <i>Effectiveness of a multidrug therapy consisting of ivermectin, azithromycin, montelukast and acetylsalicylic acid to prevent hospitalization and death among ambulatory COVID-19 cases in Tlaxcala, Mexico</i> . Int J Infect Dis, 2021.	N	Multidrug combination of ivermectin, azithromycin, montelukast and acetylsalicylic acid. Study not designed to isolate safety of ivermectin alone.	combined medications were: gastrointestinal issues such as abdominal pain, nausea, vomiting, diarrhea, constipation, diarrhea and constipation (5.9%), headache and dizziness (3.1%), asthenia, fatigue, and confusion (1.4%), and urticarial and itchy feeling (0.9%).
36	35	López-Medina, E., et al., <i>Effect of ivermectin on time to resolution of symptoms among adults with mild COVID-19: a randomized clinical trial</i> . JAMA, 2021.	N	Previously dismissed by PSLS	None
37	36	Mittal, N. and Mittal, R., <i>Inhaled route and anti-inflammatory action of ivermectin: Do they hold promise in fighting against COVID-19?</i> Med Hypotheses, 2021. 146: p. 110364.	N	Review paper.	N/A
38	37	Mohan, A., et al., <i>Ivermectin in mild and moderate COVID-19 (RIVET-COV): a randomized, placebo-controlled trial</i> . Research Square, 2021.	N	12 mg or 24 mg ivermectin "No serious adverse events were encountered"	There were no serious adverse events reported during the study (Table 6). The frequency of all adverse events in the ITT population was similar in the three arms (ivermectin 24 mg, 11.8%; ivermectin 12 mg, 16.3%; and placebo, 11.5%; p-value = 0.76). The most frequent adverse event was epigastric burning sensation, which occurred in 17 (11.2%) patients.
39	38	Niaee, M.S., <i>Ivermectin as an adjunct treatment for hospitalized adult COVID-19 patients: a randomized multi-center clinical trial</i> . Research Square, 2020.	N	Low quality study. Combination of HCQ + heparin + ivermectin vs HCQ +heparin. No discussion of safety outcomes or Aes.	None
40	39	Okumuş, N., et al., <i>Evaluation of the effectiveness and safety of adding ivermectin to treatment in severe COVID-19 Patients</i> . Research Square, 2021.	Y	Low study quality. 200 mcg/kg daily for 5 days + HCQ + favipiravir + AZM vs HCQ+favipiravir+AZM. No presentation of Aes in tabular format (only descriptive)	Serious side effects such as delirium-like behavior, agitation, aggressive attitude and altered state of consciousness were observed in the remaining two of the 6 patients. In one of these two patients, side effects were controlled with haloperidol and the patient's symptoms disappeared within 1 week. In the other patient, the side effects continued for 2 weeks, were controlled with remifentanyl and dexmedetomidine and discharged with full recovery after being followed up in the hospital for one month.
41	40	Patel, A., Desai, S., et al, <i>RETRACTED, Ivermectin in COVID-19 related critical illness</i> . 2020.	N	Paper was retracted. Will not be considered.	N/A
42	41	Podder, C.S., et al., <i>Outcome of ivermectin treated mild to moderate COVID-19 cases: a single-centre, open-label, randomised controlled study</i> . IMC J Med Sci, Rajter, J.C., et al., <i>Use of ivermectin is associated with lower mortality in hospitalized patients with coronavirus disease 2019: the ivermectin in covid nineteen study</i> . Chest, 2021. 159(1): p. 85-92.	Unk	Abstract or article not available.	
43	42		N	At least one dose of 200 mcg/kg, with second at 7 day if required. No discussion of Aes	None
44	43	Ravikirti, R., et al., <i>Ivermectin as a potential treatment for mild to moderate COVID-19 – a double blind randomized placebo-controlled trial</i> . Medrxiv, 2021.	N	12 mg for 2 days vs placebo. No discussion of Aes.	None

	A	B	C	D	E
45	44	Bukhari, S.K.H.S., et al., <i>Efficacy of ivermectin in COVID-19 patients with mild to moderate disease</i> . Medrxiv, 2021.	N	Single 12 mg dose. "No adverse reaction or derangements in laboratory parameters was noted in the intervention arm during the trial period."	None
46	45	Soto-Becerra, P., et al., <i>Real-world effectiveness of hydroxychloroquine, azithromycin, and ivermectin among hospitalized COVID-19 patients: results of a target trial emulation using observational data from a nationwide healthcare system in Peru</i> . Medrxiv, 2020.	N	Study did not report results for specific doses of ivermectin. No discussion of Aes.	None
47	46	Spoorthi, V., and Surapaneni, S., <i>Utility of ivermectin and doxycycline combination for the treatment of SARS-CoV-2</i> . International Archives of Integrated Medicine, 2020.	N	Single dose of 200 mcg/kg + doxycycline for 7 days vs placebo. "There was no significant difference in the side effect profile of either groups"	None
48					
49		Criteria for inclusion: Must report potential safety issue with ivermectin use other than lack of efficacy for COVID-19 (COVID-19 outcomes such as mortality ICU status or hospitalization are interpreted as efficacy-related).			

From: Lefebvre, Larissa (HC/SC)
Sent: 2021-01-26 1:50 PM
To: Keene, Daniel (HC/SC)
Cc: Legare, Carole (HC/SC)
Subject: RE: 21-000464 - 133 for / pour: Branch Input Required/Information requise de la direction générale

Here are the list of CTs for IVERMECTIN only ... there are also other trials that include IVERMECTIN (see screenshot below).
 Let me know if you want further details on the trials the have ivermectin as 1 of the ingredients.
 Merci
 Larissa

239129 PH1 BIO IVERMECTIN Sponsor: SubstiPharm France (submitted by AltaSciences) ONGOING (1 site in Montreal)
 Title: SINGLE DOSE CROSSOVER COMPARATIVE BIOAVAILABILITY PILOT STUDY OF IVERMECTIN 12 MG CAPSULES VERSUS 3 MG TABLETS IN HEALTHY MALE AND FEMALE VOLUNTEERS FOLLOWING ADMINISTRATION OF A 12 MG DOSE/ FASTING STATE

235791 PH1 BIO IVERMECTIN Sponsor: Vygoris Limited UK (submitted by AltaSciences) CLOSED

232746 PH1 BIO IVERMECTIN Sponsor: Chemo Research Spain (submitted by Lambda Therapeutic Research Inc.) CLOSED

224224 PH1 BIO IVERMECTIN Sponsor: Vygoris Limited UK (submitted by AltaSciences) PENDING

168820 PH1 BIO IVERMECTIN Sponsor: SubstiPharm France (submitted by Algorithm Inc.) CLOSED

165720 PH1 BIO IVERMECTIN Sponsor: SubstiPharm France (submitted by Algorithm Inc.) CLOSED

NOTE: 151821 CD5024 (ivermectin) by Galderman Canada Inc. PH3 NOL issued in 2011 still shows as ONGOING
 151820 CD5024 (ivermectin) by Galderman Canada Inc. PH3 NOL issued in 2011 still shows as ONGOING

239125	CTA	PH1 BIOEQ	IVERMECTIN	ORL	CAP	IVERMECTIN	12	MG	CAP	CLEARED	1	CTBG
235791	CTA	PH1 BIOEQ	IVERMECTIN	ORL	TAB	IVERMECTIN	3	MG	TAB	CLEARED	1	CTBG
232746	CTA	PH1 BIOEQ	IVERMECTIN	ORL	TAB	IVERMECTIN	3	MG	TAB	CLEARED	1	CTBG
224224	CTA	PH1 BIOEQ	IVERMECTIN	ORL	TAB	IVERMECTIN	3	MG	TAB	CLEARED	1	CTBG
204748	CTA	PH3 - 30 DA	IVERMECTIN / I	TOP	CRM	IVERMECTIN	10	MG	G	CLEARED	2	CTBG
198476	CTA	PH2 - 30 DA	IVERMECTIN (I	TOP	CRM	IVERMECTIN	3	MG	G	CLEARED	1	CT-C1
193495	CTA	PH2 - 30 DA	IVERMECTIN (I	TOP	CRM	IVERMECTIN	10	MG	G	CLEARED	1	CT-C1
186815	CTA	PH1 BIOEQ	IVERMECTIN /	ORL	TAB	IVERMECTIN	3	MG	TAB	WITHDRAW	1	CT-C1
181279	CTA	PH1 BIOEQ	IVERMECTIN /	ORL	TAB	IVERMECTIN	3	MG	TAB	CLEARED	1	CT-C1
168820	CTA	PH1 BIOEQ	IVERMECTIN	ORL	TAB	IVERMECTIN	3	MG	TAB	CLEARED	1	CT-C1
165720	CTA	PH1 BIOEQ	IVERMECTIN	ORL	TAB	IVERMECTIN	3	MG	TAB	CLEARED	1	CT-C1
151821	CTA	PH3 - 30 DA	CD5024 (IVERN	TOP	CRM	IVERMECTIN	10	MG	G	CLEARED	1	CT-C1
151820	CTA	PH3 - 30 DA	CD5024 (IVERN	TOP	CRM	IVERMECTIN	10	MG	G	CLEARED	1	CT-C1

From: Keene, Daniel (HC/SC) <daniel.keene@canada.ca>
Sent: 2021-01-26 1:21 PM
To: Lefebvre, Larissa (HC/SC) <larissa.lefebvre@canada.ca>
Cc: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Subject: FW: 21-000464 - 133 for / pour: Branch Input Required/Information requise de la direction générale

Larissa – would you mind helping me find the list of clinical trials using this drug that are presently on going? thanks

From: Punch, Vincent (HC/SC) <vincent.punch@canada.ca>
Sent: 2021-01-26 10:11 AM
To: Legare, Carole (HC/SC) <carole.legare@canada.ca>

Cc: Keene, Daniel (HC/SC) <daniel.keene@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>
Subject: FW: 21-000464 - 133 for / pour: Branch Input Required/Information requise de la direction générale

Good morning Carole,

We received another tasking for ivermectin this morning. I just wanted to check with your group to see if there were any updates regarding the status of ivermectin trials in Canada, or if were aware of any new clinical data.

Thanks,

Vincent Punch, PhD
A/Associate Director
Bureau of Gastroenterology Infection and Viral Diseases
Therapeutic Products Directorate
Health Canada
613-404-6204
vincent.punch@canada.ca

From: Hamilton, Andrea (HC/SC) <andrea.hamilton@canada.ca>
Sent: 2021-01-26 9:39 AM
To: Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>; Punch, Vincent (HC/SC) <vincent.punch@canada.ca>; Durno, Laura (HC/SC) <laura.durno@canada.ca>
Subject: FW: 21-000464 - 133 for / pour: Branch Input Required/Information requise de la direction générale

Good Morning,

Please find attached a MECS tasked to BGIVD. **Due to DGO: February 2, 2021.**

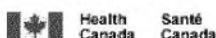
The following notes were provided by DGO:

1. Please seek input from OCT as required (ask them to check with OCT as well in case there are new trials for this drug and/or if we are aware of any new clinical data).
2. Attachment provided which has previously approved lines to see if they want to use/update based on any new knowledge.

Kind Regards,

Andrea

From: Jacqueline Farah <jacqueline.farah@hc-sc.gc.ca>
Sent: 2021-01-26 9:09 AM
To: Hamilton, Andrea (HC/SC) <andrea.hamilton@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>
Subject: 21-000464 - 133 for / pour: Branch Input Required/Information requise de la direction générale



Canada

Audit Trail / Suivi de vérification
Ministerial Correspondence / Correspondance ministérielle

Subject / Sujet: 21-000464 - 133 for / pour: Branch Input Required/Information requise de la direction générale

21-000464 - 133


Send From / Envoyé de	Send To / Envoyé a	Date Sent / Date de l'envoi	Bring Forward / Rappel
HPFB-TPD-DGO Jacqueline Farah/HC-SC/GC/CA	Organization/Organisme HPFB-TPD-BGIVD-DO Person/Personne Andrea Hamilton/HC-SC/GC/CA	2021-01-26	2021-02-02 Due Date/Date d'échéance 2021-02-08
Special Instructions / Instructions spéciales: Multi			

Document Status / Statut du dossier: Open/Ouvert

Action / Intervention: Branch Input Required/Information requise de la direction générale

Comment / Commentaires:

Request to provide input for Minister's signature. Also sent to CIHR. Please seek input from OCT as required. Due DGO Feb 2. thanks, jackie

Here is the link to document / Voici le lien au document: 

The documents provided to you may contain personal information.

If you have received these documents in error, notify the MECS-USER-SUPPORT group immediately.

Les documents qui vous sont fournis peuvent contenir des renseignements personnels.

Si vous avez reçu ces documents par erreur, avisez immédiatement le groupe courriel des MECS-USER-SUPPORT.

Created By / Créé par: Jacqueline Farah

Date Created / Créé le: 2021-01-26

From: Legare, Carole (HC/SC)
Sent: 2021-01-26 10:41 AM
To: Punch, Vincent (HC/SC)
Subject: RE: 21-000464 - 133 for / pour: Branch Input
Required/Information requise de la direction générale- 10:41

We do not have any clinical trials for ivermectin for COVID in Canada.

Carole

From: Punch, Vincent (HC/SC) <vincent.punch@canada.ca>
Sent: 2021-01-26 10:11 AM
To: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Cc: Keene, Daniel (HC/SC) <daniel.keene@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>
Subject: FW: 21-000464 - 133 for / pour: Branch Input Required/Information requise de la direction générale

Good morning Carole,

We received another tasking for ivermectin this morning. I just wanted to check with your group to see if there were any updates regarding the status of ivermectin trials in Canada, or if we were aware of any new clinical data.

Thanks,

Vincent Punch, PhD
A/Associate Director
Bureau of Gastroenterology Infection and Viral Diseases
Therapeutic Products Directorate
Health Canada
613-404-6204
vincent.punch@canada.ca

From: Hamilton, Andrea (HC/SC) <andrea.hamilton@canada.ca>
Sent: 2021-01-26 9:39 AM
To: Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>; Punch, Vincent (HC/SC) <vincent.punch@canada.ca>;
Durno, Laura (HC/SC) <laura.durno@canada.ca>
Subject: FW: 21-000464 - 133 for / pour: Branch Input Required/Information requise de la direction générale

Good Morning,

Please find attached a MECS tasked to BGIVD. **Due to DGO: February 2, 2021.**

The following notes were provided by DGO:

1. Please seek input from OCT as required (ask them to check with OCT as well in case there are new trials for this drug and/or if we are aware of any new clinical data).
2. Attachment provided which has previously approved lines to see if they want to use/update based on any new knowledge.

Kind Regards,

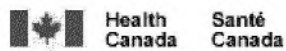
Andrea

From: Jacqueline Farah <jacqueline.farah@hc-sc.gc.ca>

Sent: 2021-01-26 9:09 AM

To: Hamilton, Andrea (HC/SC) <andrea.hamilton@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>

Subject: 21-000464 - 133 for / pour: Branch Input Required/Information requise de la direction générale



Canada

Audit Trail / Suivi de vérification
Ministerial Correspondence / Correspondance ministérielle

Subject / Sujet: 21-000464 - 133 for / pour: Branch Input Required/Information requise de la direction générale

21-000464 - 133

Send From / Envoyé de	Send To / Envoyé a	Date Sent / Date de l'envoi	Bring Forward / Rappel
HPFB-TPD-DGO Jacqueline Farah/HC-SC/GC/CA	Organization/Organisme HPFB-TPD-BGIVD-DO Person/Personne Andrea Hamilton/HC-SC/GC/CA	2021-01-26	2021-02-02 Due Date/Date d'échéance 2021-02-08

Special Instructions / Instructions spéciales: Multi
Document Status / Statut du dossier: Open/Ouvert
Action / Intervention: Branch Input Required/Information requise de la direction générale

Comment / Commentaires:
Request to provide input for Minister's signature. Also sent to CIHR. Please seek input from OCT as required. Due DGO Feb 2. thanks, jackie

Here is the link to document / Voici le lien au document:

The documents provided to you may contain personal information.
If you have received these documents in error, notify the MECS-USER-SUPPORT group immediately.

Les documents qui vous sont fournis peuvent contenir des renseignements personnels.
Si vous avez reçu ces documents par erreur, avisez immédiatement le groupe courriel des MECS-USER-SUPPORT.

Created By / Créé par: Jacqueline Farah
Date Created / Créé le: 2021-01-26

From: Mineau, Philippe (HC/SC)
Sent: 2021-02-23 4:09 PM
To: Randall, Bruce (HC/SC)
Subject: RE: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Ok thanks!

P

From: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Sent: 2021-02-23 3:58 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Hi Philippe,

I would keep the Merck line out for the moment.

Thanks.

B

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-02-23 11:08 AM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Subject: FW: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Hey there Bruce,

For approval another Ivermectin reply,

Of note, I added the paragraph on the MERCK statement issued last week:

The manufacturer of ivermectin in Canada, Merck, has also issued a public statement (available at <https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/>) on the use of ivermectin during the COVID-19 pandemic, stating that:

“It is important to note that, to-date, [MERCK’s] analysis has identified:

- *No scientific basis for a potential therapeutic effect against COVID-19 from pre-clinical studies;*
- *No meaningful evidence for clinical activity or clinical efficacy in patients with COVID-19 disease, and;*
- *A concerning lack of safety data in the majority of studies.”*

Let me know what you think,

P

From: Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>
Sent: 2021-02-22 3:13 PM

To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Subject: FW: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Hi Phil,

Direct Reply re – Ivermectin.

I attached a draft response

Due ECD March 2

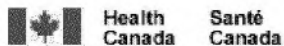
Thanks,

Jacqueline Farah

(she | elle)

Executive Correspondence Officer / Agente de la correspondance exécutive
Director General's Office / Bureau du directeur général
Therapeutic Products Directorate / Direction des produits thérapeutiques
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
jacqueline.farah@canada.ca / Cell.: 343-552-4415

From: Christa Racicot <christa.racicot@hc-sc.gc.ca>
Sent: 2021-02-22 3:05 PM
To: Beattie, Deborah (HC/SC) <deborah.beattie@canada.ca>; Cain, Francoise (HC/SC) <francoise.cain@canada.ca>; Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>; Mattia-Pepin, Isabelle (HC/SC) <isabelle.mattia-pepin@canada.ca>; Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: 21-001394 - 120 for / pour: Direct Reply/Réponse directe



Canada

Audit Trail / Suivi de vérification
Ministerial Correspondence / Correspondance ministérielle

Subject / Sujet: 21-001394 - 120 for / pour: Direct Reply/Réponse directe


21-001394 - 120

Send From / Envoyé de	Send To / Envoyé a	Date Sent / Date de l'envoi	Bring Forward / Rappel

HPFB-ADM-ADMO Christa Racicot/HC-SC/GC/CA	Organization/Organisme HPFB-TPD-DGO Person/Personne Deborah Beattie/HC-SC/GC/CA	2021-02-22	Due Date/Date d'échéance 2021-03-02
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Special Instructions / Instructions spéciales: Direct Reply Week 6 (2021)
Document Status / Statut du dossier: Closed/Fermé
Action / Intervention: Direct Reply/Réponse directe

Comment / Commentaires:
 Scan copy to Final response in MECS and audit trail to ECDCST when done. Thanks

Here is the link to document / Voici le lien au document: 

The documents provided to you may contain personal information.
 If you have received these documents in error, notify the MECS-USER-SUPPORT group immediately.

Les documents qui vous sont fournis peuvent contenir des renseignements personnels.
 Si vous avez reçu ces documents par erreur, avisez immédiatement le groupe courriel des MECS-USER-SUPPORT.

Created By / Créé par: Christa Racicot
 Date Created / Créé le: 2021-02-22

From: Mineau, Philippe (HC/SC)
Sent: 2021-06-14 11:33 AM
To: Abdulla, Rosemin (HC/SC)
Subject: RE: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

Correct, to Ms Schulz,
I sent the response to [REDACTED] myself (from my own email, as he had written to me personally),
Thank you!
P

From: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Sent: 2021-06-14 11:25 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

Hi Phil,

On this one – I am only replying the letter to [REDACTED] I am not sending it to [REDACTED] – correct?

Have a wonderful day / Bonne journée

Rosemin
Tel: 613-327-0578

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-06-14 9:54 AM
To: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Subject: FW: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

Hey Rosemin, the following response is approved by Bruce and can be sent out,
Thank you!
P

From: Mineau, Philippe (HC/SC)
Sent: 2021-06-07 12:09 PM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>
Subject: FW: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

Hey Pat, hey Bruce,

If you remember, we received some correspondence a couple of weeks ago that accused HC of “blocking access to ivermectin” – I had written to the Dr involved to find out more about how he had been blocked, and he had responded with the email attached (“ivermectin concern”).

Long story short, he had prescribed ivermectin, the pharmacy had returned to him with a SAP form, he assumed that HC would not allow it so did not pursue further.

Here are the proposed responses back to the letter-writer, and to [REDACTED] I just want to make sure you're both comfortable with these before they get sent.

[REDACTED]

[REDACTED]

Let me know what you think,

P

From: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Sent: 2021-05-20 12:11 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Subject: RE: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

Hi Philippe,

Here is the standard direct reply response prepared for this MECS as requested.

Have a wonderful day / Bonne journée

Rosemin
Tel: 613-327-0578

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-05-20 10:15 AM
To: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Subject: RE: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

Yes the standard ivermectin response please,

Thanks,

P

From: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Sent: 2021-05-20 10:07 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Subject: FW: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

Hi Phil,

Enclosed please find the incoming documents for which we have to provide a direct reply re:
Coronavirus - I-MASK + Protocol for Covid-19 Treatment/ Ivermectin

Redirected from PHAC

This was originally Due: to ECDCST on Mar 4 however, it is due whenever done.

Did do want to use the standard direct reply for ivermectin or want to task BGIVD or MDD?

Have a wonderful day / Bonne journée

Rosemin

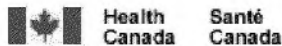
Tel: 613-327-0578

From: Christa Racicot <christa.racicot@hc-sc.gc.ca>

Sent: 2021-05-20 9:48 AM

To: Beattie, Deborah (HC/SC) <deborah.beattie@canada.ca>; Cain, Francoise (HC/SC) <francoise.cain@canada.ca>; Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>; Mattia-Pepin, Isabelle (HC/SC) <isabelle.mattia-pepin@canada.ca>; Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>

Subject: 21-001396 - 449 for / pour: Direct Reply/Réponse directe



Canada

Audit Trail / Suivi de vérification

Ministerial Correspondence / Correspondance ministérielle

Subject / Sujet: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

21-001396 - 449

Send From / Envoyé de	Send To / Envoyé à	Date Sent / Date de l'envoi	Bring Forward / Rappel
HPFB-ADM-ADMO Christa Racicot/HC-SC/GC/CA	Organization/Organisme HPFB-TPD-DGO Person/Personne Deborah Beattie/HC-SC/GC/CA	2021-05-20	Due Date/Date d'échéance 2021-03-08


Special Instructions / Instructions spéciales: Direct reply week 6 (2021)

Document Status / Statut du dossier: Open/Ouvert

Action / Intervention: Direct Reply/Réponse directe

Comment / Commentaires:

As per PHAC (As per program, this issue is not within PHAC's purview. Please redirected to HC)/ HPFB - Scan copy to Final response in MECS and audit trail to ECDCST when done. Thanks

Here is the link to document / Voici le lien au document: 

The documents provided to you may contain personal information.

If you have received these documents in error, notify the MECS-USER-SUPPORT group immediately.

Les documents qui vous sont fournis peuvent contenir des renseignements personnels.
Si vous avez reçu ces documents par erreur, avisez immédiatement le groupe courriel des MECS-USER-SUPPORT.

Created By / Créé par: Christa Racicot
Date Created / Créé le: 2021-05-20

From: [Mineau, Philippe \(HC/SC\)](#)
Sent: 2021-06-25 3:08 PM
To: [Racicot, Christa \(HC/SC\)](#)
Cc: [Abdulla, Rosemin \(HC/SC\)](#)
Subject: RE: 21-007306 - 134 for / pour: See note

Ok thanks Christa!

Rosemin will send this back, if she hasn't already,

Thanks again and have a great weekend!

P

From: Racicot, Christa (HC/SC) <christa.racicot@canada.ca>
Sent: 2021-06-25 2:36 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Subject: RE: 21-007306 - 134 for / pour: See note

Thanks Phillippe, Margaret asked me to send this back to redirect to PHAC.

May I please ask for the audit trail back?

Thanks again and have a great weekend

Christa

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-06-25 2:18 PM
To: Zimmermann, Margaret (HC/SC) <margaret.zimmermann@canada.ca>
Cc: Racicot, Christa (HC/SC) <christa.racicot@canada.ca>; Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Subject: FW: 21-007306 - 134 for / pour: See note

Hey Margaret,

I don't know if your correspondence staff had talked to you about this one,

PHAC is currently undertaking a review of emerging evidence related to ivermectin for COVID-19. As the following correspondence just points us to a new article on ivermectin, and is not asking any questions related to the drug approval process, we really feel it would be better directed to PHAC, as there's nothing TPD can respond to here,

I'm not sure why PHAC correspondence is sending this to HPFB – maybe because so much ivermectin correspondence has been coming our way, and been responded to here. But we really feel this one should go to them,

Thanks!

P

From: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>

Sent: 2021-06-25 2:02 PM

To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>

Cc: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>

Subject: FW: 21-007306 - 134 for / pour: See note

Hi Phil,

The one that we redirected to PHAC's Emerging Evidence group, as they are undertaking a review of emerging evidence related to ivermectin, has been audit trailed back to us with the following note: This request was already sent to PHAC and they redirected it to HPFB. I spoke with the ADMO - Advisor and she requested that TPD please respond. Thank you CR

Please advice what you would like me to do it – task to BGIVD?

Have a wonderful day / Bonne journée

Rosemin

Tel: 613-327-0578

From: Christa Racicot <christa.racicot@hc-sc.gc.ca>

Sent: 2021-06-25 1:57 PM

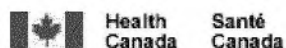
To: Beattie, Deborah (HC/SC) <deborah.beattie@canada.ca>; Cain, Francoise (HC/SC)

<francoise.cain@canada.ca>; Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>;

Mattia-Pepin, Isabelle (HC/SC) <isabelle.mattia-pepin@canada.ca>; Farah, Jacqueline (HC/SC)

<jacqueline.farah@canada.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>

Subject: 21-007306 - 134 for / pour: See note



Canada

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Ministerial Correspondence / Correspondance ministérielle

Subject / Sujet: 21-007306 - 134 for / pour: See note


21-007306 - 134

Send From / Envoyé de	Send To / Envoyé à	Date Sent / Date de l'envoi	Bring Forward / Rappel
HPFB-ADM-ADMO	Organization/Organisme HPFB-TPD-DGO	2021-06-25	Due Date/Date d'échéance 2021-07-12

Christa Racicot/HC-SC/GC/CA	Person/Personne Deborah Beattie/HC-SC/GC/CA		
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Document Status / Statut du dossier: Open/Ouvert
Action / Intervention: See note

Comment / Commentaires:
This request was already sent to PHAC and they redirected it to HPFB. I spoke with the ADMO - Advisor and she requested that TPD please respond. Thank you CR

Here is the link to document / Voici le lien au document: 

The documents provided to you may contain personal information.
If you have received these documents in error, notify the MECS-USER-SUPPORT group immediately.

Les documents qui vous sont fournis peuvent contenir des renseignements personnels.
Si vous avez reçu ces documents par erreur, avisez immédiatement le groupe courriel des MECS-USER-SUPPORT.

Created By / Créé par: Christa Racicot
Date Created / Créé le: 2021-06-25

From: Mineau, Philippe (HC/SC)
Sent: 2021-07-08 12:06 PM
To: Randall, Bruce (HC/SC)
Subject: RE: 21-007306-134 - HPFB Input.docx

To complicate matters further – was just alerted to this: a recap of seemingly one of the strongest metanalyses to date:

Ivermectin for the treatment of COVID-19 disease: Too good to pass up or too good to be true? | Open Forum Infectious Diseases | Oxford Academic (oup.com)

On balance, we are left with a compelling meta-analysis (indeed, a handful of them), suggesting a modest to large benefit of a low-cost, widely available, well-tolerated therapy for COVID-19 – a dream scenario – but based on studies with small sample sizes, design flaws, incomplete results, or some combination thereof. Ultimately, guideline authors must review this data and ask themselves if this information crosses the threshold for support of ivermectin outside of clinical trials. Although some have argued that the minimal risk afforded by a well-tolerated medicine does just that, there are secondary harms of early support for therapies prior to a solid evidence base, such as creating drug shortages of essential medicines ²² and the erosion of trust in the scientific community, which has certainly been degraded over the past year ²³. Nonetheless, if larger clinical trials ultimately confirm the efficacy of this low-cost, widely available drug, we must be willing to add ivermectin to the long list of therapeutic agents in medicine for which the best we can do is guess the mechanism of action. As of this writing, there at least five large, placebo-controlled clinical trials on the use of ivermectin for COVID-19 underway that should be powered to allay residual concerns about the available data. Until those data are released, ivermectin might be best considered as an extremely promising therapy, but one not quite ready for public use. Otherwise, there is a real risk that the scientific community will once again be bitten by over-enthusiasm and forced to answer to a public that will not be shy about holding us to account.

From: Mineau, Philippe (HC/SC)
Sent: 2021-07-08 11:56 AM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Subject: 21-007306-134 - HPFB Input.docx

Hey Bruce, for approval, this is the one we've been talking about where Supriya wants to mention a specific article.

Let me know what you think,

P

From: Mineau, Philippe (HC/SC)
Sent: 2021-09-15 4:55 PM
To: Randall, Bruce (HC/SC)
Subject: RE: 21-012119 - 945 for / pour: See note

Hey Bruce,

Your digging prompted me to look back at prior correspondence, as I remembered someone from [REDACTED] emailing directly to TPD General – it is indeed the same individual, and at the time (April) he was advocating for a change from prescription to non-prescription for ivermectin... So this correspondence is from around then, prior even...

At the time, this is what we answered (see below). I think there's sufficiently no overlap to send our standard response still?

Dear [REDACTED]

Thank you for contacting us and apologies for the delayed reply. Your question regarding the procedure to change a drug from prescription to non-prescription status was forwarded to our team for response.

These status changes are initiated by manufacturers/sponsors filing an application to Health Canada seeking a switch from prescription to OTC status, supported by evidence that the drug and its conditions of use remain safe and effective in a self-care environment. This can include scenarios where a prescription ingredient is changed to non-prescription only for certain conditions (eg. dose threshold, specific indication, specific route of administration), known as a "partial switch", and scenarios where the ingredient is moved in full to non-prescription status. For additional information on these "prescription to OTC switch" applications, including evidence requirements, the following guidance document will provide some detail and an overview of the process: <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/data-requirements-switching-medicinal-ingredients-prescription-to-non-prescription-status.html>

Thank you again for contacting us and I hope this information helps to answer your questions. If you have additional questions then please do not hesitate to ask.

Sincerely,
BGIVD Enquiries

From: Randall, Bruce (HC/SC) <bruce.randall@hc-sc.gc.ca>
Sent: 2021-09-15 4:20 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Subject: RE: 21-012119 - 945 for / pour: See note

Thanks Phil. No issue with the reply. [REDACTED]
[REDACTED]

I don't have issue with response. Given some of the more recent retractions of Ivermectin I wonder if he has a different opinion now.

From: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>

Sent: 2021-09-15 3:20 PM

To: Randall, Bruce (HC/SC) <bruce.randall@hc-sc.gc.ca>

Subject: FW: 21-012119 - 945 for / pour: See note

Hey Bruce,

For approval, this is a standard (new) ivermectin response – seems like we're still dealing with backlog correspondence, as this one is from end of March,

Cheers!

P

From: Adlani, Souad (HC/SC) <SOUAD.ADLANI@hc-sc.gc.ca>

Sent: 2021-09-15 3:05 PM

To: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>

Cc: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@hc-sc.gc.ca>; Adlani, Souad (HC/SC) <SOUAD.ADLANI@hc-sc.gc.ca>

Subject: Fw: 21-012119 - 945 for / pour: See note

Hello Philippe,

Please see attached incoming and a standard direct reply response for Ivermectin – due to ECD-CST by September 28.

Many Thanks,

Souad

De : Christa Racicot <christa.racicot@hc-sc.gc.ca>

Envoyé : 2021-09-15 13:16

À : Cain, Francoise (HC/SC) <francoise.cain@hc-sc.gc.ca>; Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@hc-sc.gc.ca>; Mattia-Pepin, Isabelle (HC/SC) <isabelle.mattia-pepin@hc-sc.gc.ca>; Farah, Jacqueline (HC/SC) <jacqueline.farah@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Abdulla, Rosemin (HC/SC) <rosemin.abdulla@hc-sc.gc.ca>; Adlani, Souad (HC/SC) <SOUAD.ADLANI@hc-sc.gc.ca>

Objet : 21-012119 - 945 for / pour: See note

Audit Trail / Suivi de vérification
Ministerial Correspondence / Correspondance ministérielle


Subject / Sujet: 21-012119 - 945 for / pour: See note

21-012119 - 945

Send From / Envoyé de	Send To / Envoyé a	Date Sent / Date de l'envoi	Bring Forward / Rappel
HPFB-ADM-ADMO Christa Racicot/HC-SC/GC/CA	Organization/Organisme HPFB-TPD-DGO Person/Personne Deborah Beattie/HC-SC/GC/CA	2021-09-15	Due Date/Date d'échéance 2021-09-29

Special Instructions / Instructions spéciales: Direct reply - week 37 (2021)
Document Status / Statut du dossier: Open/Ouvert
Action / Intervention: See note

Comment / Commentaires:
Please proceed with DR or audit trail back to ADMO to put on hold. Thanks CR

Here is the link to document / Voici le lien au document: 

The documents provided to you may contain personal information.
If you have received these documents in error, notify the MECS-USER-SUPPORT group immediately.

Les documents qui vous sont fournis peuvent contenir des renseignements personnels.
Si vous avez reçu ces documents par erreur, avisez immédiatement le groupe courriel des MECS-USER-SUPPORT.

Created By / Créé par: Christa Racicot
Date Created / Créé le: 2021-09-15

From: [Stewart, John Patrick \(HC/SC\)](#)
Sent: 2021-08-23 8:08 AM
To: [Robinson, Kelly \(HC/SC\)](#); [Sommerer, Sophie \(HC/SC\)](#)
Cc: [Hollett, Linsey \(HC/SC\)](#); [Mineau, Philippe \(HC/SC\)](#); [Peate, Jaspyn \(HC/SC\)](#); [Rahim, Hamida \(HC/SC\)](#); [Berg, Jason \(HC/SC\)](#); [HC.F MHPD Action Requests F.SC](#)
Subject: RE: [REDACTED] Ivermectin signage concern [REDACTED]

Great. Thanks Kelly.

Dr. J. Patrick Stewart, MD, CCFP(EM)
Director General/ Directeur général
Therapeutic Products Directorate/ Direction des produits thérapeutiques
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
613-859-2433 (cell)

From: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Sent: 2021-08-23 8:06 AM
To: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Cc: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>; Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>; Berg, Jason (HC/SC) <jason.berg@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: RE: [REDACTED] Ivermectin signage concern [REDACTED]

Good morning Pat.

Thanks for sending this along. I am ccing Hamida and Jason for action.

Best, Kelly

From: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>
Sent: 2021-08-23 7:52 AM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Cc: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>
Subject: FW: [REDACTED] Ivermectin signage concern [REDACTED]

Hi Kelly

As this compliant involves what appears to be inappropriate advertising of an approved health product I am forwarding this onto for MHPD's assessment. I have cc'd Linsey Hollet as well.

If you are okay with it, I will respond back to [REDACTED] indicating receipt of the email and that I have forwarded it onto to MHPD for action.

Thanks.

Pat

Dr. J. Patrick Stewart, MD, CCFP(EM)
Director General/ Directeur général
Therapeutic Products Directorate/ Direction des produits thérapeutiques
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
613-859-2433 (cell)

From: [REDACTED]
Sent: 2021-08-20 6:44 PM
To: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>
Cc: prescription.drug.enquiries / renseignements.drogue.ordonnance (HC/SC)
<prescription.drug.enquiries-renseignements.drogue.ordonnance@hc-sc.gc.ca> [REDACTED]
Subject: [REDACTED] - Ivermectin signage concern [REDACTED]

Dear Dr. Stewart,

I am writing to you on behalf of the [REDACTED] regarding a concern that had been brought to our attention recently involving the advertisement of the use of Ivermectin in treating Covid-19.

[REDACTED]

[REDACTED] has recently received notification from two rural pharmacists about a sign along a rural highway in Manitoba that reads "Ivermectin treats COVID-19 [REDACTED]". I have attached a picture for your review as well. These pharmacists have expressed great concern about this apparent misinformation, placed in a region with extremely poor/low vaccination uptake, combined with the potentially lower educational levels of some residents of the particular area.

In my initial review of the website, [REDACTED]
[REDACTED] The information was originally shared with the provincial College of Physicians and Surgeons of Manitoba (CPSM) for their review and considerations for further action. Unfortunately, none of the HCPs fall under the jurisdiction of the CPSM [REDACTED]

Requester agreed to
Remove 3rd Party Info

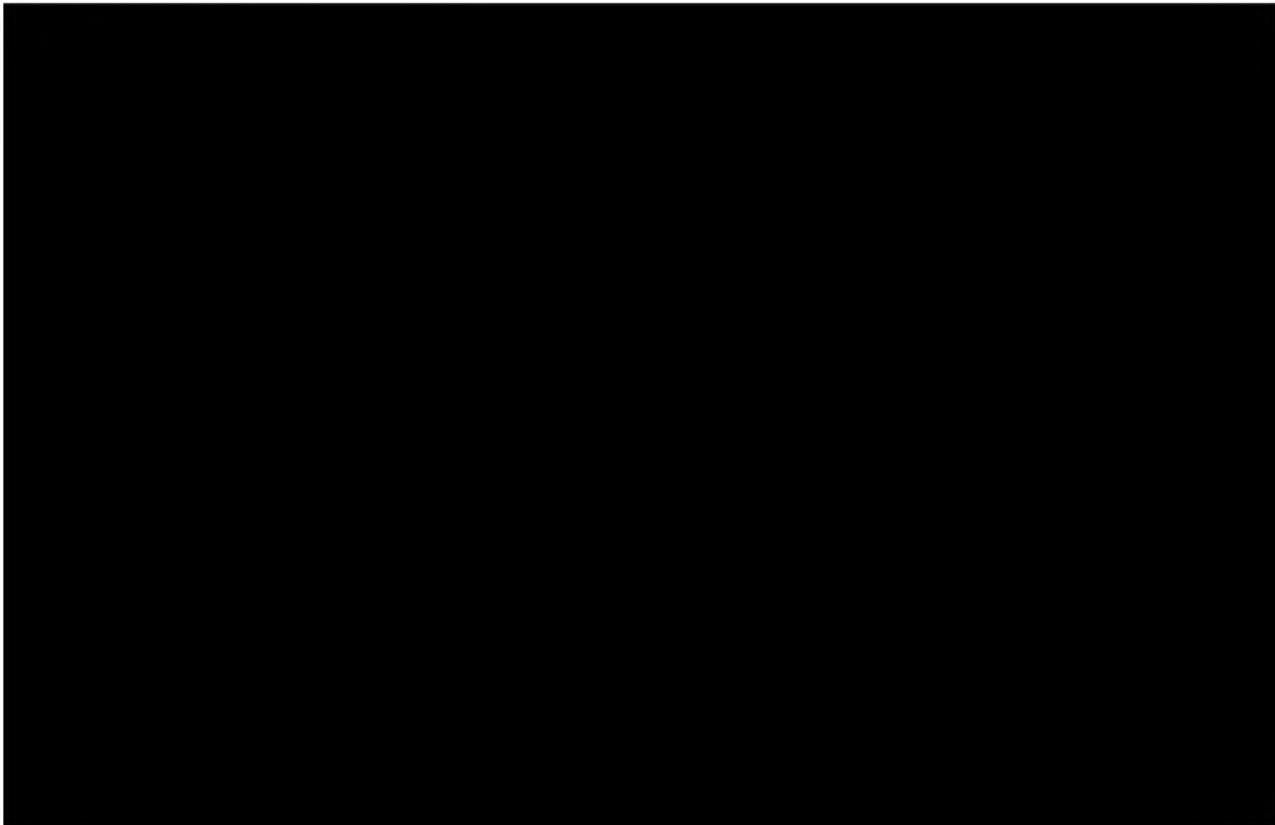
The TPD may already be aware of this inaccurate/non-compliant advertising, and I'm forwarding to you for your consideration on how best to address and manage. Perhaps the TPD may consider direct communication to [REDACTED] to remove all non-compliant advertisements regarding Ivermectin use in Covid-19. Is there anything further that the TPD can do about this advertising considering this drug is not approved for use in Covid-19 in Canada?

For your reference, I have also brought this to the attention of our provincial Vaccine Implementation Task Force (VITF) Medical Team Leads for their consideration of addressing provincially as well.

[REDACTED] is very open to any direction you may wish to provide on this, and would be agreeable to any further discussions as well. Please feel welcome to contact me should you wish to discuss further and I will ensure arrangements are made.

I look forward to hearing from you.

Kind regards,



From: Renart-McGowan, Isabel (HC/SC)
Sent: 2021-01-22 3:26 PM
To: Legare, Carole (HC/SC)
Cc: Loo, Wayne (HC/SC)
Subject: RE: Controversy Flares Over Ivermectin for COVID-19

Very interesting, also reminds me of the remdesivir debates. Thank you for including me. Looping in Wayne as well.

Have a lovely weekend. 😊

From: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Sent: 2021-01-22 1:40 PM
To: Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>; Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>; Punch, Vincent (HC/SC) <vincent.punch@canada.ca>
Cc: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Subject: Controversy Flares Over Ivermectin for COVID-19

Still much debate

[https://www.medscape.com/viewarticle/944440?
src=WNL_mdpls_210122_mscpedit_wir&uac=68877MJ&spon=17&implID=3146929&faf=1](https://www.medscape.com/viewarticle/944440?src=WNL_mdpls_210122_mscpedit_wir&uac=68877MJ&spon=17&implID=3146929&faf=1)

Carole

From: Mineau, Philippe (HC/SC)
Sent: 2021-06-22 3:45 PM
To: TPD General / Général DPT (HC/SC)
Subject: RE: COVID-19 treatment

Oui merci!
P

From: Adlani, Souad (HC/SC) <souad.adlani@canada.ca> **On Behalf Of** TPD General / Général DPT (HC/SC)
Sent: 2021-06-22 3:01 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: TR: COVID-19 treatment

Salut encore Philippe,

Penses-tu que je pourrais lui envoyer la réponse sur Ivermectin et Hydroxychloroquine ci-après?:

“ Thank you for your email dated, 2021, regarding access to ivermectin and hydroxychloroquine in Canada.

Health Canada is closely tracking all potential therapeutic treatments, vaccines, diagnostic tests, medical devices, and disinfectants currently available and in development in Canada and abroad. Every day, we are adding to our knowledge of COVID-19, keeping pace with the rapid growth of new scientific evidence as it emerges.

Health Canada (HC) authorizes drugs based on the safety, efficacy and quality information that is submitted by pharmaceutical companies looking to sell their products in Canada.

Ivermectin (brand name STROMEKTOL) and Hydroxychloroquine are already approved by Health Canada for specific uses. Ivermectin is an antiparasitic drug authorized for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMEKTOL has been marketed in Canada since 2018. Hydroxychloroquine is indicated for the treatment of malaria and certain autoimmune conditions, such as lupus.

At this time, no ivermectin or hydroxychloroquine manufacturer has made an application for these drugs to be authorized for the treatment or prevention of COVID-19. Therefore, the effectiveness of ivermectin or hydroxychloroquine as therapeutic options for COVID-19 has not been reviewed or authorized for any COVID-19 indication in Canada.

A list of all drug and vaccine applications received by Health Canada related to the COVID-19 pandemic can be found at: <https://www.canada.ca/en/health-canada/services/drugs-health->

[products/covid19-industry/drugs-vaccines-treatments/authorization/applications.html](https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/authorization/applications.html)

While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. HC has no jurisdiction over how health care professionals prescribe drugs once they are authorized.

Healthcare practitioners may prescribe drugs, including ivermectin and hydroxychloroquine, outside of their authorized indications (this is referred to as “off-label use”), based on other sources of information such as medical literature. Off-label use falls under the practice of medicine and is regulated at the provincial and territorial level.

For drugs that have potential to be helpful in treating COVID-19, Health Canada encourages drug manufacturers to conduct clinical trials. This would provide an opportunity for the healthcare community to collect information on the effectiveness of the treatment and its associated risks. Evidence from well-designed studies is needed to determine whether ivermectin and hydroxychloroquine might be helpful in preventing or treating COVID-19. HC has not received clinical trial applications related to ivermectin, though Health Canada is aware that such clinical trials may be planned or underway internationally. HC has authorized clinical trials related to hydroxychloroquine. The list of COVID-19 clinical trials authorized by Health Canada is available at <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/list-authorized-trials.html>.

Clinical trials can be pursued by a range of sponsors, such as a drug manufacturer, an academic institution, a research centre, or a physician. It should be noted that Health Canada does not actively conduct the research. For more information on how to submit a COVID-19 Clinical Trial, please refer to the following link: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/drug-guidance.html>.

Health Canada recognizes that Canadians who are ill with COVID-19 need access to safe and effective medicines and treatments. To facilitate access to a vaccine or therapeutic product for COVID-19, Health Canada will expedite its regulatory process for any COVID-19 related health product, including the review of submissions and the authorization of clinical trial applications.

I hope that this information is helpful, and I thank you for writing to share your views.

Thanks / Merci

Therapeutic Products Directorate/Direction des produits thérapeutiques
Health Products and Food Branch/ Direction générale des produits de santé et des aliments
Health Canada/ Santé Canada



Health
Canada

Santé
Canada

De : Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>

Envoyé : 2021-06-22 14:33

À : [REDACTED]

Objet : RE: COVID-19 treatment

Thank you for contacting Health Canada.

Your recent enquiry has been redirected to the appropriate area for a response.

Sincerely,

Health Canada | Santé Canada

Ottawa, Canada K1A 0K9

info@hc-sc.gc.ca

Telephone | Téléphone 613-957-2991 / Toll free | Sans frais 1 866-225-0709 /

Facsimile | Télécopieur 613-941-5366 / Teletypewriter | Télécopieur 1 800-267-1245

Government of Canada | Gouvernement du Canada

From [REDACTED]

Sent: 2021-06-14 12:37 PM

To: Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>

Subject: COVID-19 treatment

Good Morning,

Perhaps 6 months ago, I noted Ivermectin was listed as a treatment under investigation. What has become of it?

Secondly, why is Hydroxychloroquine not being investigated? It has shown some efficacy in the treatment and yet I don't see it listed.

Lastly, I would like to point out that Ivermectin and Hydroxychloroquine are quite safe, so regardless of their efficacy, doctors should be authorized to use as needed to treat patients. Why is this not being done?

Yours truly,

[REDACTED]

[REDACTED]

From: Legare, Carole (HC/SC)
Sent: 2021-05-07 1:33 PM
To: Piecha, Maryanne (HC/SC)
Subject: RE: CTs in Canada for Ivermectin - quetion

I meant we did not receive any clinical trial for ivermectin for COVID. This is why she did not find any.

From: Legare, Carole (HC/SC)
Sent: 2021-05-07 1:30 PM
To: Piecha, Maryanne (HC/SC) <maryanne.piecha@canada.ca>
Subject: RE: CTs in Canada for Ivermectin - quetion

Health Canada has not received any clinical trial application for Ivermectin.

From: Piecha, Maryanne (HC/SC) <maryanne.piecha@canada.ca>
Sent: 2021-05-07 1:28 PM
To: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Subject: FW: CTs in Canada for Ivermectin - quetion

Hi Carole

This person called the OCT main line this week requesting for CTs on Ivermectin.
 I contacted Larissa who suggested I send this link to Lisa

<https://health-products.canada.ca/ctdb-bdec/index-eng.jsp>

She feels she did not find all CTs for Ivermectin and sent me the email below

How should I proceed?

Maryanne



Canada

From: [REDACTED]
Sent: 2021-05-07 1:22 PM
To: Piecha, Maryanne (HC/SC)
Subject: Re: CTs in Canada for Ivermectin

Hi Maryanne,

I would like to request under the freedom of information act:

1. A list of all clinical trials applied for to Health Canada specifically for the use of Ivermectin for Covid.
2. A list of any clinical trials declined by Health Canada specifically for the use of Ivermectin for Covid.

Please note: Due to high volumes response times could be delayed up to 48 hours.

To book a time to connect either by phone or zoom call, please click on the following link to select a time that works for both of us:

[REDACTED]

Kindest regards,

[REDACTED]

On Wed, 5 May 2021 at 09:43, Piecha, Maryanne (HC/SC) <maryanne.piecha@canada.ca> wrote:

Hi [REDACTED]

As discussed please find the weblink for the Clinical Trials below, you can search for Ivermectin:

<https://health-products.canada.ca/ctdb-bdec/index-eng.jsp>

Thank you

Maryanne Piecha

Executive Assistant to the Director /The Office of Clinical Trials/
Therapeutic Products Directorate/Health Products and Food Branch
Health Canada, Government of Canada
Tel : 343-553-3922
maryanne.piecha@canada.ca

Adjointe exécutive à la Directrice / Bureau des essais cliniques
Direction des produits thérapeutiques/ Direction générale des produits de santé et des aliments
Santé Canada, Gouvernement du Canada
Tel : 343-553-3922
maryanne.piecha@canada.ca



Canada

From: [Soo, Evelyn \(HC/SC\)](#)
Sent: 2021-03-26 12:32 PM
To: [Bettle, Megan \(HC/SC\)](#); [Randall, Bruce \(HC/SC\)](#); [Mineau, Philippe \(HC/SC\)](#); [Stewart, John Patrick \(HC/SC\)](#)
Cc: [Legare, Carole \(HC/SC\)](#)
Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment

Hi Megan

The only comment I would have is to remove "unusually" in the last bullet.

Thanks
Evelyn

From: Bettle, Megan (HC/SC) <megan.bettle@canada.ca>
Sent: 2021-03-26 12:21 PM
To: [Soo, Evelyn \(HC/SC\) <evelyn.soo@canada.ca>](#); [Randall, Bruce \(HC/SC\) <bruce.randall@canada.ca>](#); [Mineau, Philippe \(HC/SC\) <philippe.mineau@canada.ca>](#); [Stewart, John Patrick \(HC/SC\) <johnpatrick.stewart@canada.ca>](#)
Cc: [Legare, Carole \(HC/SC\) <carole.legare@canada.ca>](#)
Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment

OK. So, I've discussed with ADMO and they suggest just a high level one pager, so I think using your lines and links should do the trick.

If there are any comments on this, please send to me before 3:30 pm.

Thx, megan

From: [Soo, Evelyn \(HC/SC\) <evelyn.soo@canada.ca>](#)
Sent: 2021-03-26 11:58 AM
To: [Bettle, Megan \(HC/SC\) <megan.bettle@canada.ca>](#); [Randall, Bruce \(HC/SC\) <bruce.randall@canada.ca>](#); [Mineau, Philippe \(HC/SC\) <philippe.mineau@canada.ca>](#); [Stewart, John Patrick \(HC/SC\) <johnpatrick.stewart@canada.ca>](#)
Cc: [Legare, Carole \(HC/SC\) <carole.legare@canada.ca>](#)
Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment

We are only creating product briefs for promising treatments so sorry, there is no one in the works for this.

Thanks
Evelyn

From: Bettie, Megan (HC/SC) <megan.bettie@canada.ca>
Sent: 2021-03-26 11:42 AM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>
Cc: Legare, Carole (HC/SC) <carole.legare@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>
Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment

I will throw together something really short. I assume there's been no product brief done previously?

From: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Sent: 2021-03-26 10:53 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>; Bettie, Megan (HC/SC) <megan.bettie@canada.ca>
Cc: Legare, Carole (HC/SC) <carole.legare@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>
Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment

Hi Megan,

We can help inform response from any CTs or pre-market discussions, however I believe PHAC was responsible for tracking potential therapies. I know Merck has come out with a position saying they don't have evidence that it's effective. We have our current stock lines.

Bruce

From: Smith4, Melissa (HC/SC) <melissa.smith4@canada.ca>
Sent: 2021-03-26 10:17 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>; Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Bettie, Megan (HC/SC) <megan.bettie@canada.ca>
Subject: DM Request - Update on Ivermectin in the context of COVID-19 treatment

Good morning TPD and Megan,

The DM has requested, by COB today, a summary of what we know about Ivermectin studies and use as COVID-19 treatment. This request is triggered by [REDACTED] to the DM to ask if HC is systematically tracking it.

Megan – would you mind reaching out to Kaili's group to see if they've been tracking and thus would have input to provide?

Thanks,
Melissa

From: Randall, Bruce (HC/SC)
Sent: 2021-03-26 11:45 AM
To: Bettle, Megan (HC/SC); Mineau, Philippe (HC/SC); Stewart, John Patrick (HC/SC)
Cc: Legare, Carole (HC/SC); Soo, Evelyn (HC/SC)
Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment --11:45

Follow Up Flag: Follow up
Flag Status: Flagged

I don't believe so as it was never expected to come in for review. Feel free to pick and chose as not all may be necessary.

Here are our standard lines as well as FDA, EMA, Alberta and Merck links. Nothing new from our side.

<https://www.ema.europa.eu/en/news/ema-advises-against-use-ivermectin-prevention-treatment-covid-19-outside-randomised-clinical-trials>

<https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>

<https://www.albertahealthservices.ca/assets/info/ppih/if-ppih-covid-19-sag-ivermectin-in-treatment-and-prevention-rapid-review.pdf>

<https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/>

Thanks!

B

- Ivermectin (brand name STROMEOTOL) is an antiparasitic drug approved by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMEOTOL has been marketed in Canada since 2018.
- Health Canada is closely monitoring all potential therapeutic treatments and vaccines in development in Canada and abroad, including products such as ivermectin that are being use outside of their authorized indication (off-label use), as potential treatments for COVID-19.
- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Health Canada has no jurisdiction over how health care professionals prescribe drugs once they are approved.
- Healthcare practitioners may prescribe drugs, including ivermectin, outside of their authorized indications (off-label use), based on other sources of information such as medical literature. Off-label use falls under the practice of medicine and is regulated at the provincial and territorial level.

- However, at this time, no ivermectin manufacturer has made an application for this drug to be approved for the treatment or prevention of COVID-19. Therefore, the effectiveness of ivermectin as a therapeutic option for COVID-19 has not been evaluated by Health Canada.
- For drugs that have potential to be helpful in treating COVID-19, Health Canada encourages drug manufacturers to conduct clinical trials. This would provide an opportunity for the healthcare community to collect information on the effectiveness of the treatment and its associated risks. Evidence from well-designed studies is needed to determine whether ivermectin might be helpful in preventing or treating COVID-19.
- A list of all clinical trials approved for the prevention or treatment of COVID-19 can be found on Health Canada's website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-clinical-trials/list-authorized-trials.html>
- In Canada, clinical trials for COVID-19 are facilitated under an Interim Order, which was signed by the Minister of Health on May 23, 2020: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/notice-interim-order.html>
- Clinical trials can be pursued by a range of sponsors, such as a drug manufacturer, an academic institution or research centre, or a physician. It should be noted that Health Canada does not actively conduct the research. For more information on how to submit a COVID-19 Clinical Trial, please refer to the following link: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/drug-guidance.html>
- To date, Health Canada has not received any clinical trial application for studying the safety and efficacy of ivermectin for the prevention or treatment of COVID-19. However, Health Canada is aware that such clinical trials may be planned or underway internationally.
- Following the clinical trial stage, companies can choose between two different authorization pathways for COVID-19-related drugs and vaccines: existing regulatory pathways outlined in the *Food and Drug Regulations* or the Interim Order pathway for COVID-19-related drugs and vaccines, which was signed by the Minister of Health and came into effect on September 16, 2020: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs/note.html>

- This interim order facilitates timely access for Canadians to drugs and vaccines that have demonstrated the ability to diagnose, prevent, treat or cure COVID-19. It introduces temporary regulations to expedite the authorization for importing, selling and advertising COVID-19-related drugs without compromising patient safety.
- Health Canada's position on ivermectin is aligned with that of other regulators. Ivermectin has not been approved by the U.S. Food and Drug Administration or the European Medicines Agency for the prevention or treatment of COVID-19.

From: Bettie, Megan (HC/SC) <megan.bettie@canada.ca>

Sent: 2021-03-26 11:42 AM

To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Mineau, Philippe (HC/SC)

<philippe.mineau@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>

Cc: Legare, Carole (HC/SC) <carole.legare@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>

Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment

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From: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>

Sent: 2021-03-26 10:53 AM

To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Stewart, John Patrick (HC/SC)

<johnpatrick.stewart@canada.ca>; Bettie, Megan (HC/SC) <megan.bettie@canada.ca>

Cc: Legare, Carole (HC/SC) <carole.legare@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>

Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment

Hi Megan,

We can help inform response from any CTs or pre-market discussions, however I believe PHAC was responsible for tracking potential therapies. I know Merck has come out with a position saying they don't have evidence that it's effective. We have our current stock lines.

Bruce

From: Smith4, Melissa (HC/SC) <melissa.smith4@canada.ca>

Sent: 2021-03-26 10:17 AM

To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Stewart, John Patrick (HC/SC)

<johnpatrick.stewart@canada.ca>; Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Bettie, Megan

(HC/SC) <megan.bettie@canada.ca>

Subject: DM Request - Update on Ivermectin in the context of COVID-19 treatment

Good morning TPD and Megan,

The DM has requested, by COB today, a summary of what we know about Ivermectin studies and use as COVID-19 treatment. This request is triggered by [REDACTED] to the DM to ask if HC is systematically tracking it.

Megan – would you mind reaching out to Kaili's group to see if they've been tracking and thus would have input to provide?

Thanks,
Melissa

From: Legare, Carole (HC/SC)
Sent: 2021-04-09 4:17 PM
To: Lefebvre, Larissa (HC/SC)
Subject: RE: ENQ re: COVID drug question

See suggestions below

From: Lefebvre, Larissa (HC/SC) <larissa.lefebvre@canada.ca>
Sent: 2021-04-09 3:53 PM
To: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Subject: FW: ENQ re: COVID drug question

Hi Carole

Just wanted to run this by you .. someone is asking why Canada does have CT with ivermectin for COVID.

Steph prepared a great response and now they are pushing back.

We've drafted the response below.. just wondering if you have anything other suggestions?

If not we will send ☺

Merci

Larissa

From: Gran-Ruaz, Stephanie (HC/SC) <stephanie.gran-ruaz@canada.ca> **On Behalf Of** OCT ENQUIRIES / REQUETES BEC (HC/SC)
Sent: 2021-04-09 3:50 PM
To: Lefebvre, Larissa (HC/SC) <larissa.lefebvre@canada.ca>
Subject: FW: Important Covid drug question

DRAFT follow-up response, as discussed.

Dear [REDACTED]

Thank you for your email. As noted in our email, as the federal regulator, Health Canada cannot conduct clinical trials. This would put us in a conflict of interest situation since we authorize clinical trials.

To date, Health Canada has not received any application for a sponsor to conduct a trial on ivermectin. Health Canada cannot compel nor force a manufacturer/sponsor to run a clinical trial in Canada. You may wish to reach out to ivermectin manufacturers, hospitals and/or institutions to discuss your interest in having access to an ivermectin clinical trial in Canada and their interest in conducting one.

We hope this answers your questions sufficiently. If you have any further questions, please do not hesitate to contact our office.

Kind regards,

Office of Clinical Trials
Therapeutic Products Directorate
Health Canada

From: [REDACTED]
Sent: 2021-04-08 4:39 PM
To: OCT ENQUIRIES / REQUETES BEC (HC/SC) <hc.oct.enquiries-requetes.bec.sc@canada.ca>
Subject: Re: Important Covid drug question

Hello, thank you for your response however this did not answer my question at all. It is simple, why is Ivermectin not on this list when many other countries are seeing great success with it?

The question is about Ivermectin specifically and Canadians need to know WHY we are being denied this treatment!

[REDACTED]
Sent from my iPhone

On Apr 8, 2021, at 4:23 PM, OCT ENQUIRIES / REQUETES BEC (HC/SC) <hc.oct.enquiries-requetes.bec.sc@canada.ca> wrote:

Dear [REDACTED]

Thank you for your email. Health Canada plays an active role in ensuring that Canadians have access to safe and effective drugs and health products. The Department strives to maintain a balance between the potential health benefits and risks posed by all drugs and health products. Our highest priority in determining the balance is public safety. To clarify, Health Canada is not a manufacturer or distributor of drugs and health products; we are the federal regulator. Health Canada does not sponsor clinical trials, nor can we compel a manufacturer to run a clinical trial in Canada.

Health Canada is closely tracking all potential therapeutic treatments and vaccines in development in Canada and abroad, including products that are being used off-label. The Department is working with vaccine developers, researchers, and manufacturers to help expedite the availability of medical products such as vaccines, antibodies, and drugs to prevent and/or treat COVID-19.

Health Canada is working to fast-track COVID-19 related clinical trials, and we have received a number of clinical trial applications in this regard, many of which have already been authorized. Health Canada is also maintaining a [list of all authorized COVID-19 clinical trials](#). Included on this website is the hyperlink for the publicly available [clinicaltrials.gov](#) website (when available), where sponsors may provide more detailed information regarding their studies and may also include study results. Please refer to these sites for detailed information on the ongoing studies.

We hope this answers your questions sufficiently. If you have any further questions, please do not hesitate to contact our office.

Kind regards,
Office of Clinical Trials
Therapeutic Products Directorate
Health Canada

-----Original Message-----

From: Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>
Sent: 2021-04-07 11:17 AM
To: [REDACTED]
Cc: OCT ENQUIRIES / REQUETES BEC (HC/SC) <hc.oct.enquiries-requetes.bec.sc@canada.ca>
Subject: RE: Important Covid drug question

Thank you for contacting Health Canada.

Your recent enquiry has been redirected to the appropriate area for a response.

Sincerely,

Health Canada | Santé Canada
Ottawa, Canada K1A 0K9
info@hc-sc.gc.ca
Telephone | Téléphone 613-957-2991 / Toll free | Sans frais 1 866-225-0709 / Facsimile |
Télécopieur 613-941-5366 / Teletypewriter | Télécopieur 1 800-267-1245
Government of Canada | Gouvernement du Canada

-----Original Message-----

From: [REDACTED]
Sent: 2021-04-03 6:19 PM
To: Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>
Subject: Important Covid drug question

Hello,

After seeing numerous doctors around the world speak so highly of Ivermectin as a very effective drug used to treat Covid 19, I am SHOCKED it is not even in trials in Canada! I would like to know WHY? the NIH lifted its prohibition after mountains of data was provided by doctors in the US. Now It is available if you ask for it in the US. Is this the same for Canada? And if not WHY? A potential life saving drug not even in trials, I hope to god this is not true.

Thank you,



Sent from my iPhone

From: Chiu, Bobbie (HC/SC)
Sent: 2021-09-14 4:12 PM
To: Kearns-Justin, Dayna (HC/SC); Zayoun, Toufic (HC/SC); Rajwani, Salima (HC/SC)
Cc: Stankevitch, Tatiana (HC/SC); Bak, Celina (HC/SC)
Subject: CSF - Public Enquiry - Central - Sep 14, 2021

Hello,

Central received a public enquiry in the form of a voice mail message in the afternoon of Sep 14.

The enquirer asked how an individual can acquire Ivermectin and Hydroxychloroquine. The enquirer did not mention COVID in the message and the tone of the message seemed innocent.

We propose to contact the caller back on Sep 15. Below is the proposed response:

- Ask enquirer whether the enquiry was about obtaining commercial supplies of the drugs for sale or distribution in Canada
 - Inform enquirer on licensing requirements of prescription drugs
- If enquirer was interested in obtaining personal supply
 - Refer the enquirer to consult with the family physician or pharmacist
- If the enquirer was interested in the two drug products as related to COVID-19:
 - Information in *Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems* and the link below can be shared
 - [Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems - Recalls and safety alerts \(healthycanadians.gc.ca\)](#)

Please let me know if the proposed approach is suitable. There does not appear to be a risk of escalation at this time. However, given the current media attention and the ATIP request today on the two drug products, the brief is being sent for concurrence.

Regards,
Bobbie

From: Chiu, Bobbie (HC/SC)
Sent: 2021-09-15 4:22 PM
To: Rajwani, Salima (HC/SC); Zayoun, Toufic (HC/SC)
Cc: Kearns-Justin, Dayna (HC/SC); Bak, Celina (HC/SC); Stankevitch, Tatiana (HC/SC)
Subject: CSF Update - Public Enquiry - Central - Sep 15, 2021

Hello,

Enquirer: [REDACTED]

Summary of the Outcome:

- Central inspector contacted [REDACTED] on Sep 15 by telephone and confirmed she heard the two drug products (Ivermectin and Hydrochloroquine) could be acquired in Canada for personal use
- [REDACTED] confirmed she lives in USA
- Inspector confirmed Canadian residents would need to consult with their physicians to obtain the products in Canada as they are both classified as prescription drugs
- [REDACTED] confirmed the advice and information from the USFDA for both products will be sought
- The caller appeared to be satisfied with the information provided and did not request for other information
- No further follow-up necessary at this time, the enquiry is considered closed

Regards,
Bobbie

From: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Sent: 2021-09-15 9:24 AM
To: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>
Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

Good morning

ADMO confirmed no concerns with responding to the caller and recommends proceeding with the call back as planned and any necessary follow-up action.

Please send a brief summary up of the call once completed in light of the recent media attention .

Thanks,
Salima

Salima Rajwani
salima.rajwani@canada.ca | Tel: 416-305-4041

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Sent: 2021-09-14 4:48 PM
To: Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>; Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

Hi Ranjeet,

As Bobbie stated below, ivermectin can be prescribed for human use for below indication. If they mention COVID-19 we can use wording from our recent advisory.

I would still recommend a call back while sticking to standard lines as part of the script.

Cheers,

Toufic

From: Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>
Sent: 2021-09-14 4:45 PM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

According to the HC Advisory on Ivermectin:

"Ivermectin, a prescription drug product, is authorized for sale in Canada for the treatment of parasitic worm infections in humans, specifically intestinal strongyloidiasis and onchocerciasis, and should only be used for this purpose, under the supervision of a healthcare professional. A veterinary version of this medication is available to treat parasitic infections in animals. People should never use the veterinary version of this product."

For clarification, if the person would like to obtain for personal use, then it would require a prescription, therefore, the enquirer should be referred to contact the family physician or pharmacist

for medical advice.

Our responses are fairly standard in terms of the regulatory requirements for commercial vs personal use.

Bobbie

From: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Sent: 2021-09-14 4:38 PM
To: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021
Importance: High

Hey Toufic,

I seem unclear as to the second bullet highlighted in red. Personal supply for what? Not sure why we would refer them to a family physician or pharmacist for Ivermectin since we know that it should be used in humans right?

[REDACTED]

With that lens how do you think your approach will change? Anything else we should be considering here?

Salima – I think we can still give an early heads up to DGO on this and let them know we are formulating a factual response back to the enquirer.

Let me know,

R

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Sent: Tuesday, September 14, 2021 4:30 PM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>
Subject: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

Hi Ranjeet,

Central received a public enquiry in the form of a voice mail message in the afternoon of Sep 14, 2021.

The enquirer asked how an individual can acquire Ivermectin and Hydroxychloroquine. The enquirer did not mention COVID in the message [REDACTED]

Central proposes to contact the caller back on Sep 15, 2021 and use the approach (below) to respond:

- Ask enquirer whether the enquiry was about obtaining commercial supplies of the drugs for sale or distribution in Canada
 - Inform enquirer on licensing requirements of prescription drugs
- If enquirer was interested in obtaining personal supply
 - Refer the enquirer to consult with the family physician or pharmacist
- If the enquirer was interested in the two drug products as related to COVID-19:
 - Information in *Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems* and the link below can be shared
 - [Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems - Recalls and safety alerts \(healthycanadians.gc.ca\)](#)

I don't see anything wrong with the proposed approach above. It is factual, lines up with publicly available info and would show us as being responsive (getting back to them within a day). Only thing I find strange is this request given the timing of the recent ATI request on both Ivermectin and Hydroxychloroquine.

Any issues from your side Ranjeet to move ahead? I think this should def. be flagged to DGO as an FYI.

Cheers,

Toufic



Toufic Zayoun

(he | il)

Health Product Compliance and Enforcement Unit
Health Product Compliance Directorate
Regulatory Operations & Enforcement Branch
Health Canada / Government of Canada

toufic.zayoun@hc-sc.gc.ca / Tél: 613-301-3970

From: Massey, Ranjeet (HC/SC)
Sent: 2021-08-24 1:29 PM
To: Morgan, Mary (HC/SC); Zayoun, Toufic (HC/SC)
Cc: Jeyakanthan, Thivya (HC/SC); Kearns-Justin, Dayna (HC/SC)
Subject: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED]
[REDACTED] - Ivermectin signage concern [REDACTED] - August 24, 2021
Attachments: [REDACTED] Jun2021.jpg

*****Mary** for your weigh-in/concurrence on this what I'm dubbing as a Caretaker Sensitivity File (CSF) and possible next steps***

Hey Toufic in response to your email below I've reorganize your update with some additional info for Mary as well as some proposed next steps for consideration below **including** Health Canada being proactive and issuing a Public Advisory on Ivermectin similar to that which the FDA has already done.

- Ivermectin, a drug meant for livestock, is being touted as a treatment/prevention for COVID-19. The US FDA has already warned about not using this drug and the issue is already being heavily covered by the media (ex: CNN , Global News) .
- With this context MHPD (STARS) sent the complaint below (and see attachment) which we agree constitutes advertising of a health product to the public for the treatment of a Schedule A disease.
- The billboard reads: "Ivermectin Treats COVID-19." [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- MHPD wants ROEB to dispatch a regional inspector to determine the advertiser, via the billboard rental company and request required corrective actions.

Given:

- Ivermectin, is an authorized product (MHPD scope)
- [REDACTED] lists physicians/pharmacies that will prescribe Ivermectin for COVID
- No evidence that billboard was posted by [REDACTED]
- No information provided in picture of billboard rental company
- Obligation of billboard rental company to disclose rental information.
- If MHPD is not able to identify any non-compliances [REDACTED] perhaps no action recommended

Requester agreed to
Remove 3rd Party Info

Considerations however:

- May be able to provide educational materials to the billboard rental company to identify the false/misleading advertising so they can remove the billboard if they can't share the renters name (and share the compliance information with the renter).
- If this a privately owned billboard on public property have someone (not sure if HPCRM CV) to identify to the city manager for removal given it is a false/misleading claim.
- We will want to consider a Public Advisory similar to the FDA's to show that Health Canada is being proactive on these issues. (Perhaps post before having the billboard taken down).

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Sent: Tuesday, August 24, 2021 11:12 AM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>

Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>

Subject: For Director's Office Input: OPRAA for action due ASAP: [REDACTED]
- Ivermectin signage concern [REDACTED] August 24, 2021

Hi Ranjeet,

I want to flag the below issue that was sent to us by MHPD (STARS). MHPD received the complaint below (and see attachment) and we believe it constitutes advertising of a health product to the public for the treatment of a Schedule A disease. [REDACTED]

MHPD wants ROEB to dispatch a regional inspector to determine the advertiser, via the billboard rental company and request required corrective actions.

I am unsure about assigning this one, given the following considerations:

- Ivermectin, is an authorized product (MHPD scope)
- [REDACTED] lists physicians/pharmacies that will prescribe Ivermectin for COVID
- No evidence that billboard was posted [REDACTED]
- No information provided in picture of billboard rental company
- Obligation of billboard rental company to disclose rental information?
- If MHPD is not able to identify any non-compliances with FLCCC website, then no action recommended

Anything else I am missing? Should we be looking at it from a different angle?

Let me know,

Toufic

Requester agreed to
Remove 3rd Party Info



Toufic Zayoun

(he | il)

A/Manager, Health Product Compliance and Enforcement Unit
Health Product Compliance Directorate
Regulatory Operations & Enforcement Branch
Health Canada / Government of Canada

toufic.zayoun@canada.ca / Tél: 613-301-3970

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>

Sent: 2021-08-23 4:09 PM

To: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>

Cc: Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>

Subject: FW: OPRAA for action due ASAP [REDACTED] - Ivermectin signage concern [REDACTED]

Hello Toufic, Dayna, and Mimi,

I hope you are all excellent! We received the complaint below (and see attachment) and we believe it constitutes advertising of a health product to the public for the treatment of a Schedule A disease, in contravention of the *FOOD & Drugs Act*. [REDACTED]

As such, we propose as a course of action that the case be referred to ROEB for dispatching a regional inspector to determine the advertiser, probably via the billboard rental company and request required corrective actions.

Have a pleasant evening!

Requester agreed to
Remove 3rd Party Info

Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca
Tel: Office : (613) 954-6780 / Cell : (613) 302-4856
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

From: Morgan, Haylee (HC/SC) <haylee.morgan@hc-sc.gc.ca>
Sent: 2021-08-23 8:26 AM
To: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: OPRAA for action due ASAP: [REDACTED] Ivermectin signage concern [REDACTED]

LEAD BUREAU	OPRAA
RESPONSE TO BE SENT TO	MHPD Action Requests
MECS NUMBER	Nil
DUE IN DGO BY	ASAP
CONSULTATIONS	The "lead" bureau is responsible to include and incorporate all relevant information and approvals in the final response being submitted to DGO.
	Please indicate (via email or MECS) whom your bureau has consulted with: (i.e. other MHPD Bureaux, a Directorate, Legal Services, ROEB, SPB, etc.)

Please consult directly with other bureaus if necessary prior to submission to DGO

From: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>
Sent: 2021-08-23 7:52 AM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Cc: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>
Subject: FW: [REDACTED] - Ivermectin signage concern [REDACTED]

Hi Kelly

As this compliant involves what appears to be inappropriate advertising of an approved health product I am forwarding this onto for MHPD's assessment. I have cc'd Linsey Hollett as well.

If you are okay with it, I will respond back to Rani indicating receipt of the email and that I have forwarded it onto to MHPD for action.

Thanks.

Pat

Dr. J. Patrick Stewart, MD, CCFP(EM)
Director General/ Directeur général
Therapeutic Products Directorate/ Direction des produits thérapeutiques
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
613-859-2433 (cell)

From: [REDACTED]
Sent: 2021-08-20 6:44 PM
To: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>
Cc: prescription.drug.enquiries / renseignements.drogue.ordonnance (HC/SC) <prescription.drug.enquiries-renseignements.drogue.ordonnance@hc-sc.gc.ca>; [REDACTED]
Subject: [REDACTED] - Ivermectin signage concern [REDACTED]

Dear Dr. Stewart,

I am writing to you [REDACTED] regarding a concern that had been brought to our attention recently involving the advertisement of the use of Ivermectin in treating Covid-19.

[REDACTED]

[REDACTED] recently received notification from two rural pharmacists about a sign along a rural highway in Manitoba that reads "Ivermectin treats COVID-19 [REDACTED]". I have attached a picture for your review as well. These pharmacists have expressed great concern about this apparent misinformation, placed in a region with extremely poor/low vaccination uptake, combined with the potentially lower educational levels of some residents of the particular area.

In my initial review of the website [REDACTED]

[REDACTED] The information was originally shared with the provincial College of Physicians and Surgeons of Manitoba (CPSM) for their review and considerations for further action. Unfortunately, none of the HCPs fall under the jurisdiction of the CPSM [REDACTED]

Requester agreed to
Remove 3rd Party Info

The TPD may already be aware of this inaccurate/non-compliant advertising, and I'm forwarding to you for your consideration on how best to address and manage. Perhaps the TPD may consider direct communication to the [REDACTED] to remove all non-compliant advertisements regarding Ivermectin use in Covid-19. Is there anything further that the TPD can do about this advertising considering this drug is not approved for use in Covid-19 in Canada?

For your reference, I have also brought this to the attention of our provincial Vaccine Implementation Task Force (VITF) Medical Team Leads for their consideration of addressing provincially as well.

[REDACTED] to any direction you may wish to provide on this, and would be agreeable to any further discussions as well. Please feel welcome to contact me should you wish to discuss further and I will ensure arrangements are made.

I look forward to hearing from you.

Kind regards,



Confidentiality Notice:

This communication (including all attachments) is confidential and is intended for the use of the named addressee(s) only, and may contain information that is private, confidential, privileged, and exempt from disclosure under law. All rights to privilege are expressly claimed and reserved and are not waived. Any use, dissemination, distribution, copying or disclosure of this message and any attachments, in whole or in part, by anyone other than the intended recipient(s) is strictly prohibited. If you have received this communication in error, please notify the sender immediately, delete this communication from all data storage devices and destroy all hard copies.

Simard, Chris (HC/SC)

From: Zayoun, Toufic (HC/SC)
Sent: 2021-09-23 12:48 PM
To: Massey, Ranjeet (HC/SC)
Cc: Rajwani, Salima (HC/SC); Bak, Celina (HC/SC); Kearns-Justin, Dayna (HC/SC); Shelley, Dennis (HC/SC); Kluchnik, Ian (HC/SC); Simard, Chris (HC/SC)
Subject: DIRECTOR Concurrence: Update on Ivermectin Signage in MB (September 23, 2021)
Attachments: 3013457_Regulatory Letter-COVID-19_Magnetsigns.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Requester agreed to
Remove 3rd Party Info

Hi Ranjeet,

As discussed at look-ahead, please find an update below on the ivermectin signage issues being dealt with by MHPD.

Current Status:

- At the end of August of 2021, MHPD received a complaint [REDACTED] regarding a billboard advertising Ivermectin treating COVID in Manitoba.
- MHPD contacted the sign company and have received confirmation that the signs have been removed.
 - The letter sent by MHPD to Magnetsigns referenced the 3 locations (Winkler, Morden, Carman) identified in the complaints they received, this includes the location referenced [REDACTED] (Winkler) which was the file we had previously discussed with them.
- A Public Advisory has been posted warning Canadians that Ivermectin is not authorized to prevent or treat COVID-19 (<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>)

MHPD has requested that ROEB drives to the location of the signage (Winkler, Manitoba) to further confirm that it has indeed been removed.

HPCE Recommendation:

Based on the fact that the signage company has provided confirmation that all signage has been removed and the location of the sign of concern is about 1.5 hrs away from an inspector, we do not think this is necessary to provide this visual confirmation that MHPD is requesting. Please let me know if you concur with this approach.

Cheers,

Toufic



Toufic Zayoun

(he | il)

Health Product Compliance and Enforcement Unit
Health Product Compliance Directorate
Regulatory Operations & Enforcement Branch
Health Canada / Government of Canada

toufic.zayoun@hc-sc.gc.ca / Tél: 613-301-3970

From: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Sent: 2021-09-23 10:53 AM
To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Subject: FW: Response received Re: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

Hi Celina,

Received the email below from Alain (MHPD STARS) regarding a complaint [REDACTED] they received for billboards advertising Ivermectin treating COVID in Manitoba. MHPD contacted the sign company and have received confirmation that the signs have been removed, however, MHPD is now requesting that ROEB drive to the location of where the sign was posted to confirm it has indeed been removed.

Based on the company's confirmation, I'm not sure it is necessary to send an inspector out to confirm, however, I understand there are some sensitivities regarding this product. I did speak with Ian and he said they could drive out to the location if required, however, we wanted to check in with management on the expectation of ROEB confirming compliance that was requested by MHPD.

I've also attached a previous thread that was briefed up for additional context.

Please let me know if you'd like to discuss.

Thanks,
Dayna

Requester agreed to
Remove 3rd Party Info

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Sent: 2021-09-23 10:41 AM
To: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Subject: FW: Response received Re: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

Good morning Dayana,

I hope you are excellent and thank you for the discussion yesterday! Please see below, Magnetic Signs, the sponsor of the Ivermectin billboard in Wrinkler Manitoba, [REDACTED]

The MHPD would like to hereby ask that ROEB Manitoba verifies whether the billboard in Wrinkler Manitoba has indeed been removed.

Let me know whether you need further information.

Have a pleasant day!

ATIA - 19(1)

Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca
Tel: Cell: (613) 302-4856 / Office: Cell: (613) 954-6780
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

From: [REDACTED]
Sent: 2021-09-13 7:35 AM
To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>
Subject: RE: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

Good morning;

Magnetsigns Winkler [REDACTED]

Magnetsigns Winkler management is now fully aware of Health Canada's rules with regard to advertising and will conduct itself accordingly to ensure no more inadvertent advertising mistakes are made.

[REDACTED]

From: IllegalMarketingIllegal (HC/SC) [<mailto:illegalmarketingillegal@hc-sc.gc.ca>]
Sent: September 12, 2021 1:33 PM
To: [REDACTED]
Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

Dear [REDACTED]

Thank you very much for your prompt acknowledgement.

Could Magnetsigns confirm that it has ceased any advertising of Ivermectin in all media for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19?

Moreover, could Magnetsigns advise us by September 14, 2021, on the steps it has taken to cease the contravening advertising described in Health Canada's regulatory letter?

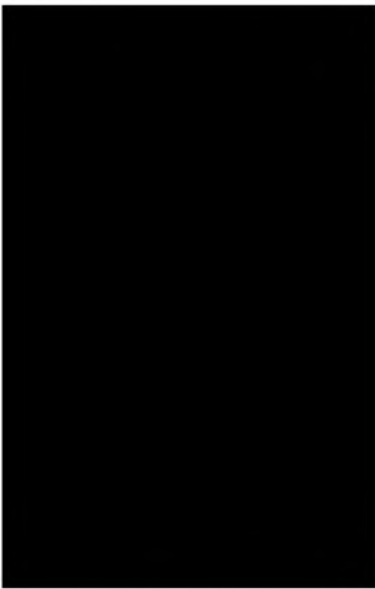
We look forward to hearing from you at your earliest opportunity.

Kindest regards,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From [REDACTED]
Sent: 2021-09-08 3:48 PM
To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>
Cc: 'drug-device-marketing@hc-sc.gc.ca.'
Subject: RE: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

received



From: IllegalMarketingIllegal (HC/SC) [<mailto:illegalmarketingillegal@hc-sc.gc.ca>]
Sent: September 8, 2021 1:22 PM
To: [REDACTED]
Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

Dear [REDACTED]

Health Canada would like to resend you the attached regulatory letter pertaining to "Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin" on Magnetsigns signs in the Winkler, Manitoba area.

Upon calling Magnetsigns [REDACTED] today, [REDACTED] kindly informed us that the e-mail address [REDACTED]

We request that you immediately acknowledge receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Sincerely,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: illegalmarketingillegal@hc-sc.gc.ca

From: IllegalMarketingIllegal (HC/SC)

Sent: 2021-08-31 2:55 PM

To: [REDACTED]
Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

To Whom It May Concern,

Please find attached a correspondence from the Marketed Health Products Directorate – File# 3013457 regarding "Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin."

Health Canada requests that Magnetsigns immediately acknowledges receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Thank you,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

Simard, Chris (HC/SC)

From: Massey, Ranjeet (HC/SC)
Sent: 2021-08-25 11:54 PM
To: Zayoun, Toufic (HC/SC); Mary Morgan (HC/SC)
Cc: Jeyakanthan, Thivya (HC/SC); Kearns-Justin, Dayna (HC/SC); Simard, Chris (HC/SC)
Subject: DIRECTOR Update to Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED]
[REDACTED] - Ivermectin signage concern [REDACTED] August 25, 2021

Follow Up Flag: Follow up
Flag Status: Flagged

Requester agreed to
Remove 3rd Party Info

Current Status:

- Referral from MHPD on August 23, 2021 [REDACTED] regarding the advertising of a health product (Ivermectin) to the public for the treatment of COVID-19 (schedule A disease). The billboard is posted on a rural highway in Manitoba and mentions the [REDACTED] for more information [REDACTED]. At this time it cannot be establish that the billboard is associated with [REDACTED]
- Meeting on August 25, 2021 with MHPD, HPCEU and HPC-West to discuss the complaint. At this time there continue to many unknowns on the source of the billboard and any potential non-compliances. More information will be gathered ahead of finalising next steps.

Next Steps:

- CTU to contact [REDACTED] to gather additional details on the location of the billboard and contact details for the rental company of the billboard, for potential case creation. The contact will be initiated in the next day.
- HPCEU to flag to CPAB the potential of a PA (if needed) and to seek advice on communicating out during a caretaker government. To be initiated on August 25, 2021.

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Sent: 2021-08-24 2:31 PM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>; Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>
Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Johnston, Craig (HC/SC) <craig.johnston@hc-sc.gc.ca>
Subject: RE: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED]
[REDACTED] Ivermectin signage concern [REDACTED] - August 24, 2021

Sounds good.

As mentioned on teams, we will link up to MHPD to see if they can lead on an external comms on Ivermectin (we can feed into it).

We will also link up to West to discuss potential best paths forward on validating the below info. The issue for us is that MHPD has not and will not take action [REDACTED] so it may be tough for an inspector to get traction on this case.

@ Dennis/Craig, copying you both to give you a heads up.

Cheers,

Toufic

Requester agreed to
Remove 3rd Party Info

From: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Sent: 2021-08-24 1:55 PM
To: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP [REDACTED]
[REDACTED] Ivermectin signage concern [REDACTED] August 24, 2021

Those are my thoughts as well.

From: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>
Sent: Tuesday, August 24, 2021 1:54 PM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP [REDACTED]
[REDACTED] Ivermectin signage concern [REDACTED] - August 24, 2021

Thank you for this update.

What are the potential next steps – from what I see:

- Issue a PA
- Send a CV inspector to confirm who is doing the advertising

Anything else?

From: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Sent: 2021-08-24 1:29 PM
To: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>

Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Subject: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED]

[REDACTED] - Ivermectin signage concern [REDACTED] - August 24, 2021

****Mary for your weigh-in/concurrence on this what I'm dubbing as a Caretaker Sensitivity File (CSF) and possible next steps****

Hey Toufic in response to your email below I've reorganize your update with some additional info for Mary as well as some proposed next steps for consideration below **including** Health Canada being proactive and issuing a Public Advisory on Ivermectin similar to that which the FDA has already done.

- Ivermectin, a drug meant for livestock, is being touted as a treatment/prevention for COVID-19. The US FDA has already warned about not using this drug and the issue is already being heavily covered by the media (ex: CNN , Global News) .
- With this context MHPD (STARS) sent the complaint below (and see attachment) which we agree constitutes advertising of a health product to the public for the treatment of a Schedule A disease.
- The billboard reads: "Ivermectin Treats COVID-19" [REDACTED]
- [REDACTED]
- [REDACTED]
- MHPD wants ROEB to dispatch a regional inspector to determine the advertiser, via the billboard rental company and request required corrective actions.

Given:

Requester agreed to
Remove 3rd Party Info

- Ivermectin, is an authorized product (MHPD scope)
- [REDACTED] lists physicians/pharmacies that will prescribe Ivermectin for COVID
- No evidence that billboard was posted [REDACTED]
- No information provided in picture of billboard rental company
- Obligation of billboard rental company to disclose rental information.
- If MHPD is not able to identify any non-compliances [REDACTED] perhaps no action recommended

Considerations however:

- May be able to provide educational materials to the billboard rental company to identify the false/misleading advertising so they can remove the billboard if they can't share the renters name (and share the compliance information with the renter).
- If this a privately owned billboard on public property have someone (not sure if HPCRM CV) to identify to the city manager for removal given it is a false/misleading claim.
- We will want to consider a Public Advisory similar to the FDA's to show that Health Canada is being proactive on these issues. (Perhaps post before having the billboard taken down).

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>

Sent: Tuesday, August 24, 2021 11:12 AM

To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>

Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>

Subject: For Director's Office Input: OPRAA for action due ASAP: [REDACTED]

[REDACTED] Ivermectin signage concern [REDACTED] August 24, 2021

Hi Ranjeet,

Requester agreed to
Remove 3rd Party Info

I want to flag the below issue that was sent to us by MHPD (STARS). MHPD received the complaint below (and see attachment) and we believe it constitutes advertising of a health product to the public for the treatment of a Schedule A disease. Although the [REDACTED]

[REDACTED]

MHPD wants ROEB to dispatch a regional inspector to determine the advertiser, via the billboard rental company and request required corrective actions.

I am unsure about assigning this one, given the following considerations:

- Ivermectin, is an authorized product (MHPD scope)
- [REDACTED] lists physicians/pharmacies that will prescribe Ivermectin for COVID
- No evidence that billboard was posted [REDACTED]
- No information provided in picture of billboard rental company
- Obligation of billboard rental company to disclose rental information?

- If MHPD is not able to identify any non-compliances [REDACTED] then no action recommended

Anything else I am missing? Should we be looking at it from a different angle?

Let me know,

Toufic

<image001.jpg>

Requester agreed to
Remove 3rd Party Info

Toufic Zayoun

(he | il)

A/Manager, Health Product Compliance and Enforcement Unit

Health Product Compliance Directorate
Regulatory Operations & Enforcement Branch
Health Canada / Government of Canada

toufic.zayoun@canada.ca / Tél: 613-301-3970

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>

Sent: 2021-08-23 4:09 PM

To: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>

Cc: Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>

Subject: FW: OPRAA for action due ASAP [REDACTED] ivermectin
signage concern [REDACTED]

Hello Toufic, Dayna, and Mimi,

I hope you are all excellent! We received the complaint below (and see attachment) and we believe it constitutes advertising of a health product to the public for the treatment of a Schedule A disease, in contravention of the *FOOD & Drugs Act*. [REDACTED]

[REDACTED]

As such, we propose as a course action that the case be referred to ROEB for dispatching a regional inspector to determine the advertiser, probably via the billboard rental company and request required corrective actions.

Requester agreed to
Remove 3rd Party Info

Have a pleasant evening!

Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca

Requester agreed to
Remove 3rd Party Info

Tel: Office : (613) 954-6780 / Cell : (613) 302-4856
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

From: Morgan, Haylee (HC/SC) <haylee.morgan@hc-sc.gc.ca>
Sent: 2021-08-23 8:26 AM
To: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>;
HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: OPRAA for action due ASAP [REDACTED] Ivermectin
signage concern [REDACTED]

LEAD BUREAU	OPRAA
RESPONSE TO BE SENT TO	MHPD Action Requests
MECS NUMBER	Nil
DUE IN DGO BY	ASAP
CONSULTATIONS	The "lead" bureau is responsible to include and incorporate all relevant information and approvals in the final response being submitted to DGO.
	Please indicate (via email or MECS) whom your bureau has consulted with: (i.e. other MHPD Bureaux, a Directorate, Legal Services, ROEB, SPB, etc.)

Please consult directly with other bureaus if necessary prior to submission to DGO

From: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>
Sent: 2021-08-23 7:52 AM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Cc: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>
Subject: FW [REDACTED] Ivermectin signage concern [REDACTED]

Hi Kelly

As this compliant involves what appears to be inappropriate advertising of an approved health product I am forwarding this onto for MHPD's assessment. I have cc'd Linsey Hollet as well.

If you are okay with it, I will respond back to [REDACTED] indicating receipt of the email and that I have forwarded it onto to MHPD for action.

Thanks.

Pat

Dr. J. Patrick Stewart, MD, CCFP(EM)

Director General/ Directeur général

Therapeutic Products Directorate/ Direction des produits thérapeutiques

Health Products and Food Branch / Direction générale des produits de santé et des aliments

Health Canada / Santé Canada

613-859-2433 (cell)

Requester agreed to
Remove 3rd Party Info

From: [REDACTED]

Sent: 2021-08-20 6:44 PM

To: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>

Cc: prescription.drug.enquiries@hc-sc.gc.ca / renseignements.drogue.ordonnance@hc-sc.gc.ca (HC/SC)

<prescription.drug.enquiries@hc-sc.gc.ca>; [REDACTED]

Subject: [REDACTED] Ivermectin signage concern [REDACTED]

Dear Dr. Stewart,

I am writing to you on behalf of the [REDACTED] regarding a concern that had been brought to our attention recently involving the advertisement of the use of Ivermectin in treating Covid-19.

[REDACTED]

[REDACTED] has recently received notification from two rural pharmacists about a sign along a rural highway in Manitoba that reads "Ivermectin treats COVID-19 [REDACTED]". I have attached a picture for your review as well. These pharmacists have expressed great concern about this apparent misinformation, placed in a region with extremely poor/low vaccination uptake, combined with the potentially lower educational levels of some residents of the particular area.

[REDACTED] The information was originally shared

ATIA - 19(1)

with the provincial College of Physicians and Surgeons of Manitoba (CPSM) for their review and considerations for further action. Unfortunately, none of the HCPs fall under the jurisdiction of the CPSM [REDACTED]

The TPD may already be aware of this inaccurate/non-compliant advertising, and I'm forwarding to you for your consideration on how best to address and manage. Perhaps the TPD may consider direct communication [REDACTED] to remove all non-compliant advertisements regarding Ivermectin use in Covid-19. Is there anything further that the TPD can do about this advertising considering this drug is not approved for use in Covid-19 in Canada?

For your reference, I have also brought this to the attention of our provincial Vaccine Implementation Task Force (VITF) Medical Team Leads for their consideration of addressing provincially as well.

[REDACTED]
[REDACTED] Please feel welcome to contact me should you wish to discuss further and I will ensure arrangements are made.

I look forward to hearing from you.

Kind regards,

Requester agreed to
Remove 3rd Party Info

From: Bak, Celina (HC/SC)
Sent: 2021-09-22 1:44 PM
To: Zayoun, Toufic (HC/SC)
Cc: Rajwani, Salima (HC/SC); Kearns-Justin, Dayna (HC/SC)
Subject: For director approval: Due @ 1 today: For HPCD input: Media Query: Winnipeg Free Press [REDACTED]
[REDACTED] Regulations of agricultural ivermectin

Hi Toufic,

Some background preamble to provide you with context. Team effort on this one.

We understand is that Ivermectin veterinary drugs are OTC (according to DPD) and available as oral pastes, syrups, topicals and subcutaneous injectables. As far as we know, a consumer could buy them off the shelf without any oversight. VDD might be able to clarify this as the products may only be available through vet offices; some online sources say a prescription is required.

Two Ivermectin products are licensed for human use including a topical and a tablet, physician oversight would be required for these as they are listed as prescription drugs.

For Q1, we hope that VDD takes the lead as it seems to relate to the licensing/classification aspect of ivermectin for veterinary use.

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

A1. HPCD input:

While Health Canada oversees the regulation of drugs, it has no jurisdiction over how health care professionals prescribe drugs once they are approved nor how consumers choose to consume the drug outside of approved directions for use (off-label use).

While Health Canada does not regulate off-label use by consumers, following reports of the use of veterinary ivermectin drugs to prevent or treat COVID-19, Health Canada issued a public advisory to inform Canadians that Ivermectin is not authorized to prevent or treat COVID-19 and may pose serious health risks: <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

MHPD to provide answer.

Thanks,
Celina

From: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Sent: 2021-09-22 11:58 AM

To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Subject: Due @ 1 today: For HPCD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin
Importance: High

Hi Celina

Media request for response please. DGO has requested an extension but hasn't heard back yet, so (for now) a response is requested back by 1 pm today. I've added our previous response in red to Q2 below and also asked that MHPD be tasked for Q2.

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

At this time, Health Canada has not directly received complaints or reports of adverse events associated with the use of ivermectin-containing products in humans for COVID-19 purposes. (please confirm this is still accurate)

Thanks,
Salima

Salima Rajwani
salima.rajwani@hc-sc.gc.ca | Tel: 416-305-4041

From: St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>
Sent: 2021-09-22 10:47 AM
To: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Cc: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Subject: FW: For HPCD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Salima,

For your action. I have requested an extension to COB but that has not been confirmed. A response to DGO by 1pm would be appreciated, until informed otherwise.

Thank you,
Carole

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>
Sent: 2021-09-22 10:17 AM
To: HC.F RORB HPC Media F.SC <rorb_hpc_media@hc-sc.gc.ca>
Cc: HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Francis-Lamb, Laura (HC/SC) <laura.francis-lamb@hc-sc.gc.ca>
Subject: For HPCD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Good morning,

We have received a media query on agricultural ivermectin. Initially, this query was sent to CFIA but they confirmed that HC may have a role to play.

Can you take a look at the request below and advise whether your team can provide input?

If so, your input by 1 pm would be greatly appreciated.

Thank you,

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Tasked to:
Approved by:

Anne Génier

Senior Media Relations Advisor, Communication and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Conseillère principale des relations avec les médias, Direction générale des communications et des
affaires publiques

Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du
Canada

anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

- - -

Media | Média T: [613-957-2983](tel:613-957-2983), E/CE: media@hc-sc.gc.ca

From: Bak, Celina (HC/SC)
Sent: 2021-09-23 11:42 AM
To: Zayoun, Toufic (HC/SC)
Cc: Kluchnik, Ian (HC/SC); Shelley, Dennis (HC/SC); Kearns-Justin, Dayna (HC/SC); Rajwani, Salima (HC/SC)
Subject: For Director's office: update on Ivermectin signage in MB

Hi Toufic,

Update on Ivermectin Signage:

- At the end of August, MHPD received a complaint [REDACTED] regarding a billboard advertising Ivermectin treating COVID in Manitoba.
- MHPD contacted the sign company and have received confirmation that the signs have been removed.
- A Public Advisory has been posted warning Canadians that Ivermectin is not authorized to prevent or treat COVID-19 (<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>)

MHPD has requested that ROEB drives to the location of the signage (Wrinkler, Manitoba) to further confirm that it has indeed been removed, however I do not think this is necessary given that the signage company has confirmed the signs have been removed.

Please let us know if there is any concerns.

Thanks,
Celina

Requester agreed to
Remove 3rd Party Info

From: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Sent: 2021-09-23 10:53 AM
To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Subject: FW: Response received Re: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

Hi Celina,

Received the email below from Alain (MHPD STARS) regarding a complaint [REDACTED]
[REDACTED] they received for billboards advertising Ivermectin treating COVID in Manitoba. MHPD contacted the sign company and have received confirmation that the signs have been removed, however, MHPD is now requesting that ROEB drive to the location of where the sign was posted to confirm it has indeed been removed.

Based on the company's confirmation, I'm not sure it is necessary to send an inspector out to confirm, however, I understand there are some sensitivities regarding this product. I did speak with Ian and he said they could drive out to the location if required, however, we wanted to check in with management on the expectation of ROEB confirming compliance that was requested by MHPD.

I've also attached a previous thread that was briefed up for additional context.

Please let me know if you'd like to discuss.

Thanks,
Dayna

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Sent: 2021-09-23 10:41 AM
To: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Subject: FW: Response received Re: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

Good morning Dayana,

I hope you are excellent and thank you for the discussion yesterday! Please see below, Magnetic Signs, the sponsor of the Ivermectin billboard in Wrinkler Manitoba [REDACTED]

The MHPD would like to hereby ask that ROEB Manitoba verifies whether the billboard in Wrinkler Manitoba has indeed been removed.

Let me know whether you need further information.

Have a pleasant day!

Requester agreed to
Remove 3rd Party Info

Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca
Tel: Cell: (613) 302-4856 / Office:: Cell: (613) 954-6780
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

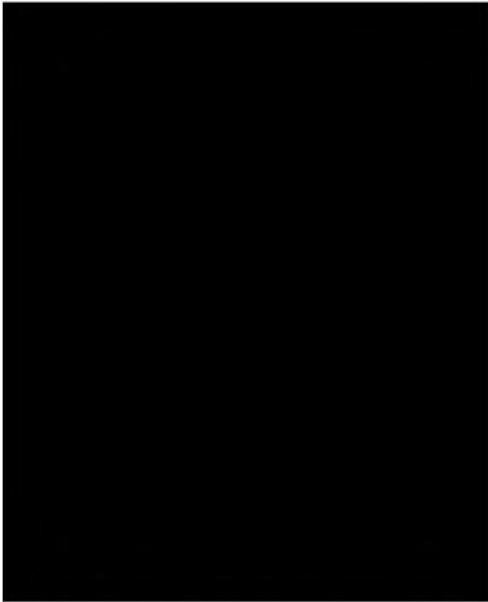
From: [REDACTED]
Sent: 2021-09-13 7:35 AM
To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>

Subject: RE: File# 3013457 Correspondence from the Marketed Health Products
Directorate_Magnetsigns

Good morning;

Magnetsigns Winkler [REDACTED]

Magnetsigns Winkler management is now fully aware of Health Canada's rules with regard to advertising and will conduct itself accordingly to ensure no more inadvertent advertising mistakes are made.



From: IllegalMarketingIllegal (HC/SC) [<mailto:illegalmarketingillegal@hc-sc.gc.ca>]

Sent: September 12, 2021 1:33 PM

To: [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

Dear [REDACTED]

Thank you very much for your prompt acknowledgement.

Could Magnetsigns confirm that it has ceased any advertising of Ivermectin in all media for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19?

Moreover, could Magnetsigns advise us by September 14, 2021, on the steps it has taken to cease the contravening advertising described in Health Canada's regulatory letter?

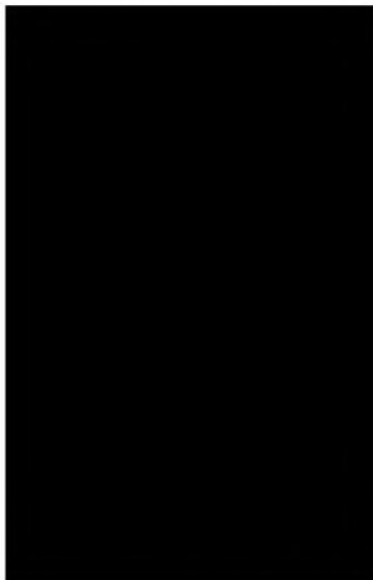
We look forward to hearing from you at your earliest opportunity.

Kindest regards,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From: [REDACTED]
Sent: 2021-09-08 3:48 PM
To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>
Cc: 'drug-device-marketing@hc-sc.gc.ca.'
Subject: RE: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

received



Requester agreed to
Remove 3rd Party Info

From: IllegalMarketingIllegal (HC/SC) [<mailto:illegalmarketingillegal@hc-sc.gc.ca>]
Sent: September 8, 2021 1:22 PM
To: [REDACTED]
Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

Dear [REDACTED]

Health Canada would like to resend you the attached regulatory letter pertaining to "Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin" on Magnetsigns signs in the Winkler, Manitoba area.

Upon calling [REDACTED] kindly informed us that the e-mail address [REDACTED]

[REDACTED]

We request that you immediately acknowledge receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Sincerely,

Requester agreed to
Remove 3rd Party Info

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: illegalmarketingillegal@hc-sc.gc.ca

From: IllegalMarketingIllegal (HC/SC)

Sent: 2021-08-31 2:55 PM

To: [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

To Whom It May Concern,

Please find attached a correspondence from the Marketed Health Products Directorate – File# 3013457 regarding “Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin.”

Health Canada requests that Magnetsigns immediately acknowledges receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Thank you,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From: Zayoun, Toufic (HC/SC)
Sent: 2021-08-30 10:58 AM
To: Morgan, Mary (HC/SC)
Cc: Jeyakanthan, Thivya (HC/SC); Kearns-Justin, Dayna (HC/SC); Shelley, Dennis (HC/SC); Johnston, Craig (HC/SC); Lin, Mimi (HC/SC); Kluchnik, Ian (HC/SC)
Subject: For Director's Office Information- Update to Caretaker Sensitivity File - OPRAA for action due ASAP [REDACTED] Ivermectin signage concern [REDACTED] August 30, 2021

Hi Mary,

MHPD (STARS) uncovered additional information (advertiser) in past complaints about the signage company responsible for the "Ivermectin and COVID-19" billboards in Manitoba. MHPD ended up contacting the company late last week since they now had the information needed. We just became aware of this.

MHPD also sent an email to us this am to retract their referral to our group, as they are in the process of sending a regulatory letter to the signage company with the request to immediately remove all signs with the contravening information. If potential escalation is required, they may refer the case back over to us, as per usual process.

We have let them know about current ongoing work related to the PA. If anything else pops up, we will keep you informed.

Cheers,

Toufic



Requester agreed to
Remove 3rd Party Info

Toufic Zayoun
(he | il)
A/Manager, Health Product Compliance and Enforcement Unit
Health Product Compliance Directorate
Regulatory Operations & Enforcement Branch
Health Canada / Government of Canada

toufic.zayoun@canada.ca / Tél: 613-301-3970

From: Zayoun, Toufic (HC/SC)
Sent: 2021-08-25 4:45 PM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Simard, Chris (HC/SC) <chris.simard@hc-sc.gc.ca>; Shelley, Dennis (HC/SC) <dennis.shelley@hc-sc.gc.ca>; Johnston, Craig (HC/SC) <craig.johnston@hc-sc.gc.ca>; Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Subject: For Director's Office Information- Update to Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED] Ivermectin signage concern [REDACTED] - August 25, 2021

Hi Ranjeet,

I wanted to give you an update on this case.

Current Status:

- Referral from MHPD on August 23, 2021 [REDACTED] regarding the advertising of a health product (Ivermectin) to the public for the treatment of COVID-19 (schedule A disease). The billboard is posted on a rural highway in Manitoba [REDACTED]
[REDACTED]
- Meeting on August 25, 2021 with MHPD, HPCEU and HPC-West to discuss the complaint. At this time there continue to many unknowns on the source of the billboard and any potential non-compliances. More information will be gathered ahead of finalising next steps.

Next Steps:

- CTU to contact [REDACTED] to gather additional details on the location of the billboard and contact details for the rental company of the billboard, for potential case creation. The contact will be initiated in the next day.
- HPCEU to flag to CPAB the potential of a PA (if needed) and to seek advice on communicating out during a caretaker government. To be initiated on August 25, 2021.

Please let me know if you have any questions and/or concerns.

Cheers,

Toufic

Requester agreed to
Remove 3rd Party Info

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>

Sent: 2021-08-24 2:31 PM

To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>; Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>

Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Johnston, Craig (HC/SC) <craig.johnston@hc-sc.gc.ca>

Subject: RE: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED]
[REDACTED] Ivermectin signage concern [REDACTED] August 24, 2021

Sounds good.

As mentioned on teams, we will link up to MHPD to see if they can lead on an external comms on Ivermectin (we can feed into it).

We will also link up to West to discuss potential best paths forward on validating the below info. The issue for us is that MHPD has not and will not take action [REDACTED] so it may be tough for an inspector to get traction on this case.

@ Dennis/Craig, copying you both to give you a heads up.

Cheers,

Toufic

From: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>

Sent: 2021-08-24 1:55 PM

To: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>

Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Subject: RE: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED]
[REDACTED] Ivermectin signage concern [REDACTED] - August 24, 2021

Those are my thoughts as well.

From: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>
Sent: Tuesday, August 24, 2021 1:54 PM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED]
[REDACTED] Ivermectin signage concern [REDACTED] - August 24, 2021

Thank you for this update.

What are the potential next steps – from what I see:

- Issue a PA
- Send a CV inspector to confirm who is doing the adverti

Requester agreed to
Remove 3rd Party Info

Anything else?

From: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Sent: 2021-08-24 1:29 PM
To: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED]
[REDACTED] Ivermectin signage concern [REDACTED] - August 24, 2021

*****Mary** for your weigh-in/concurrence on this what I'm dubbing as a Caretaker Sensitivity File (CSF) and possible next steps***

Hey Toufic in response to your email below I've reorganize your update with some additional info for Mary as well as some proposed next steps for consideration below **including** Health Canada being proactive and issuing a Public Advisory on Ivermectin similar to that which the FDA has already done.

- Ivermectin, a drug meant for livestock, is being touted as a treatment/prevention for COVID-19. The US FDA has already warned about not using this drug and the issue is already being heavily covered by the media (ex: CNN , Global News) .
- With this context MHPD (STARS) sent the complaint below (and see attachment) which we agree constitutes advertising of a health product to the public for the treatment of a Schedule A disease.
- The billboard reads: "Ivermectin Treats COVID-19. [REDACTED]"
- [REDACTED]
- [REDACTED]
- MHPD wants ROEB to dispatch a regional inspector to determine the advertiser, via the billboard rental company and request required corrective actions.

Given:

- Ivermectin, is an authorized product (MHPD scope)

- [REDACTED] lists physicians/pharmacies that will prescribe Ivermectin for COVID
- [REDACTED]
- No information provided in picture of billboard rental company
- Obligation of billboard rental company to disclose rental information.
- If MHPD is not able to identify any non-compliances with [REDACTED] perhaps no action recommended

Considerations however:

- May be able to provide educational materials to the billboard rental company to identify the false/misleading advertising so they can remove the billboard if they can't share the renters name (and share the compliance information with the renter).
- If this a privately owned billboard on public property have someone (not sure if HPCRM CV) to identify to the city manager for removal given it is a false/misleading claim.
- We will want to consider a Public Advisory similar to the FDA's to show that Health Canada is being proactive on these issues. (Perhaps post before having the billboard taken down).

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>

Sent: Tuesday, August 24, 2021 11:12 AM

To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>

Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>

Subject: For Director's Office Input: OPRAA for action due ASAP: [REDACTED]
- Ivermectin signage concern [REDACTED] August 24, 2021

Hi Ranjeet,

I want to flag the below issue that was sent to us by MHPD (STARS). MHPD received the complaint below (and see attachment) and we believe it constitutes advertising of a health product to the public for the treatment of a Schedule A disease. [REDACTED]

MHPD wants ROEB to dispatch a regional inspector to determine the advertiser, via the billboard rental company and request required corrective actions.

I am unsure about assigning this one, given the following considerations:

- Ivermectin, is an authorized product (MHPD scope)
- [REDACTED] lists physicians/pharmacies that will prescribe Ivermectin for COVID
- [REDACTED]
- No information provided in picture of billboard rental company
- Obligation of billboard rental company to disclose rental information?
- If MHPD is not able to identify any non-compliances [REDACTED] then no action recommended

Anything else I am missing? Should we be looking at it from a different angle?

Let me know,

Toufic

Requester agreed to
Remove 3rd Party Info



Toufic Zayoun

(he | il)

A/Manager, Health Product Compliance and Enforcement Unit
Health Product Compliance Directorate
Regulatory Operations & Enforcement Branch
Health Canada / Government of Canada

toufic.zayoun@canada.ca / Tél: 613-301-3970

Requester agreed to
Remove 3rd Party Info

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>

Sent: 2021-08-23 4:09 PM

To: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>

Cc: Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>

Subject: FW: OPRAA for action due ASAP: [REDACTED] Ivermectin signage concern [REDACTED]

Hello Toufic, Dayna, and Mimi,

I hope you are all excellent! We received the complaint below (and see attachment) and we believe it constitutes advertising of a health product to the public for the treatment of a Schedule A disease, in contravention of the *FOOD & Drugs Act*. [REDACTED]

As such, we propose as a course of action that the case be referred to ROEB for dispatching a regional inspector to determine the advertiser, probably via the billboard rental company and request required corrective actions.

Have a pleasant evening!

Alain G. Musende, PhD

Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité

Marketed Health Products Directorate/
Direction des produits de santé commercialisés

Government of Canada | Gouvernement du Canada
alain.musende@canada.ca

Tel: Office : (613) 954-6780 / Cell : (613) 302-4856
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

From: Morgan, Haylee (HC/SC) <haylee.morgan@hc-sc.gc.ca>

Sent: 2021-08-23 8:26 AM

To: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>

Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>; HC.F

MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>

Subject: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage concern [REDACTED]

LEAD BUREAU	OPRAA
RESPONSE TO BE SENT TO	MHPD Action Requests
MECS NUMBER	Nil
DUE IN DGO BY	ASAP
CONSULTATIONS	The "lead" bureau is responsible to include and incorporate all relevant information and approvals in the final response being submitted to DGO.
	Please indicate (via email or MECS) whom your bureau has consulted with: (i.e. other MHPD Bureaux, a Directorate, Legal Services, ROEB, SPB, etc.)

Please consult directly with other bureaus if necessary prior to submission to DGO

From: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>

Sent: 2021-08-23 7:52 AM

To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>

Cc: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>

Subject: FW: [REDACTED] Ivermectin signage concern [REDACTED]

Hi Kelly

As this compliant involves what appears to be inappropriate advertising of an approved health product I am forwarding this onto for MHPD's assessment. I have cc'd Linsey Hollet as well.

If you are okay with it, I will respond back to Rani indicating receipt of the email and that I have forwarded it onto to MHPD for action.

Thanks.

Pat

Dr. J. Patrick Stewart, MD, CCFP(EM)
Director General/ Directeur général
Therapeutic Products Directorate/ Direction des produits thérapeutiques
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
613-859-2433 (cell)

From: [REDACTED]

Sent: 2021-08-20 6:44 PM

To: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>

Cc: prescription.drug.enquiries / renseignements.drogue.ordonnance (HC/SC) <prescription.drug.enquiries-renseignements.drogue.ordonnance@hc-sc.gc.ca>; [REDACTED]

Subject: [REDACTED] Ivermectin signage concern [REDACTED]

Dear Dr. Stewart,

I am writing to you [REDACTED] regarding a concern that had been brought to our attention recently involving the advertisement of the use of Ivermectin in treating Covid-19.

[REDACTED]
[REDACTED] has recently received notification from two rural pharmacists about a sign along a rural highway in Manitoba that reads "Ivermectin treats COVID-19 [REDACTED] I have attached a picture for your review as well. These pharmacists have expressed great concern about this apparent misinformation, placed in a region with extremely poor/low vaccination uptake, combined with the potentially lower educational levels of some residents of the particular area.

In my initial review [REDACTED]

[REDACTED] The information was originally shared with the provincial College of Physicians and Surgeons of Manitoba (CPSM) for their review and considerations for further action. Unfortunately, none of the HCPs fall under the jurisdiction of the CPSM [REDACTED]

The TPD may already be aware of this inaccurate/non-compliant advertising, and I'm forwarding to you for your consideration on how best to address and manage. Perhaps the TPD may consider direct communication [REDACTED] to remove all non-compliant advertisements regarding Ivermectin use in Covid-19. Is there anything further that the TPD can do about this advertising considering this drug is not approved for use in Covid-19 in Canada?

For your reference, I have also brought this to the attention of our provincial Vaccine Implementation Task Force (VITF) Medical Team Leads for their consideration of addressing provincially as well.

[REDACTED]
I look forward to hearing from you.

Kind regards,

Requester agreed to
Remove 3rd Party Info

From: [Morgan, Mary \(HC/SC\)](#)
Sent: 2021-08-30 9:03 AM
To: [Zayoun, Toufic \(HC/SC\)](#)
Cc: [Kearns-Justin, Dayna \(HC/SC\)](#)
Subject: FW: Clippings

Importance: High

Hi Toufic – can you please let me know the status of the potential risk comms?

From: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Sent: 2021-08-30 9:01 AM
To: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>
Cc: Scarito, Rosalee (HC/SC) <rosalee.scarito@hc-sc.gc.ca>
Subject: FW: Clippings
Importance: High

Morning Mary!

See below – request from ADMs that we consider a risk comms.

Can you call LFL asap to discuss?

Thanks!

L

From: Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Sent: 2021-08-30 8:52 AM
To: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Cc: McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>; LeBrun, Matt (HC/SC) <matt.lebrun@hc-sc.gc.ca>
Subject: FW: Clippings

Hi Linsey,

You are probably already aware of this. I'm thinking we should do a risk comms asap today.
Grateful your thoughts.

S

From: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>
Sent: 2021-08-30 8:46 AM
To: Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>; Hollett, Linsey (HC/SC)

<linsey.hollett@hc-sc.gc.ca>

Cc: Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>

Subject: RE: Clippings

Thanks Eric, I missed that one! I am copying Manon, Linsey and Stefania as there may be post market follow up that is in train.

Pam

From: Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>

Sent: 2021-08-30 8:42 AM

To: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>

Cc: Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>

Subject: Clippings

Hi Pam:

Just wanted to make sure you had seen this one:

<https://www.cbc.ca/news/canada/calgary/ivermectin-alberta-covid-1.6157200>

Eric Bélair

Associate Assistant Deputy Minister / Sous-ministre adjoint délégué
Strategic Policy Branch / Direction générale de la politique stratégique
Health Canada / Santé Canada
343-552-1733
eric.belair@hc-sc.gc.ca

From: Kearns-Justin, Dayna (HC/SC)
Sent: 2021-09-27 8:41 AM
To: Bak, Celina (HC/SC)
Cc: Lin, Mimi (HC/SC)
Subject: FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query:
Follow-up: Winnipeg Free Press [REDACTED] Regulations of
agricultural ivermectin

Hey,

Thanks for the draft Mimi. Revised the response a bit based on a previous response for a similar question.

Celina – let me know your preference and if you want me to send up.

Thanks,
Dayna

Proposed revised draft:

It is prohibited in Canada to sell or advertise a drug in a false, misleading or deceptive manner and would be a contravention of the *Food and Drugs Act*.

Drugs are regulated under the *Food and Drugs Act* and associated Regulations. Fines and penalties for convictions related to contraventions of this Act and its regulations are described under Section 31 of the *Food and Drugs Act*. Health Canada may also refer charges under the *Food and Drugs Act* to the Public Prosecution Service of Canada (PPSC) for potential prosecution. The courts have the sole discretion to impose penalties.

The primary objective of Health Canada's compliance and enforcement approach is to manage the risks to Canadians using the most appropriate level of intervention. When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred and takes action based on the risk to the health of Canadians. A number of compliance and enforcement options are available to correct non-compliance or mitigate a risk to Canadians, including, for example, issuing public communications, product recalls, product seizures and referrals to the Public Prosecution Service of Canada for potential prosecution.

The Department encourages anyone who has information regarding the potential sale or advertising of any non-compliant health product to report it using the [online complaint form](#).

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Sent: 2021-09-27 8:19 AM
To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-

justin@hc-sc.gc.ca>

Subject: RE: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg
Free Press [REDACTED] Regulations of agricultural ivermectin

Morning Ladies,

Please see draft response below.

**Q5. And can businesses be fined for selling ivermectin if they know it won't be used for
its intended purpose? (HPCD)**

It is prohibited in Canada to sell or advertise a drug in a false, misleading or deceptive manner as per
section 9(1) of the *Food and Drugs Act* (FDA) which states:

9 (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that
is false, misleading or deceptive or is likely to create an erroneous impression regarding its character,
value, quantity, composition, merit or safety.

Health Canada can refer cases under the FDA to the Public Prosecution Service of Canada for potential
prosecution. The courts have the sole discretion to impose fines. The primary objective of Health
Canada's compliance and enforcement approach is to manage the risks to Canadians using the most
appropriate level of intervention.

Thanks!

Mimi

From: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>

Sent: 2021-09-27 6:41 AM

To: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-
sc.gc.ca>

Subject: FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg
Free Press [REDACTED] Regulations of agricultural ivermectin

Importance: High

Good morning ladies,

Please see below follow up question to the media request on advertising of ivermectin in MB.

**Q5. And can businesses be fined for selling ivermectin if they know it won't be used for
its intended purpose? (HPCD)**

[REDACTED]

[REDACTED] If I am
not there, please skip me from the approval process and route to Ranjeet and Salima directly.

Requester agreed to
Remove 3rd Party Info

Thanks,
Celina

From: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Sent: 2021-09-26 10:47 PM
To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Subject: FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hey Celina,
Realize you're not cc'ed. Adding you. Linsey noting need a response first thing Monday morning.
R

From: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Sent: Friday, September 24, 2021 5:23 PM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Cc: Scarito, Rosalee (HC/SC) <rosalee.scarito@hc-sc.gc.ca>; St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>
Subject: FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

See below from CPAB. No weekend work required but we will need to draft something for Q5 first thing Monday morning.

Thanks!

L

From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Sent: 2021-09-24 5:18 PM
To: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; HC.F RORB HPC Media F.SC <rorb_hpc_media@hc-sc.gc.ca>
Cc: Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>
Subject: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Team, These are follow-up questions about the billboard ad. To OPRAA if not already tasked. Many thanks,
RS

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>
Sent: Friday, September 24, 2021 4:17 PM

To: HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; HC.F RORB HPC Media F.SC <rorb_hpc_media@hc-sc.gc.ca>

Cc: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>

Subject: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED]
Regulations of agricultural ivermectin

Hi MHPD,

As expected the reporter is asking for more details on the case in Manitoba.

Rong- you said that in this case, it was a third party we were dealing with, not the company/group that paid for the ad. At this point we have not released this information, given it was a third party. Can we put that as a response?

Carole – I believe Q5 falls under HPCD.

Input by noon on Monday would be greatly appreciated.

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 27

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Do you have more information on the false advertising in Manitoba?

Q2. How many billboards were there and where were they located?

Q3. Were they claiming ivermectin cures COVID-19?

Q4. Was the company fined?

Q5. And can businesses be fined for selling ivermectin if they know it won't be used for its intended purpose? (HPCD)

.

Response previously provided:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

One of Health Canada's roles, as the federal regulator, is the approval of veterinary drug products. The Department helps ensure that all veterinary drugs fully satisfy requirements under the Food and Drug Regulations before they can be marketed. Health Canada is also responsible for compliance monitoring and enforcement activities related to veterinary drugs in Canada, including verifying that they are marketed in a manner that is consistent with their terms of market authorization and federal legislation and are not advertised in a false, misleading or deceptive manner. Depending on the province or territory where the drugs are sold, there may be restrictions on who is permitted to purchase products intended for use in livestock. Health Canada does not have jurisdiction over how a product is ultimately used.

Following reports of the use of veterinary ivermectin drugs outside of approved directions for use (off-label use), Health Canada issued a public advisory to inform Canadians that Ivermectin is not authorized to prevent or treat COVID-19 and may pose serious health risks:

<https://healthykanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of billboard advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the company displaying these ads removed them immediately, confirmed that these ads were no longer being displayed and committed to refraining from engaging in this non-compliant act in the future.

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred. Incidents of non-compliance are prioritised and action is taken based on the risk they may pose to the general public. It is the responsibility of companies to comply with regulatory requirements and to investigate incidents of potential non-compliance, take appropriate action to correct non-compliance, mitigate any risk to health, and inform Health Canada as appropriate.

To report marketing that is false or misleading or does not meet regulatory requirements, visit <https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/illegal-marketing/complaint.html>.

As part of its ongoing commitment to openness and transparency, Health Canada posts a [summary of health product advertising complaints](#) as well as [health product advertising incidents related to COVID-19](#) addressed by the Department. This case is expected to be posted online in the coming weeks.

Tasked to:
Approved by:

Anne Génier

Senior Media Relations Advisor, Communication and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Conseillère principale des relations avec les médias, Direction générale des communications et des
affaires publiques

Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du
Canada

anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

- - -

Media | Média T: [613-957-2983](tel:613-957-2983), E/CE: media@hc-sc.gc.ca

From: [Kearns-Justin, Dayna \(HC/SC\)](#)
Sent: 2021-09-27 8:54 AM
To: [Zayoun, Toufic \(HC/SC\)](#); [Massey, Ranjeet \(HC/SC\)](#); [Rajwani, Salima \(HC/SC\)](#)
Cc: [Bak, Celina \(HC/SC\)](#)
Subject: FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Morning all,

Please see below for draft response.

Thanks,
Dayna

Q5. And can businesses be fined for selling ivermectin if they know it won't be used for its intended purpose? (HPCD)

It is prohibited in Canada to sell or advertise a drug in a false, misleading or deceptive manner and would be a contravention of the *Food and Drugs Act*.

Drugs are regulated under the *Food and Drugs Act* and associated Regulations. Fines and penalties for convictions related to contraventions of this Act and its regulations are described under [Section 31](#) of the *Food and Drugs Act*. Health Canada may refer charges under the *Food and Drugs Act* to the Public Prosecution Service of Canada (PPSC) for potential prosecution. The courts have the sole discretion to impose penalties.

*Don't think we need to include the below as it was previously included in other questions but just in case:

The primary objective of Health Canada's compliance and enforcement approach is to manage the risks to Canadians using the most appropriate level of intervention. When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred and takes action based on the risk to the health of Canadians. A number of compliance and enforcement options are available to correct non-compliance or mitigate a risk to Canadians, including, for example, issuing public communications, product recalls, product seizures and referrals to the Public Prosecution Service of Canada for potential prosecution.

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Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>

Subject: FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hey Celina,

Realize you're not cc'ed. Adding you. Linsey noting need a response first thing Monday morning.

R

From: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>

Sent: Friday, September 24, 2021 5:23 PM

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Cc: Scarito, Rosalee (HC/SC) <rosalee.scarito@hc-sc.gc.ca>; St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>

Subject: FW: DGO to OPRAA please: For MHPD and HPCD input: Media Query: Follow-up: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

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Thanks!

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From: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>

Sent: 2021-09-24 5:18 PM

To: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; HC.F RORB HPC Media F.SC <rorb_hpc_media@hc-sc.gc.ca>

Cc: Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>

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Cc: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>

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Input by noon on Monday would be greatly appreciated.

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 27

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Do you have more information on the false advertising in Manitoba?

Q2. How many billboards were there and where were they located?

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Response previously provided:

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As part of its ongoing commitment to openness and transparency, Health Canada posts a [summary of health product advertising complaints](#) as well as [health product advertising incidents related to COVID-19](#) addressed by the Department. This case is expected to be posted online in the coming weeks.

Tasked to:
Approved by:

Anne Génier

Senior Media Relations Advisor, Communication and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Conseillère principale des relations avec les médias, Direction générale des communications et des
affaires publiques

Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du
Canada

anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

- - -

Media | Média T: [613-957-2983](tel:613-957-2983), E/CE: media@hc-sc.gc.ca

From: Zayoun, Toufic (HC/SC)
Sent: 2021-09-15 12:36 PM
To: Chiu, Bobbie (HC/SC)
Subject: FW: DIRECTOR Concurrence: CSF - Public
Enquiry - Central - Sep 14, 2021

Email on go-ahead below.

TZ

From: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Sent: 2021-09-15 9:24 AM
To: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>
Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

Good morning

ADMO confirmed no concerns with responding to the caller and recommends proceeding with the call back as planned and any necessary follow-up action.

Please send a brief summary up of the call once completed in light of the recent media attention .

Thanks,
Salima

Salima Rajwani
salima.rajwani@canada.ca | Tel: 416-305-4041

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Sent: 2021-09-14 4:48 PM
To: Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>; Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

Hi Ranjeet,

As Bobbie stated below, ivermectin can be prescribed for human use for below indication. If they mention COVID-19 we can use wording from our recent advisory.

I would still recommend a call back while sticking to standard lines as part of the script.

Cheers,

Toufic

From: Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>
Sent: 2021-09-14 4:45 PM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

According to the HC Advisory on Ivermectin:

"Ivermectin, a prescription drug product, is authorized for sale in Canada for the treatment of parasitic worm infections in humans, specifically intestinal strongyloidiasis and onchocerciasis, and should only be used for this purpose, under the supervision of a healthcare professional. A veterinary version of this medication is available to treat parasitic infections in animals. People should never use the veterinary version of this product."

For clarification, if the person would like to obtain for personal use, then it would require a prescription, therefore, the enquirer should be referred to contact the family physician or pharmacist for medical advice.

Our responses are fairly standard in terms of the regulatory requirements for commercial vs personal use.

Bobbie

From: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Sent: 2021-09-14 4:38 PM
To: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021
Importance: High

Hey Toufic,

I seem unclear as to the second bullet highlighted in red. Personal supply for what? Not sure why we would refer them to a family physician or pharmacist for Ivermectin since we know that it should be used in humans right?

[REDACTED]

With that lens how do you think your approach will change? Anything else we should be considering here?

Salima – I think we can still give an early heads up to DGO on this and let them know we are formulating a factual response back to the enquirer.

Let me know,

R

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>

Sent: Tuesday, September 14, 2021 4:30 PM

To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>

Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>

Subject: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

Hi Ranjeet,

Central received a public enquiry in the form of a voice mail message in the afternoon of Sep 14, 2021.

The enquirer asked how an individual can acquire Ivermectin and Hydroxychloroquine. The enquirer did not mention COVID in the message [REDACTED]

Central proposes to contact the caller back on Sep 15, 2021 and use the approach (below) to respond:

- Ask enquirer whether the enquiry was about obtaining commercial supplies of the drugs for sale or distribution in Canada
 - Inform enquirer on licensing requirements of prescription drugs
- If enquirer was interested in obtaining personal supply
 - Refer the enquirer to consult with the family physician or pharmacist
- If the enquirer was interested in the two drug products as related to COVID-19:
 - Information in *Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems* and the link below can be shared
 - Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems - Recalls and safety alerts (healthycanadians.gc.ca)

I don't see anything wrong with the proposed approach above. It is factual, lines up with publicly available info and would show us as being responsive (getting back to them within a day). Only thing I find strange is this request given the timing of the recent ATI request on both Ivermectin and Hydroxychloroquine.

Any issues from your side Ranjeet to move ahead? I think this should def. be flagged to DGO as an FYI.

Cheers,

Toufic

Toufic Zayoun

(he | il)

Health Product Compliance and Enforcement Unit
Health Product Compliance Directorate
Regulatory Operations & Enforcement Branch
Health Canada / Government of Canada

toufic.zayoun@hc-sc.gc.ca / Tél: 613-301-3970

From: Chiu, Bobbie (HC/SC)
Sent: 2021-09-15 9:26 AM
To: Stankevitch, Tatiana (HC/SC)
Cc: Mariadevasan, Andrew (HC/SC)
Subject: FW: DIRECTOR Concurrence: CSF - Public
Enquiry - Central - Sep 14, 2021

Hi Tatiana and Andrew,

Please note we have received the green light to respond to the enquirer.

Please let me know the outcome of the contact.

Thanks,
Bobbie

From: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Sent: 2021-09-15 9:24 AM
To: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>
Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

Good morning

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Please send a brief summary up of the call once completed in light of the recent media attention .

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Salima

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Sent: 2021-09-14 4:48 PM
To: Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>; Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

Hi Ranjeet,

As Bobbie stated below, ivermectin can be prescribed for human use for below indication. If they mention COVID-19 we can use wording from our recent advisory.

I would still recommend a call back while sticking to standard lines as part of the script.

Cheers,

Toufic

From: Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>
Sent: 2021-09-14 4:45 PM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

According to the HC Advisory on Ivermectin:

"Ivermectin, a prescription drug product, is authorized for sale in Canada for the treatment of parasitic worm infections in humans, specifically intestinal strongyloidiasis and onchocerciasis, and should only be used for this purpose, under the supervision of a healthcare professional. A veterinary version of this medication is available to treat parasitic infections in animals. People should never use the veterinary version of this product."

For clarification, if the person would like to obtain for personal use, then it would require a prescription, therefore, the enquirer should be referred to contact the family physician or pharmacist for medical advice.

Our responses are fairly standard in terms of the regulatory requirements for commercial vs personal use.

Bobbie

From: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Sent: 2021-09-14 4:38 PM
To: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021
Importance: High

Hey Toufic,

I seem unclear as to the second bullet highlighted in red. Personal supply for what? Not sure why we would refer them to a family physician or pharmacist for Ivermectin since we know that it should be

used in humans right?

[REDACTED]

With that lens how do you think your approach will change? Anything else we should be considering here?

Salima – I think we can still give an early heads up to DGO on this and let them know we are formulating a factual response back to the enquirer.

Let me know,
R

Requester agreed to
Remove 3rd Party Info

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>

Sent: Tuesday, September 14, 2021 4:30 PM

To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>

Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>

Subject: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

Hi Ranjeet,

Central received a public enquiry in the form of a voice mail message in the afternoon of Sep 14, 2021.

The enquirer asked how an individual can acquire Ivermectin and Hydroxychloroquine. The enquirer did not mention COVID in the message [REDACTED]

Central proposes to contact the caller back on Sep 15, 2021 and use the approach (below) to respond:

- Ask enquirer whether the enquiry was about obtaining commercial supplies of the drugs for sale or distribution in Canada
 - Inform enquirer on licensing requirements of prescription drugs
- If enquirer was interested in obtaining personal supply
 - Refer the enquirer to consult with the family physician or pharmacist
- If the enquirer was interested in the two drug products as related to COVID-19:
 - Information in *Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems* and the link below can be shared
 - *Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems - Recalls and safety alerts* (healthy.canadians.gc.ca)

I don't see anything wrong with the proposed approach above. It is factual, lines up with publicly available info and would show us as being responsive (getting back to them within a day). Only thing I find strange is this request given the timing of the recent ATI request on both Ivermectin and Hydroxychloroquine.

Any issues from your side Ranjeet to move ahead? I think this should def. be flagged to DGO as an FYI.

Cheers,

Toufic



Toufic Zayoun

(he | il)

Health Product Compliance and Enforcement Unit
Health Product Compliance Directorate
Regulatory Operations & Enforcement Branch
Health Canada / Government of Canada

toufic.zayoun@hc-sc.gc.ca / Tél: 613-301-3970

From: Chiu, Bobbie (HC/SC)
Sent: 2021-09-15 8:14 AM
To: Stankevitch, Tatiana (HC/SC)
Cc: Mariadevasan, Andrew (HC/SC)
Subject: FW: DIRECTOR Concurrence: CSF - Public
Enquiry - Central - Sep 14, 2021

Importance: High

Hello,

For the enquiry below, please wait until we get the "green light" before contacting the enquirer.

Bobbie

----- Original message -----

From: "Massey, Ranjeet (HC/SC)" <ranjeet.massey@hc-sc.gc.ca>
Date: 2021-09-14 4:52 p.m. (GMT-05:00)
To: "Zayoun, Toufic (HC/SC)" <toufic.zayoun@hc-sc.gc.ca>, "Chiu, Bobbie (HC/SC)" <bobbie.chiu@hc-sc.gc.ca>
Cc: "Rajwani, Salima (HC/SC)" <salima.rajwani@hc-sc.gc.ca>, "Kearns-Justin, Dayna (HC/SC)" <dayna.kearns-justin@hc-sc.gc.ca>, "Bak, Celina (HC/SC)" <CELINA.BAK@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

I stand corrected ☺. Starts taking Ivermectin.

Salima – given this is Ivermectin and Hydroxychloroquin (two drugs known to be linked to COVID-19). Let's include the steps below identified by Central in a heads up to DGO. Let's confirm if they have any concerns given these are highly controversial products.

R

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Sent: Tuesday, September 14, 2021 4:48 PM
To: Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>; Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

Hi Ranjeet,

As Bobbie stated below, ivermectin can be prescribed for human use for below indication. If they mention COVID-19 we can use wording from our recent advisory.

I would still recommend a call back while sticking to standard lines as part of the script.

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Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021
Importance: High

Hey Toufic,

I seem unclear as to the second bullet highlighted in red. Personal supply for what? Not sure why we would refer them to a family physician or pharmacist for Ivermectin since we know that it should be used in humans right?

ATIA - 21(1)(a)

[REDACTED]

With that lens how do you think your approach will change? Anything else we should be considering here?

Salima – I think we can still give an early heads up to DGO on this and let them know we are formulating a factual response back to the enquirer.

Let me know,
R

Requester agreed to
Remove 3rd Party Info

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>

Sent: Tuesday, September 14, 2021 4:30 PM

To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>

Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>

Subject: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

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Central received a public enquiry in the form of a voice mail message in the afternoon of Sep 14, 2021.

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Central proposes to contact the caller back on Sep 15, 2021 and use the approach (below) to respond:

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Inform enquirer on licensing requirements of prescription drugs

If enquirer was interested in obtaining personal supply

Refer the enquirer to consult with the family physician or pharmacist

If the enquirer was interested in the two drug products as related to COVID-19:

Information in *Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems* and the link below can be shared

[Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems - Recalls and safety alerts \(healthycanadians.gc.ca\)](https://www.healthycanadians.gc.ca/ivermectin-not-authorized-to-prevent-or-treat-covid-19-may-cause-serious-health-problems-recalls-and-safety-alerts/healthycanadians.gc.ca)

I don't see anything wrong with the proposed approach above. It is factual, lines up with publicly available info and would show us as being responsive (getting back to them within a day). Only thing I find strange is this request given the timing of the recent ATI request on both Ivermectin and Hydroxychloroquine.

Any issues from your side Ranjeet to move ahead? I think this should def. be flagged to DGO as an FYI.

Cheers,

Toufic



Toufic Zayoun

(he | il)

Health Product Compliance and Enforcement Unit

Health Product Compliance Directorate

Regulatory Operations & Enforcement Branch

Health Canada / Government of Canada

toufic.zayoun@hc-sc.gc.ca / Tél: 613-301-3970

From: Bak, Celina (HC/SC)
Sent: 2021-09-29 5:40 PM
To: Massey, Ranjeet (HC/SC)
Subject: FW: DIRECTOR Concurrence: Update on
Ivermectin Signage in MB (September 23,
2021)

Fyi, what was sent to MHPD.

From: Bak, Celina (HC/SC)
Sent: 2021-09-29 5:14 PM
To: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: Update on Ivermectin Signage in MB (September 23, 2021)

Bonjour Alain,

With regards to the ivermectin sign issue, our standard process is that if a company provides written confirmation that a non-compliance has been addressed and there is no evidence to indicate otherwise we accept the company's confirmation. At this time we believe that the written confirmation provided by the company is sufficient. With that being said, we know there are sensitivities specific to COVID surrounding this file, therefore should there be new information or concern that the company is continuing non-compliant advertising, please do let us know and we will take action as deemed necessary.

For the NHP proactive monitoring options analysis we've had internal discussions and are working on finalizing the document which will hope to share with your group soon.

Thank you,
Celina

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Sent: 2021-09-23 3:39 PM
To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: Update on Ivermectin Signage in MB (September 23, 2021)

Bon retour Celina,

[REDACTED]! Thanks for the response, I
also have another item to discuss with you 2.

In terms of Ivermectin, I would like to clarify that MHPD did not confirm that the billboard has been removed. The company claimed that it was removed but we have no evidence

of that, that's why we are seeking ROEB's help to confirm. Our DG asked us to confirm with you that it has been removed. However, if it is ROEB's position that a follow up by you is not necessary, we'll brief up and close the case.

On another note, I presume you were briefed on an NHP advertising proactive monitoring initiative launched by MHPD. Further to a meeting at director level, it was suggested that HPCD would start drafting a document presenting 3 options for streamlining the handling of the advertising incidents detected, especially those involving unauthorized products. My team would then provide input and the 2 teams would work together to finalize it. To my knowledge, HPCD has not yet sent us this document. We were supposed to present the document to the 2 directors by the beginning of September 2021. Please look into this, although I am sure you are extremely busy catching up.

Thanks,

Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca
Tel: Cell: (613) 302-4856 / Office:: Cell: (613) 954-6780
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

From: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Sent: 2021-09-23 1:57 PM
To: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: FW: DIRECTOR Concurrence: Update on Ivermectin Signage in MB (September 23, 2021)

Bonjour Alain,

[REDACTED]
[REDACTED] Toufic and I are transitioning at the moment, but please feel free to reach out to me and Dayna for any issues needing HPCE's involvement from now on.

We have reviewed the information you provided and your request for an in person confirmation of the removal of the billboard.

Given that MHPD confirmed that the billboard has been removed and associated non-compliant advertising has been addressed, ROEB doesn't believe that an additional in person verification is necessary.

Of course, should there be new information or concern that the company is continuing non-compliant advertising, we trust that MHPD will inform us and we will take action as appropriate.

Have a great day!

Thank you,
Celina

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Sent: 2021-09-23 10:41 AM
To: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Subject: FW: Response received Re: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

Good morning Dayana,

I hope you are excellent and thank you for the discussion yesterday! Please see below, Magnetic Signs, the sponsor of the Ivermectin billboard in Wrinkler Manitoba, [REDACTED]

The MHPD would like to hereby ask that ROEB Manitoba verifies whether the billboard in Wrinkler Manitoba has indeed been removed.

Let me know whether you need further information.

Have a pleasant day!

Requester agreed to
Remove 3rd Party Info

Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca
Tel: Cell: (613) 302-4856 / Office:: Cell: (613) 954-6780
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

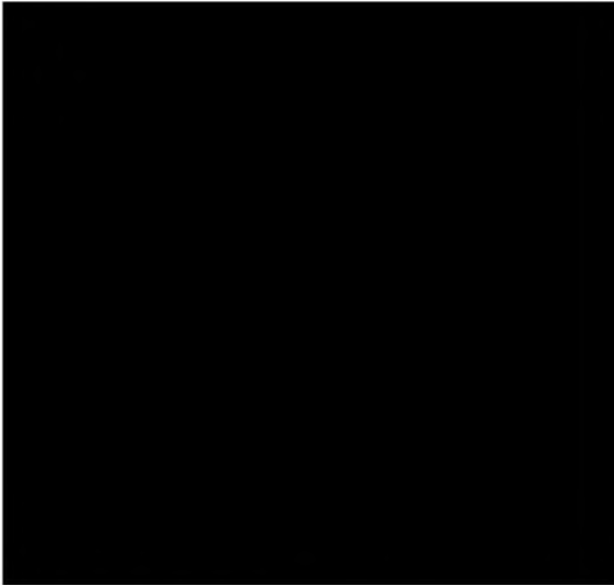
From: [REDACTED]
Sent: 2021-09-13 7:35 AM
To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>
Subject: RE: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

Good morning;

Magnetsigns Winkle [REDACTED]

Magnetsigns Winkler management is now fully aware of Health Canada's rules with regard to advertising and will conduct itself accordingly to ensure no more inadvertent advertising mistakes are

made.



From: IllegalMarketingIllegal (HC/SC) [<mailto:illegalmarketingillegal@hc-sc.gc.ca>]

Sent: September 12, 2021 1:33 PM

To [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

Dear [REDACTED]

Thank you very much for your prompt acknowledgement.

Could Magnetsigns confirm that it has ceased any advertising of Ivermectin in all media for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19?

Moreover, could Magnetsigns advise us by September 14, 2021, on the steps it has taken to cease the contravening advertising described in Health Canada's regulatory letter?

We look forward to hearing from you at your earliest opportunity.

Kindest regards,

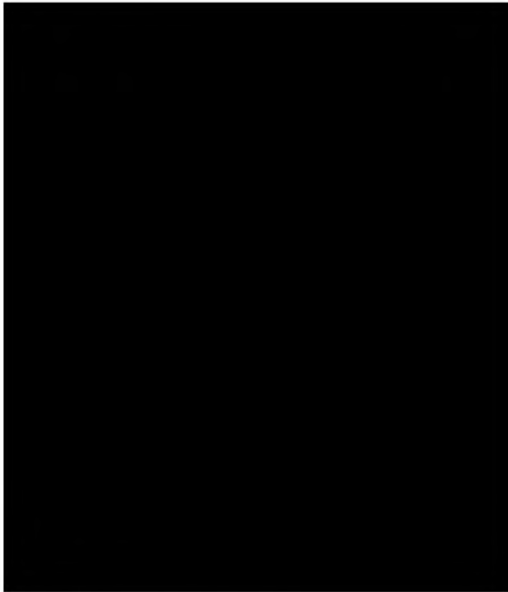
Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From [REDACTED]

Sent: 2021-09-08 3:48 PM

To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>
Cc: 'drug-device-marketing@hc-sc.gc.ca.'
Subject: RE: File# 3013457 Correspondence from the Marketed Health Products
Directorate_Magnetsigns

received



From: IllegalMarketingIllegal (HC/SC) [<mailto:illegalmarketingillegal@hc-sc.gc.ca>]
Sent: September 8, 2021 1:22 PM
To: [REDACTED]
Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457



Requester agreed to
Remove 3rd Party Info

Health Canada would like to resend you the attached regulatory letter pertaining to
"Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin"
on Magnetsigns signs in the Winkler, Manitoba area.

Upon calling [REDACTED] kindly informed us that the e-
mail address [REDACTED] listed on the [REDACTED] Web site
[REDACTED] has been updated

We request that you immediately acknowledge receipt of this correspondence by e-mail to
drug-device-marketing@hc-sc.gc.ca.

Sincerely,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance

Fax: 613-960-9754

Email: illegalmarketingillegal@hc-sc.gc.ca

From: IllegalMarketingIllegal (HC/SC)

Sent: 2021-08-31 2:55 PM

To: [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

To Whom It May Concern,

Please find attached a correspondence from the Marketed Health Products Directorate – File# 3013457 regarding “Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin.”

Health Canada requests that Magnetsigns immediately acknowledges receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Thank you,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From: Bak, Celina (HC/SC)
Sent: 2021-09-23 1:57 PM
To: Musende, Alain (HC/SC)
Cc: Kearns-Justin, Dayna (HC/SC)
Subject: FW: DIRECTOR Concurrence: Update on Ivermectin Signage in MB
(September 23, 2021)

Bonjour Alain,

[REDACTED]
[REDACTED] Toufic and I are transitioning at the moment, but please feel free to reach out to me and Dayna for any issues needing HPCE's involvement from now on.

We have reviewed the information you provided and your request for an in person confirmation of the removal of the billboard.

Given that MHPD confirmed that the billboard has been removed and associated non-compliant advertising has been addressed, ROEB doesn't believe that an additional in person verification is necessary.

Of course, should there be new information or concern that the company is continuing non-compliant advertising, we trust that MHPD will inform us and we will take action as appropriate.

Have a great day!

Thank you,
Celina

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[REDACTED]

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Requester agreed to
Remove 3rd Party Info

Let me know whether you need further information.

Have a pleasant day!

Alain G. Musende, PhD
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Marketed Health Products Directorate/
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Tel: Cell: (613) 302-4856 / Office:: Cell: (613) 954-6780
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

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Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From: [REDACTED]

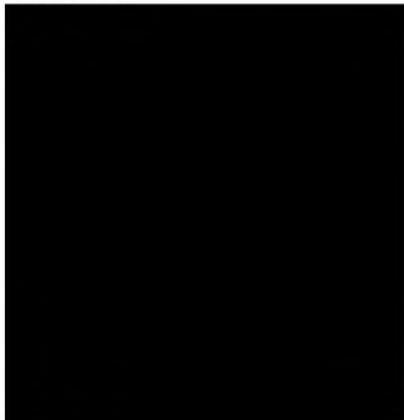
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To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>

Cc: 'drug-device-marketing@hc-sc.gc.ca.'

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received





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Sent: September 8, 2021 1:22 PM

To: 

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

Dear 

Health Canada would like to resend you the attached regulatory letter pertaining to "Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin" on Magnetsigns signs in the Winkler, Manitoba area.

Upon calling  kindly informed us that the e-mail address  Web site

 has been updated

We request that you immediately acknowledge receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Sincerely,

Requester agreed to
Remove 3rd Party Info

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: illegalmarketingillegal@hc-sc.gc.ca

From: IllegalMarketingIllegal (HC/SC)

Sent: 2021-08-31 2:55 PM

To: 

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

To Whom It May Concern,

Please find attached a correspondence from the Marketed Health Products Directorate – File# 3013457 regarding "Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin."

Health Canada requests that Magnetsigns immediately acknowledges receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Thank you,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From: Kearns-Justin, Dayna (HC/SC)
Sent: 2021-09-23 3:45 PM
To: Zayoun, Toufic (HC/SC)
Cc: Bak, Celina (HC/SC)
Subject: FW: DIRECTOR Concurrence: Update on Ivermectin Signage in MB
(September 23, 2021)

FYI Toufic – MHPD has indicated their DG asked for us to confirm the signs were removed. Just wanted to confirm approach hasn't changed.

Also Alain's second point on the NHP pilot, I believe the option analysis is still with DO, but can you confirm?

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Sent: 2021-09-23 3:39 PM
To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: Update on Ivermectin Signage in MB (September 23, 2021)

Bon retour Celina,

[REDACTED] Thanks for the response, I also have another item to discuss with you 2.

In terms of Ivermectin, I would like to clarify that MHPD did not confirm that the billboard has been removed. The company claimed that it was removed but we have no evidence of that, that's why we are seeking ROEB's help to confirm. Our DG asked us to confirm with you that it has been removed. However, if it is ROEB's position that a follow up by you is not necessary, we'll brief up and close the case.

On another note, I presume you were briefed on an NHP advertising proactive monitoring initiative launched by MHPD. Further to a meeting at director level, it was suggested that HPCD would start drafting a document presenting 3 options for streamlining the handling of the advertising incidents detected, especially those involving unauthorized products. My team would then provide input and the 2 teams would work together to finalize it. To my knowledge, HPCD has not yet sent us this document. We were supposed to present the document to the 2 directors by the beginning of September 2021. Please look into this, although I am sure you are extremely busy catching up.

Thanks,

Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés

Government of Canada | Gouvernement du Canada

alain.musende@canada.ca

Tel: Cell: (613) 302-4856 / Office:: Cell: (613) 954-6780

200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

From: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>

Sent: 2021-09-23 1:57 PM

To: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>

Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Subject: FW: DIRECTOR Concurrence: Update on Ivermectin Signage in MB (September 23, 2021)

Bonjour Alain,

[REDACTED]
Toufic and I are transitioning at the moment, but please feel free to reach out to me and Dayna for any issues needing HPCE's involvement from now on.

We have reviewed the information you provided and your request for an in person confirmation of the removal of the billboard.

Given that MHPD confirmed that the billboard has been removed and associated non-compliant advertising has been addressed, ROEB doesn't believe that an additional in person verification is necessary.

Of course, should there be new information or concern that the company is continuing non-compliant advertising, we trust that MHPD will inform us and we will take action as appropriate.

Have a great day!

Thank you,
Celina

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>

Sent: 2021-09-23 10:41 AM

To: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>

Subject: FW: Response received Re: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

Good morning Dayana,

I hope you are excellent and thank you for the discussion yesterday! Please see below, Magnetic Signs, the sponsor of the Ivermectin billboard in Wrinkler Manitoba, [REDACTED]
[REDACTED]

Requester agreed to
Remove 3rd Party Info

The MHPD would like to hereby ask that ROEB Manitoba verifies whether the billboard in Winkler Manitoba has indeed been removed.

Let me know whether you need further information.

Have a pleasant day!

Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca
Tel: Cell: (613) 302-4856 / Office:: Cell: (613) 954-6780
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

From: [REDACTED]
Sent: 2021-09-13 7:35 AM
To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>
Subject: RE: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

Good morning;

Magnetsigns Winkler [REDACTED]

Magnetsigns Winkler management is now fully aware of Health Canada's rules with regard to advertising and will conduct itself accordingly to ensure no more inadvertent advertising mistakes are made.

Requester agreed to
Remove 3rd Party Info

From: IllegalMarketingIllegal (HC/SC) [mailto:illegalmarketingillegal@hc-sc.gc.ca]

Sent: September 12, 2021 1:33 PM

To [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

Dear [REDACTED]

Thank you very much for your prompt acknowledgement.

Could Magnetsigns confirm that it has ceased any advertising of Ivermectin in all media for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19?

Moreover, could Magnetsigns advise us by September 14, 2021, on the steps it has taken to cease the contravening advertising described in Health Canada's regulatory letter?

We look forward to hearing from you at your earliest opportunity.

Kindest regards,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From [REDACTED]

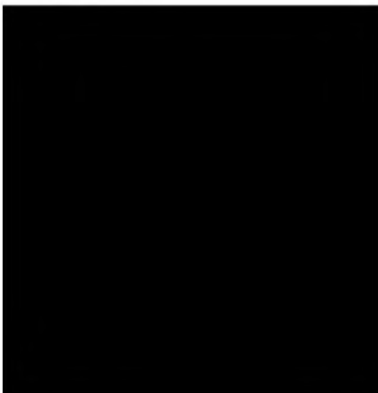
Sent: 2021-09-08 3:48 PM


To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>

Cc: 'drug-device-marketing@hc-sc.gc.ca.'

Subject: RE: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

received





From: IllegalMarketingIllegal (HC/SC) [mailto:illegalmarketingillegal@hc-sc.gc.ca]

Sent: September 8, 2021 1:22 PM

To: [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

Requester agreed to
Remove 3rd Party Info

Dear [REDACTED]

Health Canada would like to resend you the attached regulatory letter pertaining to "Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin" on Magnetsigns signs in the Winkler, Manitoba area.

Upon calling [REDACTED] kindly informed us that the e-mail address [REDACTED] listed on the [REDACTED] Web site [REDACTED] has been updated

We request that you immediately acknowledge receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Sincerely,

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Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: illegalmarketingillegal@hc-sc.gc.ca

From: IllegalMarketingIllegal (HC/SC)

Sent: 2021-08-31 2:55 PM

To: [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

To Whom It May Concern,

Please find attached a correspondence from the Marketed Health Products Directorate – File# 3013457 regarding "Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin."

Health Canada requests that Magnetsigns immediately acknowledges receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Thank you,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From: Kearns-Justin, Dayna (HC/SC)
Sent: 2021-09-28 3:15 PM
To: Bak, Celina (HC/SC)
Subject: FW: DIRECTOR Concurrence: Update on Ivermectin Signage in MB
(September 23, 2021)

Hey Celina,

As discussed, draft reply below:

Hi Alain,

With regards to the ivermectin sign issue, our standard process is that if a company provides written confirmation that a non-compliance has been addressed and there is no evidence to indicate otherwise we accept the company's confirmation. At this time we believe that the written confirmation provided by the company is sufficient. With that being said, we know there are sensitivities specific to COVID surrounding this file, therefore should there be new information or concern that the company is continuing non-compliant advertising, please do let us know and we will take action as deemed necessary.

For the NHP proactive monitoring options analysis we've had internal discussions and are working on finalizing the document which will hope to share with your group soon.

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Sent: 2021-09-23 3:39 PM
To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Roy, Christophe (HC/SC) <christophe.roy@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimirad@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: Update on Ivermectin Signage in MB (September 23, 2021)

Bon retour Celina,

[REDACTED] Thanks for the response, I also have another item to discuss with you 2.

In terms of Ivermectin, I would like to clarify that MHPD did not confirm that the billboard has been removed. The company claimed that it was removed but we have no evidence of that, that's why we are seeking ROEB's help to confirm. Our DG asked us to confirm with you that it has been removed. However, if it is ROEB's position that a follow up by you is not necessary, we'll brief up and close the case.

On another note, I presume you were briefed on an NHP advertising proactive monitoring initiative launched by MHPD. Further to a meeting at director level, it was suggested that HPCD would start drafting a document presenting 3 options for streamlining the handling of the advertising incidents detected, especially those involving unauthorized products. My team would then provide input and the 2 teams would work together to finalize it. To

my knowledge, HPCD has not yet sent us this document. We were supposed to present the document to the 2 directors by the beginning of September 2021. Please look into this, although I am sure you are extremely busy catching up.

Thanks,

Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca
Tel: Cell: (613) 302-4856 / Office:: Cell: (613) 954-6780
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

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Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: FW: DIRECTOR Concurrence: Update on Ivermectin Signage in MB (September 23, 2021)

Bonjour Alain,

[REDACTED]
[REDACTED] Toufic and I are transitioning at the moment, but please feel free to reach out to me and Dayna for any issues needing HPCE's involvement from now on.

We have reviewed the information you provided and your request for an in person confirmation of the removal of the billboard.

Given that MHPD confirmed that the billboard has been removed and associated non-compliant advertising has been addressed, ROEB doesn't believe that an additional in person verification is necessary.

Of course, should there be new information or concern that the company is continuing non-compliant advertising, we trust that MHPD will inform us and we will take action as appropriate.

Have a great day!

Thank you,
Celina

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To: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>

Subject: FW: Response received Re: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

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The MHPD would like to hereby ask that ROEB Manitoba verifies whether the billboard in Winkler Manitoba has indeed been removed.

Let me know whether you need further information.

Have a pleasant day!

Requester agreed to
Remove 3rd Party Info

Alain G. Musende, PhD
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Tel: Cell: (613) 302-4856 / Office:: Cell: (613) 954-6780
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

From: [REDACTED]

Sent: 2021-09-13 7:35 AM

To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>

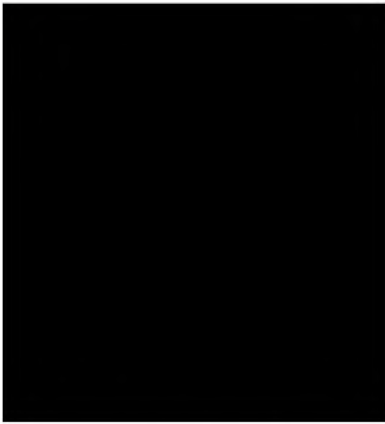
Subject: RE: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

Good morning;

Magnetsigns Winkler [REDACTED]

Magnetsigns Winkler management is now fully aware of Health Canada's rules with regard to advertising and will conduct itself accordingly to ensure no more inadvertent advertising mistakes are made.





From: IllegalMarketingIllegal (HC/SC) [mailto:illegalmarketingillegal@hc-sc.gc.ca]

Sent: September 12, 2021 1:33 PM

To: [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

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Moreover, could Magnetsigns advise us by September 14, 2021, on the steps it has taken to cease the contravening advertising described in Health Canada's regulatory letter?

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Kindest regards,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From: [REDACTED]

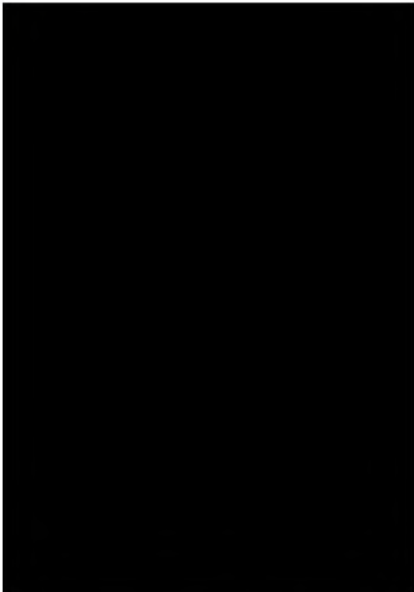
Sent: 2021-09-08 3:48 PM

To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>

Cc: 'drug-device-marketing@hc-sc.gc.ca.'

Subject: RE: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

received



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Sent: September 8, 2021 1:22 PM

To: [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

Dear [REDACTED]

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Upon calling [REDACTED] kindly informed us that the e-mail address [REDACTED] Web site [REDACTED] has been updated [REDACTED]

We request that you immediately acknowledge receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Sincerely,

Requester agreed to
Remove 3rd Party Info

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: illegalmarketingillegal@hc-sc.gc.ca

From: IllegalMarketingIllegal (HC/SC)

Sent: 2021-08-31 2:55 PM

To: [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

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Health Canada requests that Magnetsigns immediately acknowledges receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Thank you,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From: Bak, Celina (HC/SC)
Sent: 2021-09-22 12:25 PM
To: Lin, Mimi (HC/SC)
Cc: Kearns-Justin, Dayna (HC/SC)
Subject: FW: Due @ 1 today: For HPCD input: Media Query:
Winnipeg Free Press ([REDACTED]) Regulations of
agricultural ivermectin

Importance: High

Hi Mimi,

Anything we can provide quickly on this one?

Tahnks,
C

From: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Sent: 2021-09-22 11:58 AM
To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Subject: Due @ 1 today: For HPCD input: Media Query: Winnipeg Free Press ([REDACTED]) Regulations
of agricultural ivermectin
Importance: High

Hi Celina

Media request for response please. DGO has requested an extension but hasn't heard back yet, so (for now) a response is requested back by 1 pm today. I've added our previous response in red to Q2 below and also asked that MHPD be tasked for Q2.

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

At this time, Health Canada has not directly received complaints or reports of adverse events associated with the use of ivermectin-containing products in humans for COVID-19 purposes. (please confirm this is still accurate)

Thanks,
Salima

Salima Rajwani
salima.rajwani@hc-sc.gc.ca | Tel: 416-305-4041

From: St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>
Sent: 2021-09-22 10:47 AM
To: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Cc: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Subject: FW: For HPCD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Salima,

For your action. I have requested an extension to COB but that has not been confirmed. A response to DGO by 1pm would be appreciated, until informed otherwise.

Thank you,
Carole

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>
Sent: 2021-09-22 10:17 AM
To: HC.F RORB HPC Media F.SC <rorb_hpc_media@hc-sc.gc.ca>
Cc: HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Francis-Lamb, Laura (HC/SC) <laura.francis-lamb@hc-sc.gc.ca>
Subject: For HPCD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Good morning,

We have received a media query on agricultural ivermectin. Initially, this query was sent to CFIA but they confirmed that HC may have a role to play.

Can you take a look at the request below and advise whether your team can provide input?

If so, your input by 1 pm would be greatly appreciated.

Thank you,

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Tasked to:
Approved by:

Anne Génier

Senior Media Relations Advisor, Communication and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Conseillère principale des relations avec les médias, Direction générale des communications et des affaires publiques
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

- - -
Media | Média T: [613-957-2983](tel:613-957-2983), E/CE: media@hc-sc.gc.ca

From: Bak, Celina (HC/SC)
Sent: 2021-09-23 1:47 PM
To: Lin, Mimi (HC/SC)
Cc: Kearns-Justin, Dayna (HC/SC)
Subject: FW: Follow up : For HCPD, MHPD and VDD review:
 Media Query: Winnipeg Free Press [REDACTED]
 Regulations of agricultural ivermectin

Importance: High

Hi Mimi,

Can you share line a line about "HC's role re: C&E to ensure that regulated prodcuts are not being advertised or sold for indications that are not authorized".

Dayna, you can send straight to Toufic cc Salima if after 2:45.

Thanks,
 C

From: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Sent: 2021-09-23 1:17 PM
To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Subject: Follow up : For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press [REDACTED]
 Regulations of agricultural ivermectin
Importance: High

Hi Celina

ADMO has come back with comments on this media response. VDD addressed those pertaining to them. The 1st yellow highlighted comment in the 1st para is outstanding. I couldn't find any standard lines to address that one, could you add please. :

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

One of ~~The role of~~ Health Canada's roles, as the federal regulator, is the approval of veterinary drug products. [should also say something here about HC's role re: compliance and enforcement to ensure that regulated products are not being advertised or sold for indications that are not authorized] The Department helps ensure that all veterinary drugs fully satisfy requirements under the *Food and Drug Regulations* before they can be marketed in Canada. Restrictions associated with the sale of a product intended for use in livestock would be of provincial or territorial jurisdiction [please confirm accuracy: Isn't any drug subject to FDR and FDA requirements related to advertising and sale? I think we should provide more info here to clarify that HC doesn't have jurisdiction over how a product is ultimately used but we do regulate the sale and advertising of drugs and take action when a product is being

advertised or sold outside the terms of its market authorization]. Depending on the province or territory where the drugs are sold, there may be restrictions on who is permitted to purchase products intended for use in livestock. Health Canada does not have jurisdiction over how a product is ultimately used.

Following reports of the use of veterinary ivermectin drugs outside of approved directions for use (off-label use), Health Canada issued a public advisory to inform Canadians that Ivermectin is not authorized to prevent or treat COVID-19 and may pose serious health risks:

<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the sponsor of these ads removed them immediately, confirmed that these ads were no longer being disseminated and committed to refraining from engaging in this non-compliant act in the future. [I think we can expect the reporter to ask for more details regarding this case, including who the sponsor of the ad was. Is there any reason why we can't provide this info proactively? Will the case be published in the online list of advertising complaints? **MHPD to add the details they have**]

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred. Incidents of non-compliance are prioritised and action is taken based on the risk they may pose to the general public. It is the responsibility of companies to comply with regulatory requirements and to investigate incidents of potential non-compliance, and to take appropriate action to correct non-compliance, mitigate any risk to health, and inform Health Canada as appropriate.

To report marketing that is false or misleading or does not meeting regulatory requirements, visit <https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/illegal-marketing/complaint.html>.

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-

Thanks,
Salima

Salima Rajwani
salima.rajwani@hc-sc.gc.ca | Tel: 416-305-4041

From: Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>
Sent: 2021-09-23 12:34 PM

To: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
Cc: Davis, Meggan (HC/SC) <meggan.davis@hc-sc.gc.ca>; Mehrotra, Manisha (HC/SC) <manisha.mehrotra@hc-sc.gc.ca>; Burgess, Sean (HC/SC) <sean.burgess@hc-sc.gc.ca>; Legault-Thivierge, Geoffroy (HC/SC) <geoffroy.legault-thivierge@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; Tatone, Elise (HC/SC) <elise.tatone@hc-sc.gc.ca>; Geduld, Jennifer (HC/SC) <jennifer.geduld@hc-sc.gc.ca>; Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>; Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Pinard, Mike (HC/SC) <mike.pinard@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; HC.F RORB HPC Media F.SC <rorb_hpc_media@hc-sc.gc.ca>
Subject: RE: For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press [REDACTED]
 Regulations of agricultural ivermectin

Hi all,

VDD is proposing the following DG approved changes in blue to Q1. The other elements are outside of our domain.

Marilena

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

One of ~~The role of~~ Health Canada's roles, as the federal regulator, is the approval of veterinary drug products. [should also say something here about HC's role re: compliance and enforcement to ensure that regulated products are not being advertised or sold for indications that are not authorized] The Department helps ensure that all veterinary drugs fully satisfy requirements under the *Food and Drug Regulations* before they can be marketed in Canada. ~~Restrictions associated with the sale of a product intended for use in livestock would be of provincial or territorial jurisdiction~~ [please confirm accuracy. Isn't any drug subject to FDR and FDA requirements related to advertising and sale? I think we should provide more info here to clarify that HC doesn't have jurisdiction over how a product is ultimately used but we do regulate the sale and advertising of drugs and take action when a product is being advertised or sold outside the terms of its market authorization]. Depending on the province or territory where the drugs are sold, there may be restrictions on who is permitted to purchase products intended for use in livestock. ~~Health Canada does not have jurisdiction over how a product is ultimately used.~~

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Subject: For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press [REDACTED]
 Regulations of agricultural ivermectin

Carole / Rong / Marilena,

ROEB ADMO is proposing changes to the response and is asking a few things to be addressed (highlighted in yellow). Can you take a look at the response below?

Merci beaucoup!

Anne

From: Genier, Anne (HC/SC)
Sent: 2021-09-23 10:04 AM
To: St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>
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Subject: FYI - Input moving through approval this morning: Media Query: Winnipeg Free Press [REDACTED]
 [REDACTED] Regulations of agricultural ivermectin

Good morning,

For your awareness - since we have received input from VDD, MHPD and HPCD – I have collated all the responses and the response below will be circulating through your ADMs office later this morning.

Merci!

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

One of ~~The role of~~ Health Canada's roles, as the federal regulator, is the approval of veterinary drug products. [should also say something here about HC's role re: compliance and enforcement to ensure that regulated products are not being advertised or sold for indications that are not authorized] The Department helps ensure that all veterinary drugs fully satisfy requirements under the *Food and Drug Regulations* before they can be marketed in Canada. Restrictions associated with the sale of a product intended for use in livestock would be of provincial or territorial jurisdiction [please confirm accuracy. Isn't any drug subject to FDR and FDA requirements related to advertising and sale? I think we should provide more info here to clarify that HC doesn't have jurisdiction over how a product is ultimately used but we do regulate the sale and advertising of drugs and take action when a product is being advertised or sold outside the terms of its market authorization]. Depending on the province or territory where the drugs are sold, there may be restrictions on who is permitted to purchase products intended for use in livestock:

Following reports of the use of veterinary ivermectin drugs outside of approved directions for use (off-label use), Health Canada issued a public advisory to inform Canadians that Ivermectin is not authorized to prevent or treat COVID-19 and may pose serious health risks:

<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Health Canada became aware of advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the sponsor of these ads removed them immediately, confirmed that these ads were no longer being disseminated and committed to refraining from engaging in this non-compliant act in the future. [I think we can expect the reporter to ask for more details regarding this case, including who the sponsor of the ad was. Is there any reason why we can't provide this info proactively? Will the case be published in the online list of advertising complaints?]

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred. Incidents of non-compliance are prioritised and action is taken based on the risk they may pose to the general public. It

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Tasked to: HPCD, MHPD, VDD

Approved by:

Marilena Bassi, DG, VDD (approved)

Kelly Robinson, DG MHPD (approved Q2)

Linsey Hollet, DG HPCD (approved)

Eric Morrisette /Mark Johnson, Chief Media Relations (pending)

Julia Cropley, DG MCD (FYI)

Pam Aung-Thin, CPAB ADM (pending)

HPFB ADM (pending)

Stefania Trombetti, ROEB ADM (pending)

DMO (pending)

From: Kearns-Justin, Dayna (HC/SC)
Sent: 2021-09-23 2:44 PM
To: Rajwani, Salima (HC/SC)
Cc: Zayoun, Toufic (HC/SC); Bak, Celina (HC/SC)
Subject: FW: Follow up : For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Salima,

Please see addition in [REDACTED]

For Q1:

One of Health Canada's roles, as the federal regulator, is the approval of veterinary drug products. The Department helps ensure that all veterinary drugs fully satisfy requirements under the *Food and Drug Regulations* before they can be marketed in Canada and that the marketing of authorized veterinary drugs is consistent with its terms of market authorization and federal legislation. Depending on the province or territory where the drugs are sold, there may be restrictions on who is permitted to purchase products intended for use in livestock. Health Canada does not have jurisdiction over how a product is ultimately used.

Following reports of the use of veterinary ivermectin drugs outside of approved directions for use (off-label use), Health Canada issued a public advisory to inform Canadians that Ivermectin is not authorized to prevent or treat COVID-19 and may pose serious health risks:

<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>

Thanks,
Dayna

From: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Sent: 2021-09-23 1:17 PM
To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>
Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Subject: Follow up : For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press [REDACTED]
 Regulations of agricultural ivermectin
Importance: High

Hi Celina

ADMO has come back with comments on this media response. VDD addressed those pertaining to them. The 1st yellow highlighted comment in the 1st para is outstanding. I couldn't find any standard lines to address that one, could you add please. :

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

One of ~~The role of~~ Health Canada's roles, as the federal regulator, is the approval of veterinary drug products. [should also say something here about HC's role re: compliance and enforcement to ensure that regulated products are not being advertised or sold for indications that are not authorized] The Department helps ensure that all veterinary drugs fully satisfy requirements under the *Food and Drug Regulations* before they can be marketed in Canada. ~~Restrictions associated with the sale of a product intended for use in livestock would be of provincial or territorial jurisdiction~~ [please confirm accuracy: Isn't any drug subject to FDR and FDA requirements related to advertising and sale? I think we should provide more info here to clarify that HC doesn't have jurisdiction over how a product is ultimately used but we do regulate the sale and advertising of drugs and take action when a product is being advertised or sold outside the terms of its market authorization]. Depending on the province or territory where the drugs are sold, there may be restrictions on who is permitted to purchase products intended for use in livestock. ~~Health Canada does not have jurisdiction over how a product is ultimately used.~~

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Health Canada became aware of advertising of Ivermectin for the treatment of COVID-19 in Manitoba this past summer. Upon Health Canada's request, the sponsor of these ads removed them immediately, confirmed that these ads were no longer being disseminated and committed to refraining from engaging in this non-compliant act in the future. [I think we can expect the reporter to ask for more details regarding this case, including who the sponsor of the ad was. Is there any reason why we can't provide this info proactively? Will the case be published in the online list of advertising complaints? **MHPD to add the details they have**]

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred. Incidents of non-compliance are prioritised and action is taken based on the risk they may pose to the general public. It is the responsibility of companies to comply with regulatory requirements and to investigate incidents of potential non-compliance, ~~and to~~ take appropriate action to correct non-compliance, mitigate any risk to health, and inform Health Canada as appropriate.

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-

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Salima

Salima Rajwani
salima.rajwani@hc-sc.gc.ca | Tel: 416-305-4041

From: Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>
Sent: 2021-09-23 12:34 PM
To: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>
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Subject: RE: For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press [REDACTED]
 Regulations of agricultural ivermectin

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VDD is proposing the following DG approved changes in blue to Q1. The other elements are outside of our domain.

Marilena

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Subject: For HCPD, MHPD and VDD review: Media Query: Winnipeg Free Press [REDACTED]
Regulations of agricultural ivermectin

Carole / Rong / Marilena,

ROEB ADMO is proposing changes to the response and is asking a few things to be addressed (highlighted in yellow). Can you take a look at the response below?

Merci beaucoup!

Anne

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Sent: 2021-09-23 10:04 AM

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Subject: FYI - Input moving through approval this morning: Media Query: Winnipeg Free Press [REDACTED]
[REDACTED] Regulations of agricultural ivermectin

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Merci!

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

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Tasked to: HPCD, MHPD, VDD

Approved by:

Marilena Bassi, DG, VDD (approved)

Kelly Robinson, DG MHPD (approved Q2)

Linsey Hollet, DG HPCD (approved)

Eric Morrisette /Mark Johnson, Chief Media Relations (pending)

Julia Cropley, DG MCD (FYI)

Pam Aung-Thin, CPAB ADM (pending)

HPFB ADM (pending)

Stefania Trombetti, ROEB ADM (pending)

DMO (pending)

From: Bak, Celina (HC/SC)
Sent: 2021-09-22 1:45 PM
To: Elliott, Eian (HC/SC); Lin, Mimi (HC/SC); Kearns-Justin, Dayna (HC/SC)
Subject: FW: For director approval: Due @ 1 today: For HPCD input: Media Query: Winnipeg Free Press [REDACTED]
 [REDACTED] Regulations of agricultural ivermectin

Thanks guys! Forgot to cc you on what I sent up.

Thank you!

C

From: Bak, Celina (HC/SC)
Sent: 2021-09-22 1:44 PM
To: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: For director approval: Due @ 1 today: For HPCD input: Media Query: Winnipeg Free Press [REDACTED]
 [REDACTED] Regulations of agricultural ivermectin

Hi Toufic,

Some background preamble to provide you with context. Team effort on this one.

We understand is that Ivermectin veterinary drugs are OTC (according to DPD) and available as oral pastes, syrups, topicals and subcutaneous injectables. As far as we know, a consumer could buy them off the shelf without any oversight. VDD might be able to clarify this as the products may only be available through vet offices; some online sources say a prescription is required.

Two Ivermectin products are licensed for human use including a topical and a tablet, physician oversight would be required for these as they are listed as prescription drugs.

For Q1, we hope that VDD takes the lead as it seems to relate to the licensing/classification aspect of ivermectin for veterinary use.

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

A1. HPCD input:

While Health Canada oversees the regulation of drugs, it has no jurisdiction over how health care professionals prescribe drugs once they are approved nor how consumers choose to consume the drug outside of approved directions for use (off-label use).

While Health Canada does not regulate off-label use by consumers, following reports of the use of veterinary ivermectin drugs to prevent or treat COVID-19, Health Canada issued a public advisory to inform Canadians that Ivermectin is not authorized to prevent or treat COVID-19 and may pose serious health risks: <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

MHPD to provide answer.

Thanks,
Celina

From: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>

Sent: 2021-09-22 11:58 AM

To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>

Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>

Subject: Due @ 1 today: For HPCD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Importance: High

Hi Celina

Media request for response please. DGO has requested an extension but hasn't heard back yet, so (for now) a response is requested back by 1 pm today. I've added our previous response in red to Q2 below and also asked that MHPD be tasked for Q2.

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

At this time, Health Canada has not directly received complaints or reports of adverse events associated with the use of ivermectin-containing products in humans for COVID-19 purposes. (please confirm this is still accurate)

Thanks,
Salima

Salima Rajwani
salima.rajwani@hc-sc.gc.ca | Tel: 416-305-4041

From: St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>
Sent: 2021-09-22 10:47 AM
To: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Cc: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Subject: FW: For HPCD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Hi Salima,

For your action. I have requested an extension to COB but that has not been confirmed. A response to DGO by 1pm would be appreciated, until informed otherwise.

Thank you,
Carole

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>
Sent: 2021-09-22 10:17 AM
To: HC.F RORB HPC Media F.SC <rorb_hpc_media@hc-sc.gc.ca>
Cc: HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Francis-Lamb, Laura (HC/SC) <laura.francis-lamb@hc-sc.gc.ca>
Subject: For HPCD input: Media Query: Winnipeg Free Press [REDACTED] Regulations of agricultural ivermectin

Good morning,

We have received a media query on agricultural ivermectin. Initially, this query was sent to CFIA but they confirmed that HC may have a role to play.

Can you take a look at the request below and advise whether your team can provide input?

If so, your input by 1 pm would be greatly appreciated.

Thank you,

Anne

Media/Reporter: Winnipeg Free Press [REDACTED]

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. Does Health Canada have any power to make sure agricultural ivermectin isn't being sold for anything other than its intended use?

Q2. Is the agency aware of instances of Canadian sellers marketing and selling ivermectin as a treatment for COVID-19?

Tasked to:

Approved by:

Anne Génier

Senior Media Relations Advisor, Communication and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Conseillère principale des relations avec les médias, Direction générale des communications et des affaires publiques
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
anne.genier@hc-sc.gc.ca | Mobile: 613-327-1967

Media | Média T: [613-957-2983](tel:613-957-2983), E/CE: media@hc-sc.gc.ca

From: Kearns-Justin, Dayna (HC/SC)
Sent: 2021-08-25 5:12 PM
To: ctu / uct (HC/SC)
Subject: FW: For Director's Office Information- Update to Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED] - Ivermectin signage concern [REDACTED] - August 25, 2021

Importance: High

Hi CTU,

Can you please follow up with [REDACTED] regarding the complaint below (very bottom of email chain) to request additional information.

Specifically, can you please ask:

- Exact location of billboard sign
- Is the sign on public or private property
- Contact details for the rental company of the billboard sign
- Any information on who may have posted the sign

If you have any questions please let me know.

Thanks,
Dayna

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Sent: 2021-08-25 4:45 PM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Simard, Chris (HC/SC) <chris.simard@hc-sc.gc.ca>; Shelley, Dennis (HC/SC) <dennis.shelley@hc-sc.gc.ca>; Johnston, Craig (HC/SC) <craig.johnston@hc-sc.gc.ca>; Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Subject: For Director's Office Information- Update to Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED] - Ivermectin signage concern [REDACTED] - August 25, 2021

Hi Ranjeet,

I wanted to give you an update on this case.

Requester agreed to
Remove 3rd Party Info

Current Status:

- Referral from MHPD on August 23, 2021 [REDACTED] regarding the advertising of a health product (Ivermectin) to the public for the treatment of COVID-19 (schedule A disease). The billboard is posted on a rural highway in Manitoba and mentions [REDACTED] for more information, [REDACTED]
- Meeting on August 25, 2021 with MHPD, HPCEU and HPC-West to discuss the complaint. At this time there continue to many unknowns on the source of the billboard and any potential non-compliances. More information will be gathered ahead of finalising next steps.

Next Steps:

- CTU to contact [REDACTED] to gather additional details on the location of the billboard and contact details for the rental company of the billboard, for potential case creation. The contact will be initiated in the next day.

- HPCEU to flag to CPAB the potential of a PA (if needed) and to seek advice on communicating out during a caretaker government. To be initiated on August 25, 2021.

Please let me know if you have any questions and/or concerns.

Cheers,

Toufic

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Sent: 2021-08-24 2:31 PM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>; Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>
Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Johnston, Craig (HC/SC) <craig.johnston@hc-sc.gc.ca>
Subject: RE: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED]
[REDACTED] - Ivermectin signage concern [REDACTED] - August 24, 2021

Sounds good.

As mentioned on teams, we will link up to MHPD to see if they can lead on an external comms on Ivermectin (we can feed into it).

We will also link up to West to discuss potential best paths forward on validating the below info. The issue for us is that MHPD has not and will not take action [REDACTED] so it may be tough for an inspector to get traction on this case.

@ Dennis/Craig, copying you both to give you a heads up.

Cheers,

Toufic

Requester agreed to
Remove 3rd Party Info

From: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Sent: 2021-08-24 1:55 PM
To: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED]
[REDACTED] - Ivermectin signage concern [REDACTED] - August 24, 2021

Those are my thoughts as well.

From: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>
Sent: Tuesday, August 24, 2021 1:54 PM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED]
[REDACTED] - Ivermectin signage concern [REDACTED] - August 24, 2021

Thank you for this update.

What are the potential next steps – from what I see:

- Issue a PA

Requester agreed to
Remove 3rd Party Info

- Send a CV inspector to confirm who is doing the advertisement

Anything else?

From: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Sent: 2021-08-24 1:29 PM
To: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Cc: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED]
[REDACTED] - Ivermectin signage concern [REDACTED] - August 24, 2021

*****Mary** for your weigh-in/concurrence on this what I'm dubbing as a Caretaker Sensitivity File (CSF) and possible next steps***

Hey Toufic in response to your email below I've reorganize your update with some additional info for Mary as well as some proposed next steps for consideration below **including** Health Canada being proactive and issuing a Public Advisory on Ivermectin similar to that which the FDA has already done.

- Ivermectin, a drug meant for livestock, is being touted as a treatment/prevention for COVID-19. The US FDA has already warned about not using this drug and the issue is already being heavily covered by the media (ex: CNN , Global News) .
- With this context MHPD (STARS) sent the complaint below (and see attachment) which we agree constitutes advertising of a health product to the public for the treatment of a Schedule A disease.
- The billboard reads: "Ivermectin Treats COVID-19." [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- MHPD wants ROEB to dispatch a regional inspector to determine the advertiser, via the billboard rental company and request required corrective actions.

Given:

- Ivermectin, is an authorized product (MHPD scope)
- [REDACTED] lists physicians/pharmacies that will prescribe Ivermectin for COVID
- No evidence that billboard was posted [REDACTED]
- No information provided in picture of billboard rental company
- Obligation of billboard rental company to disclose rental information.
- If MHPD is not able to identify any non-compliances [REDACTED] perhaps no action recommended

Considerations however:

- May be able to provide educational materials to the billboard rental company to identify the false/misleading advertising so they can remove the billboard if they can't share the renters name (and share the compliance information with the renter).
- If this a privately owned billboard on public property have someone (not sure if HPCRM CV) to identify to the city manager for removal given it is a false/misleading claim.
- We will want to consider a Public Advisory similar to the FDA's to show that Health Canada is being proactive on these issues. (Perhaps post before having the billboard taken down).

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Sent: Tuesday, August 24, 2021 11:12 AM
To: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Cc: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>
Subject: For Director's Office Input: OPRAA for action due ASAP: [REDACTED]
- Ivermectin signage concern [REDACTED] - August 24, 2021

Hi Ranjeet,

I want to flag the below issue that was sent to us by MHPD (STARS). MHPD received the complaint below (and see attachment) and we believe it constitutes advertising of a health product to the public for the treatment of a Schedule A disease. Although [REDACTED] is mentioned for more information, [REDACTED]

MHPD wants ROEB to dispatch a regional inspector to determine the advertiser, via the billboard rental company and request required corrective actions.

I am unsure about assigning this one, given the following considerations:

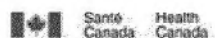
- Ivermectin, is an authorized product (MHPD scope)
- [REDACTED] lists physicians/pharmacies that will prescribe Ivermectin for COVID
- No evidence that billboard was posted [REDACTED]
- No information provided in picture of billboard rental company
- Obligation of billboard rental company to disclose rental information?
- If MHPD is not able to identify any non-compliances [REDACTED] then no action recommended

Anything else I am missing? Should we be looking at it from a different angle?

Let me know,

Toufic

Requester agreed to
Remove 3rd Party Info



Toufic Zayoun
(he | il)
A/Manager, Health Product Compliance and Enforcement Unit
Health Product Compliance Directorate
Regulatory Operations & Enforcement Branch
Health Canada / Government of Canada

toufic.zayoun@canada.ca / Tél: 613-301-3970

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Sent: 2021-08-23 4:09 PM
To: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Cc: Lejmi Mrad, Rim (HC/SC) <rim.lejmimirad@hc-sc.gc.ca>; Roy, Christophe (HC/SC)

<christophe.roy@hc-sc.gc.ca>; Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>
Subject: FW: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage
concern [REDACTED]

Hello Toufic, Dayna, and Mimi,

I hope you are all excellent! We received the complaint below (and see attachment) and we believe it
constitutes advertising of a health product to the public for the treatment of a Schedule A disease, in
contravention of the *FOOD & Drugs Act*. [REDACTED]

As such, we propose as a course action that the case be referred to ROEB for dispatching a regional
inspector to determine the advertiser, probably via the billboard rental company and request required
corrective actions.

Have a pleasant evening!

Requester agreed to
Remove 3rd Party Info

Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca
Tel: Office : (613) 954-6780 / Cell : (613) 302-4856
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

From: Morgan, Haylee (HC/SC) <haylee.morgan@hc-sc.gc.ca>
Sent: 2021-08-23 8:26 AM
To: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>; HC.F
MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage
concern [REDACTED]

LEAD BUREAU	OPRAA
RESPONSE TO BE SENT TO	MHPD Action Requests
MECS NUMBER	Nil
DUE IN DGO BY	ASAP
CONSULTATIONS	The "lead" bureau is responsible to include and incorporate all relevant information and approvals in the final response being submitted to DGO.
	Please indicate (via email or MECS) whom your bureau has consulted with: (i.e. other MHPD Bureaux, a Directorate, Legal Services, ROEB, SPB, etc.)

Please consult directly with other bureaus if necessary prior to submission to DGO

From: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>
Sent: 2021-08-23 7:52 AM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Cc: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>
Subject: FW: [REDACTED] - Ivermectin signage concern [REDACTED]

Hi Kelly

As this compliant involves what appears to be inappropriate advertising of an approved health product I am forwarding this onto for MHPD's assessment. I have cc'd Linsey Hollett as well.

If you are okay with it, I will respond back to [REDACTED] indicating receipt of the email and that I have forwarded it onto to MHPD for action.

Thanks.

Pat

Dr. J. Patrick Stewart, MD, CCFP(EM)
Director General/ Directeur général
Therapeutic Products Directorate/ Direction des produits thérapeutiques
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
613-859-2433 (cell)

From: [REDACTED]
Sent: 2021-08-20 6:44 PM
To: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>
Cc: prescription.drug.enquiries / renseignements.drogue.ordonnance (HC/SC) <prescription.drug.enquiries-renseignements.drogue.ordonnance@hc-sc.gc.ca> [REDACTED]
Subject: College of Pharmacists of Manitoba - Ivermectin signage concern (FLCCC.Net)

Dear Dr. Stewart,

I am writing to you [REDACTED] regarding a concern that had been brought to our attention recently involving the advertisement of the use of Ivermectin in treating Covid-19.

[REDACTED]

[REDACTED] has recently received notification from two rural pharmacists about a sign along a rural highway in Manitoba that reads "Ivermectin treats COVID-19 Info [REDACTED]". I have attached a picture for your review as well. These pharmacists have expressed great concern about this apparent misinformation, placed in a region with extremely poor/low vaccination uptake, combined with the potentially lower educational levels of some residents of the particular area.

In my initial review of the website, [REDACTED]

[REDACTED] The information was originally shared with the provincial College of Physicians and Surgeons of Manitoba (CPSM) for their review and considerations for further action. Unfortunately, none of the HCPs fall under the jurisdiction of the CPSM [REDACTED]

Requester agreed to
Remove 3rd Party Info

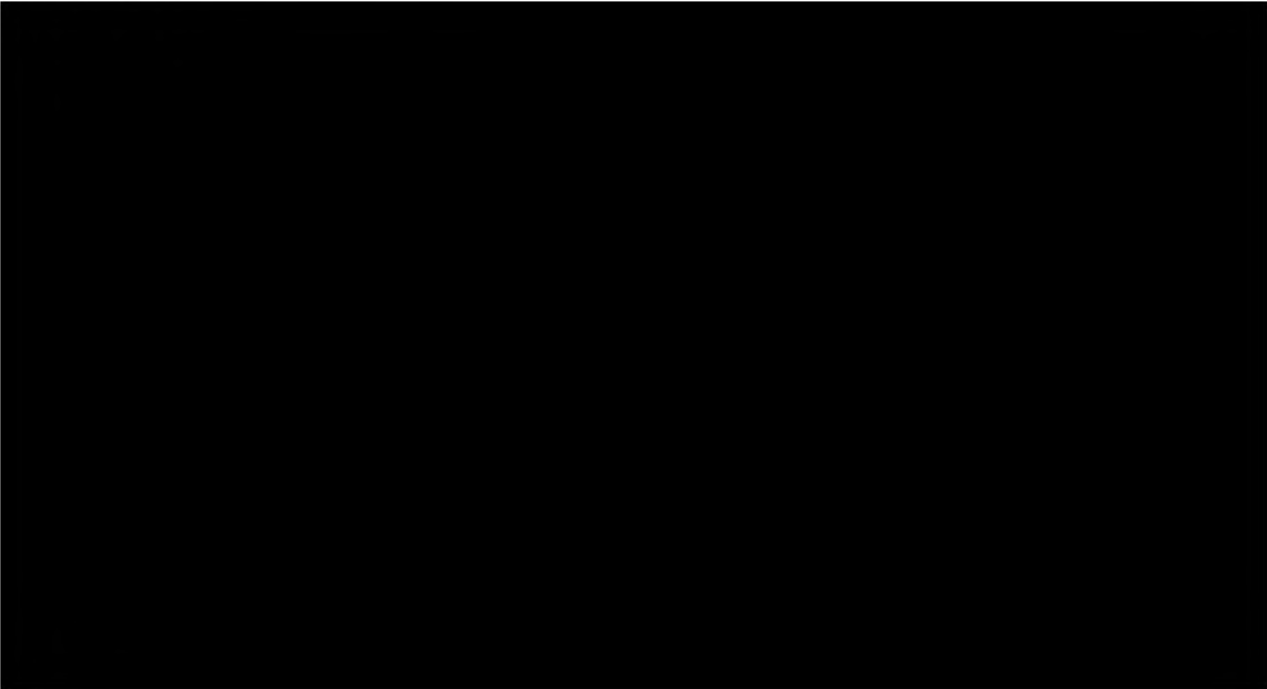
The TPD may already be aware of this inaccurate/non-compliant advertising, and I'm forwarding to you for your consideration on how best to address and manage. Perhaps the TPD may consider direct communication [REDACTED] to remove all non-compliant advertisements regarding Ivermectin use in Covid-19. Is there anything further that the TPD can do about this advertising considering this drug is not approved for use in Covid-19 in Canada?

For your reference, I have also brought this to the attention of our provincial Vaccine Implementation Task Force (VITF) Medical Team Leads for their consideration of addressing provincially as well.

[REDACTED] is very open to any direction you may wish to provide on this, and would be agreeable to any further discussions as well. Please feel welcome to contact me should you wish to discuss further and I will ensure arrangements are made.

I look forward to hearing from you.

Kind regards,



From: [Zayoun, Toufic \(HC/SC\)](#)
Sent: 2021-09-24 11:16 AM
To: [Bak, Celina \(HC/SC\)](#); [Kearns-Justin, Dayna \(HC/SC\)](#)
Subject: FW: Heads up: Ivermectin Signage Concern

From: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Sent: 2021-09-24 9:02 AM
To: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Cc: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>; Scarito, Rosalee (HC/SC) <rosalee.scarito@hc-sc.gc.ca>
Subject: RE: Heads up: Ivermectin Signage Concern

Thanks Salyma.

Ranjeet, maybe we can discuss at our bilat.

We will have to carefully consider standard practice/usual process with what would be expected of us given in this pandemic environment, the sensitivities around COVID treatments, etc.

Although I know it technically does not have to be an inspector who does a visual confirmation, I do think such an activity falls under the broad definition of cv.

L

From: Rajwani, Salima (HC/SC) <salima.rajwani@hc-sc.gc.ca>
Sent: 2021-09-23 5:47 PM
To: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Cc: Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; St-Amand, Carole (HC/SC) <carole.stamand@hc-sc.gc.ca>; Scarito, Rosalee (HC/SC) <rosalee.scarito@hc-sc.gc.ca>
Subject: Heads up: Ivermectin Signage Concern

Hi Linsey

Given Carole is away tomorrow, I'm sending you this heads up directly regarding the Ivermectin file, which MHPD is managing. Based on information shared by MHPD, it seems they may be bringing this to their DG (Kelly Robinson ?):

- Following MHPD's actions regarding non-compliant advertising of Ivermectin on billboards located in Manitoba and confirmation from the implicated company that the signs have been removed, MHPD requested that an HPCRM inspector drive to a location (i.e. Winkler, Manitoba) where a sign was seen, to verify that it has been removed
- **HPCRM recommendation:** A site visit by an HPCRM inspectors is not required:
 - The company has confirmed in writing that all signage has been removed. There is no indication that visual confirmation is required by an HPCRM inspector
 - There are no HPCRM inspectors located in the vicinity of the location of the sign of concern. The sign is located approximately 1.5 hrs away from an inspector
 - HPCRM does not have a case open for this company not has a case been referred
- **Note:** Inspector powers are not required to carry out a visual verification of a sign (i.e. MHPD staff could visually confirm this)
- **This decision was communicated to MHPD, and in response, they indicated potential DG involvement in requesting HPCRM to confirm the signs were removed**

Background information

- At the end of August of 2021, MHPD received a complaint [REDACTED] regarding a billboard located in Manitoba, advertising Ivermectin for treating COVID
- Although MHPD initially referred the case to HPCRM, they then withdrew their referral as they were able to obtain contact information for the advertiser/signage company
- MHPD contacted the sign company (Magnetsigns) and issued a letter informing them of the advertising violations, identifying 3 locations in Manitoba where the signs were seen
- The company responded and provided confirmation that the signs have been removed
- HC issued a Public Advisory to warn Canadians that Ivermectin is not authorized to prevent or treat COVID-19 (<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>)

The below email chain has additional information for context, if needed.
Please let me know if there are any questions.

Thanks,
Salima

Salima Rajwani
salima.rajwani@hc-sc.gc.ca | Tel: 416-305-4041

From: Jeyakanthan, Thivya (HC/SC)
Sent: 2021-08-30 11:26 AM
To: Scarito, Rosalee (HC/SC) <rosalee.scarito@hc-sc.gc.ca>
Cc: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Subject: FW: Heads Up: Ivermectin Signage Concern (Caretaker Sensitivity File)

Hi Rosalee,

Initial details of this case can be found below. Essentially MHPD made a referral to HPCRM regarding the inappropriate advertising of an approved health product that cures Covid-19 (Ivermectin) as the advertiser remained unknown. MHPD just informed us that they are now aware of who the advertiser/signage company is and will be reaching out to them with a regulatory letter to remove all non-compliant signage (as per their normal process).

HPCRM will continue to work on the PA, as noted during look ahead this morning.

Thanks
Thivya

From: Mahdi, Jonathan (HC/SC) <jonathan.mahdi@hc-sc.gc.ca>
Sent: 2021-08-25 8:14 AM
To: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>
Cc: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>; Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Subject: RE: Heads Up: Ivermectin Signage Concern (Caretaker Sensitivity File)

Thanks, Thivya – I've briefed Linsey. Will let you know if any additional information is required.

Best,
Jon

From: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>
Sent: 2021-08-24 3:43 PM
To: Mahdi, Jonathan (HC/SC) <jonathan.mahdi@hc-sc.gc.ca>
Cc: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>; Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>
Subject: Heads Up: Ivermectin Signage Concern (Caretaker Sensitivity File)

Hi Jon,

Flagging this file regarding the inappropriate advertising of an approved health product due to media attention. More details below:

- Referral from MHPD (STARS) that Ivermectin (an authorized drug meant for livestock) is being advertised as a treatment/prevention for COVID-19 on a billboard in Manitoba.
 - The billboard reads: "Ivermectin Treats COVID-19. [REDACTED]"
- The US FDA has already warned about not using this drug and the issue is already being heavily covered by the media (ex: CNN , Global News).
 - <https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>
- MHPD has not been able to establish that the billboard is associated with [REDACTED]
[REDACTED]
- MHPD is requesting ROEB to dispatch a regional inspector to determine the advertiser, via the billboard rental company and request required corrective actions.

Next Steps:

- HPCEU to determine advertiser and request removal of advertisement/determine pathway forward if advertiser cannot be identified.
- Consideration of a Public Advisory similar to the FDA's to demonstrate that Health Canada is being proactive on these issues.
 - MHPD to potentially take lead on external comms with HPCEU input.

Thanks,
Thivya

Requester agreed to
Remove 3rd Party Info

From: Zayoun, Toufic (HC/SC)
Sent: 2021-09-23 6:19 PM
To: Bak, Celina (HC/SC); Kearns-Justin, Dayna (HC/SC)
Subject: FW: Heads up: Ivermectin Signage Concern

Fyi

Sent from my Bell Samsung device over Canada's largest network.

----- Original message -----

From: "Rajwani, Salima (HC/SC)" <salima.rajwani@hc-sc.gc.ca>
Date: 2021-09-23 5:46 p.m. (GMT-05:00)
To: "Hollett, Linsey (HC/SC)" <linsey.hollett@hc-sc.gc.ca>
Cc: "Massey, Ranjeet (HC/SC)" <ranjeet.massey@hc-sc.gc.ca>, "Zayoun, Toufic (HC/SC)" <toufic.zayoun@hc-sc.gc.ca>, "St-Amand, Carole (HC/SC)" <carole.stamand@hc-sc.gc.ca>, "Scarito, Rosalee (HC/SC)" <rosalee.scarito@hc-sc.gc.ca>
Subject: Heads up: Ivermectin Signage Concern

Hi Linsey

Given Carole is away tomorrow, I'm sending you this heads up directly regarding the Ivermectin file, which MHPD is managing. Based on information shared by MHPD, it seems they may be bringing this to their DG (Kelly Robinson ?):

Following MHPD's actions regarding non-compliant advertising of Ivermectin on billboards located in Manitoba and confirmation from the implicated company that the signs have been removed, MHPD requested that an HPCRM inspector drive to a location (i.e. Winkler, Manitoba) where a sign was seen, to verify that it has been removed

HPCRM recommendation: A site visit by an HPCRM inspectors is not required:

The company has confirmed in writing that all signage has been removed. There is no indication that visual confirmation is required by an HPCRM inspector

There are no HPCRM inspectors located in the vicinity of the location of the sign of concern. The sign is located approximately 1.5 hrs away from an inspector

HPCRM does not have a case open for this company not has a case been referred

Note: Inspector powers are not required to carry out a visual verification of a sign (i.e. MHPD staff could visually confirm this)

This decision was communicated to MHPD, and in response, they indicated potential DG involvement in requesting HPCRM to confirm the signs were removed

Background information

- At the end of August of 2021, MHPD received a complaint [REDACTED] regarding a billboard located in Manitoba, advertising Ivermectin for treating COVID
- Although MHPD initially referred the case to HPCRM, they then withdrew their referral as they were able to obtain contact information for the advertiser/signage company
- MHPD contacted the sign company (Magnetsigns) and issued a letter informing them of the advertising violations, identifying 3 locations in Manitoba where the signs were seen
- The company responded and provided confirmation that the signs have been removed
- HC issued a Public Advisory to warn Canadians that Ivermectin is not authorized to prevent or treat COVID-19 (<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php>)

The below email chain has additional information for context, if needed. Please let me know if there are any questions.

Thanks,
Salima

Requester agreed to
Remove 3rd Party Info

Salima Rajwani
salima.rajwani@hc-sc.gc.ca | Tel: 416-305-4041

From: Jeyakanthan, Thivya (HC/SC)
Sent: 2021-08-30 11:26 AM
To: Scarito, Rosalee (HC/SC) <rosalee.scarito@hc-sc.gc.ca>
Cc: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Subject: FW: Heads Up: Ivermectin Signage Concern (Caretaker Sensitivity File)

Hi Rosalee,

Initial details of this case can be found below. Essentially MHPD made a referral to HPCRM regarding the inappropriate advertising of an approved health product that cures Covid-19 (Ivermectin) as the advertiser remained unknown. MHPD just informed us that they are now aware of who the advertiser/signage company is and will be reaching out to them with a regulatory letter to remove all non-compliant signage (as per their normal process).

HPCRM will continue to work on the PA, as noted during look ahead this morning.

Thanks
Thivya

From: Mahdi, Jonathan (HC/SC) <jonathan.mahdi@hc-sc.gc.ca>
Sent: 2021-08-25 8:14 AM
To: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>
Cc: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>; Massey, Ranjeet

(HC/SC) <ranjeet.massey@hc-sc.gc.ca>

Subject: RE: Heads Up: Ivermectin Signage Concern (Caretaker Sensitivity File)

Thanks, Thivya – I've briefed Linsey. Will let you know if any additional information is required.

Best,
Jon

From: Jeyakanthan, Thivya (HC/SC) <thivya.jeyakanthan@hc-sc.gc.ca>

Sent: 2021-08-24 3:43 PM

To: Mahdi, Jonathan (HC/SC) <jonathan.mahdi@hc-sc.gc.ca>

Cc: Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>; Massey, Ranjeet (HC/SC) <ranjeet.massey@hc-sc.gc.ca>

Subject: Heads Up: Ivermectin Signage Concern (Caretaker Sensitivity File)

Hi Jon,

Flagging this file regarding the inappropriate advertising of an approved health product due to media attention. More details below:

Referral from MHPD (STARS) that Ivermectin (an authorized drug meant for livestock) is being advertised as a treatment/prevention for COVID-19 on a billboard in Manitoba.

The billboard reads: "Ivermectin Treats COVID-19. [REDACTED]"

The US FDA has already warned about not using this drug and the issue is already being heavily covered by the media (ex: CNN , Global News).

<https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>

MHPD has not been able to establish that the billboard is associated with [REDACTED]

MHPD is requesting ROEB to dispatch a regional inspector to determine the advertiser, via the billboard rental company and request required corrective actions.

Next Steps:

HPCEU to determine advertiser and request removal of advertisement/determine pathway forward if advertiser cannot be identified.

Consideration of a Public Advisory similar to the FDA's to demonstrate that Health Canada is being proactive on these issues.

MHPD to potentially take lead on external comms with HPCEU input.

Thanks,

Requester agreed to
Remove 3rd Party Info

Thivya

From: [Zayoun, Toufic \(HC/SC\)](#)
Sent: 2021-08-30 9:57 AM
To: [Kearns-Justin, Dayna \(HC/SC\)](#); [Lin, Mimi \(HC/SC\)](#)
Subject: FW: Ivermectin PA

See below.

From: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Sent: 2021-08-30 9:56 AM
To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Cc: Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Morgan, Mary (HC/SC) <mary.morgan@hc-sc.gc.ca>
Subject: RE: Ivermectin PA

Morning Aldege.

I think HPCEU (Mimi and Dayna) have already connected with your team but copying Toufic who can confirm.

Linsey

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Sent: 2021-08-30 9:29 AM
To: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Cc: Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>
Subject: Ivermectin PA

Hello Linsey: I will be handling the ivermectin PA. Who should I liaise with on the PA? Thanks!

From: Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>
Sent: 2021-08-30 9:21 AM
To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Keeping, Elizabeth (HC/SC) <elizabeth.keeping@hc-sc.gc.ca>; Aboueid, Suzane (HC/SC) <suzane.aboueid@hc-sc.gc.ca>
Subject: FW: Clippings

Hi,

We need a risk comms on people trying to purchase veterinary ivermectin to treat COVID. Wondering if any of you would be interested in leading on this.

Thanks

From: Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>
Sent: 2021-08-30 9:07 AM

To: Nahum, Marilyn (HC/SC) <marilyn.nahum@hc-sc.gc.ca>
Subject: FW: Clippings

Hi there,
Looks like ROEB wants an urgent PA....

From: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>
Sent: 2021-08-30 9:01 AM
To: Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>; Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>; Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Cc: Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>
Subject: RE: Clippings

Yes, I agree Stefania. I am copying Cathy Lafkas as well.

From: Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Sent: 2021-08-30 8:54 AM
To: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>; Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>; Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>; Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Cc: Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>
Subject: RE: Clippings

I think a risk comms on this is in order and have asked Linsey for advice.

Pam – from a comms standpoint, I gather you would agree?

S

From: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>
Sent: 2021-08-30 8:46 AM
To: Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>; Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Cc: Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>
Subject: RE: Clippings

Thanks Eric, I missed that one! I am copying Manon, Linsey and Stefania as there may be post market follow up that is in train.

Pam

From: Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>
Sent: 2021-08-30 8:42 AM

To: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>
Cc: Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>
Subject: Clippings

Hi Pam:

Just wanted to make sure you had seen this one:

<https://www.cbc.ca/news/canada/calgary/ivermectin-alberta-covid-1.6157200>

Eric Bélair

Associate Assistant Deputy Minister / Sous-ministre adjoint délégué
Strategic Policy Branch / Direction générale de la politique stratégique
Health Canada / Santé Canada
343-552-1733
eric.belair@hc-sc.gc.ca

From: [Trombetti, Stefania \(HC/SC\)](#)
Sent: 2021-09-03 5:40 PM
To: [Hollett, Linsey \(HC/SC\)](#)
Cc: [Dodson, Heather \(HC/SC\)](#); [LeBrun, Matt \(HC/SC\)](#)
Subject: FW: Ivermectin update
Attachments: Letter to vets - ivermectinv_CVMA-HC consolidated.docx

Sharing fyi.

From: Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>
Sent: 2021-09-03 5:36 PM
To: Kochhar, Harpreet (HC/SC) <harpreet.kochhar@canada.ca>
Cc: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>; Murseli, Lissa (HC/SC) <lissa.murseli@hc-sc.gc.ca>
Subject: FW: Ivermectin update

Harpreet, since my note of yesterday evening, there have been some developments on this file. A summary is provided below. I added Stefania to this distribution list given ROEB's involvement.

Updates:

- CFIA and VDD met with the CCVO today. Most members advised that they already shared HC's PA with their networks which includes vets, retail, and Ministries of Health. The PA has also been posted in some outlets and the content has been used extensively by P/Ts in their own communications.
- As of September 2, there have been 10,000 pageviews of the PA and the tweet has been retweeted 1100 times and has almost 1600 Likes indicating that the message is being seen and shared.
- CFIA confirmed they have retweeted HC's message.

Next steps:

Week of Sept 6, CVMA will be sending a letter (see attached - authored by HC) to their members regarding the risks of ivermectin use, and include information about the PA in their e-newsletter.

- Week of Sept 6, the CCVOs will share with CFIA/VDD their communications materials and will seek HC's input as needed.

In response to Ivermectin being advertised as a treatment/prevention for COVID-19 on a [billboard](#) in Manitoba, ROEB is working with HPFB to send a regulatory letter to the advertiser to direct that all non-compliant signage be removed. Additional action will be taken should the advertiser not comply.

CPAB is continuing to work on a robust social media plan on this issue.

- CPAB is engaging with the FPT Public Health Network Comms Working Group to possibly put this item on their next weekly meeting (Wednesday September 8th) for additional P/T engagement and amplifying of messages.

MHPD is continuing to monitor this issue, including scanning literature, requesting data from Canadian Poison Control Centres and monitoring the Canada Vigilance database, to inform additional measures as required.

Any questions, please let us know. Thanks

Manon Bombardier

A/Associate Assistant Deputy Minister | Sous ministre adjointe déléguée par intérim
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada

From: Bombardier, Manon (HC/SC)

Sent: 2021-09-02 11:13 PM

To: Kochhar, Harpreet (HC/SC) <harpreet.kochhar@canada.ca>

Cc: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@canada.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>; Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>; Murseli, Lissa (HC/SC) <lissa.murseli@hc-sc.gc.ca>

Subject: Ivermectin update

Bonsoir Harpreet, here is a summary of the outreach undertaken since the release of the public advisory on Ivermectin, and proposed next steps to further amplify our message.

Actions to date:

- Upon release of the PA on Aug 31, a targeted email was sent to key vet health professional organizations/partners to make them aware and solicit their assistance in maximizing the outreach on this issue.
The list of recipients included several producer associations, the chief vet officers across the country, the PT registrars, the CVMA, NAPRA, and 2 main industry associations.
- The PA was also distributed via our medeffect list serve - which goes out to over 29,000 subscribers. It was picked up by Ottawa Public Health - <https://mobile.twitter.com/OttawaHealth/status/1432854427652743168>
- CFIA was also informed and asked to distribute the PA to their stakeholders.
- Meeting was held today between CPAB and HFPB to discuss additional outreach measures that could be taken.

Next steps:

Further tailored outreach is being considered, including to Livestock Medicine Outlets and those most likely to be buying ivermectin.

CPAB is developing social media messages on this issue.

In collaboration with CFIA, engage P/Ts to explore on measures that they could take to manage the sale of veterinary ivermectin. A meeting with the Council of Chief Veterinary Officers (CCVO) is scheduled for tomorrow.

CFIA is exploring options to amplify HC's message with their stakeholders.

VDD will connect with CVMA tomorrow regarding a letter (authored by HC) to send to CVMA members regarding the risks of ivermectin use.

- MHPD will reach out to poison control centres to see if they have received any reports related to use of ivermectin to treat or prevent COVID-19. This will help inform additional measures, as required.

Please let me know if you have any questions or wish to discuss. Thanks.

Manon Bombardier

A/Associate Assistant Deputy Minister | Sous ministre adjointe déléguée par intérim

Health Products and Food Branch | Direction générale des produits de santé et des aliments

Health Canada | Santé Canada

From: Musende, Alain (HC/SC)
Sent: 2021-08-23 4:09 PM
To: Zayoun, Toufic (HC/SC); Kearns-Justin, Dayna (HC/SC); Lin, Mimi (HC/SC)
Cc: Lejmi Mrad, Rim (HC/SC); Roy, Christophe (HC/SC); Schmidt, Stephanie (HC/SC)
Subject: FW: OPRAA for action due [REDACTED] - Ivermectin
signage concern [REDACTED]
Attachments: [REDACTED]

Follow Up Flag: Follow up
Flag Status: Flagged

Requester agreed to
Remove 3rd Party Info

Hello Toufic, Dayna, and Mimi,

I hope you are all excellent! We received the complaint below (and see attachment) and we believe it constitutes advertising of a health product to the public for the treatment of a Schedule A disease, in contravention of the *FOOD & Drugs Act*. [REDACTED]

As such, we propose as a course of action that the case be referred to ROEB for dispatching a regional inspector to determine the advertiser, probably via the billboard rental company and request required corrective actions.

Have a pleasant evening!

Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca
Tel: Office : (613) 954-6780 / Cell : (613) 302-4856
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

From: Morgan, Haylee (HC/SC) <haylee.morgan@hc-sc.gc.ca>
Sent: 2021-08-23 8:26 AM
To: HC.F MHPD OPRAA Assistants F.SC <hc.mhpd.opraa.assistants.sc@hc-sc.gc.ca>
Cc: HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>
Subject: OPRAA for action due ASAP: [REDACTED] - Ivermectin signage concern [REDACTED]

LEAD BUREAU	OPRAA
RESPONSE TO BE SENT TO	MHPD Action Requests
MECS NUMBER	Nil
DUE IN DGO BY	ASAP

CONSULTATIONS	The "lead" bureau is responsible to include and incorporate all relevant information and approvals in the final response being submitted to DGO.
	Please indicate (via email or MECS) whom your bureau has consulted with: (i.e. other MHPD Bureaux, a Directorate, Legal Services, ROEB, SPB, etc.)

Please consult directly with other bureaus if necessary prior to submission to DGO

From: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>
Sent: 2021-08-23 7:52 AM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Cc: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>
Subject: FW: [REDACTED] - Ivermectin signage concern [REDACTED]

Hi Kelly

As this compliant involves what appears to be inappropriate advertising of an approved health product I am forwarding this onto for MHPD's assessment. I have cc'd Linsey Hollet as well.

If you are okay with it, I will respond back to [REDACTED] indicating receipt of the email and that I have forwarded it onto to MHPD for action.

Thanks.

Pat

Requester agreed to
Remove 3rd Party Info

Dr. J. Patrick Stewart, MD, CCFP(EM)
 Director General/ Directeur général
 Therapeutic Products Directorate/ Direction des produits thérapeutiques
 Health Products and Food Branch / Direction générale des produits de santé et des aliments
 Health Canada / Santé Canada
 613-859-2433 (cell)

From: [REDACTED]
Sent: 2021-08-20 6:44 PM
To: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>
Cc: prescription.drug.enquiries / renseignements.drogue.ordonnance (HC/SC) <prescription.drug.enquiries-renseignements.drogue.ordonnance@hc-sc.gc.ca>; [REDACTED]
Subject: [REDACTED] - Ivermectin signage concern [REDACTED]

Dear Dr. Stewart,

I am writing to you on behalf of [REDACTED] regarding a concern that had been brought to our attention recently involving the advertisement of the use of Ivermectin in treating Covid-19.

For background, [REDACTED]

[REDACTED] has recently received notification from two rural pharmacists about a sign along a rural highway in Manitoba that reads "Ivermectin treats COVID-19". I have attached a picture for your review as well. These pharmacists have expressed great concern about this apparent misinformation, placed in a region with extremely poor/low vaccination uptake, combined with the potentially lower educational levels of some residents of the particular area.

[REDACTED]. The information was originally shared with the provincial College of Physicians and Surgeons of Manitoba (CPSM) for their review and considerations for further action. Unfortunately, none of the HCPs fall under the jurisdiction of the CPSM [REDACTED]

The TPD may already be aware of this inaccurate/non-compliant advertising, and I'm forwarding to you for your consideration on how best to address and manage. Perhaps the TPD may consider direct communication to [REDACTED] to remove all non-compliant advertisements regarding Ivermectin use in Covid-19. Is there anything further that the TPD can do about this advertising considering this drug is not approved for use in Covid-19 in Canada?

For your reference, I have also brought this to the attention of our provincial Vaccine Implementation Task Force (VITF) Medical Team Leads for their consideration of addressing provincially as well.

[REDACTED] is very open to any direction you may wish to provide on this, and would be agreeable to any further discussions as well. Please feel welcome to contact me should you wish to discuss further and I will ensure arrangements are made.

I look forward to hearing from you.

Kind regards,

Requester agreed to
Remove 3rd Party Info

From: Musende, Alain (HC/SC)
Sent: 2021-09-23 10:41 AM
To: Kearns-Justin, Dayna (HC/SC)
Cc: Zayoun, Toufic (HC/SC)
Subject: FW: Response received Re: File# 3013457 Correspondence from the
Marketed Health Products Directorate_Magnetsigns

Good morning Dayana,

I hope you are excellent and thank you for the discussion yesterday! Please see below,
Magnetic Signs, the sponsor of the Ivermectin billboard in Wrinkler Manitoba [REDACTED]

The MHPD would like to hereby ask that ROEB Manitoba verifies whether the billboard in
Wrinkler Manitoba has indeed been removed.

Let me know whether you need further information.

Have a pleasant day!

Requester agreed to
Remove 3rd Party Info

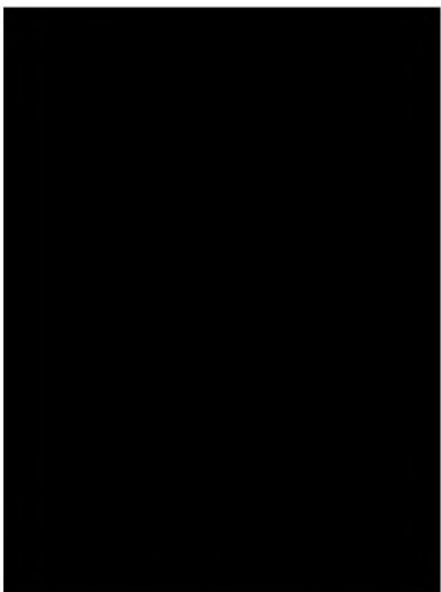
Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca
Tel: Cell: (613) 302-4856 / Office:: Cell: (613) 954-6780
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

From: [REDACTED]
Sent: 2021-09-13 7:35 AM
To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>
Subject: RE: File# 3013457 Correspondence from the Marketed Health Products
Directorate_Magnetsigns

Good morning;

Magnetsigns Winkler [REDACTED]

Magnetsigns Winkler management is now fully aware of Health Canada's rules with regard to
advertising and will conduct itself accordingly to ensure no more inadvertent advertising mistakes are
made.



From: IllegalMarketingIllegal (HC/SC) [mailto:illegalmarketingillegal@hc-sc.gc.ca]

Sent: September 12, 2021 1:33 PM

To: [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

Dear [REDACTED]

Thank you very much for your prompt acknowledgement.

Could Magnetsigns confirm that it has ceased any advertising of Ivermectin in all media for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19?

Moreover, could Magnetsigns advise us by September 14, 2021, on the steps it has taken to cease the contravening advertising described in Health Canada's regulatory letter?

We look forward to hearing from you at your earliest opportunity.

Kindest regards,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From: [REDACTED]

Sent: 2021-09-08 3:48 PM

To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>

Cc: 'drug-device-marketing@hc-sc.gc.ca.'

Subject: RE: File# 3013457 Correspondence from the Marketed Health Products
Directorate_Magnetsigns

received

Requester agreed to
Remove 3rd Party Info

From: IllegalMarketingIllegal (HC/SC) [<mailto:illegalmarketingillegal@hc-sc.gc.ca>]

Sent: September 8, 2021 1:22 PM

To [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

Dear [REDACTED]

Health Canada would like to resend you the attached regulatory letter pertaining to "Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin" on Magnetsigns signs in the Winkler, Manitoba area.

Upon calling [REDACTED] today [REDACTED]
[REDACTED] Magnetsigns Web site
[REDACTED] has been updated

We request that you immediately acknowledge receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Sincerely,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: illegalmarketingillegal@hc-sc.gc.ca

From: IllegalMarketingIllegal (HC/SC)

Sent: 2021-08-31 2:55 PM

To: [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate_Magnetsigns

File# 3013457

To Whom It May Concern,

Please find attached a correspondence from the Marketed Health Products Directorate – File# 3013457 regarding "Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin."

Health Canada requests that Magnetsigns immediately acknowledges receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Thank you,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From: Kearns-Justin, Dayna (HC/SC)
Sent: 2021-09-23 10:53 AM
To: Bak, Celina (HC/SC)
Cc: Zayoun, Toufic (HC/SC)
Subject: FW: Response received Re: File# 3013457 Correspondence from the
Marketed Health Products Directorate_Magnetsigns
Attachments: RE: Heads Up: Ivermectin Signage Concern (Caretaker Sensitivity File)

Hi Celina,

Received the email below from Alain (MHPD STARS) regarding a complaint [REDACTED]
[REDACTED] they received for billboards advertising Ivermectin treating COVID in
Manitoba. MHPD contacted the sign company and have received confirmation that the signs have
been removed, however, MHPD is now requesting that ROEB drive to the location of where the sign
was posted to confirm it has indeed been removed.

Based on the company's confirmation, I'm not sure it is necessary to send an inspector out to confirm,
however, I understand there are some sensitivities regarding this product. I did speak with Ian and he
said they could drive out to the location if required, however, we wanted to check in with
management on the expectation of ROEB confirming compliance that was requested by MHPD.

I've also attached a previous thread that was briefed up for additional context.

Please let me know if you'd like to discuss.

Thanks,
Dayna

Requester agreed to
Remove 3rd Party Info

From: Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Sent: 2021-09-23 10:41 AM
To: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Cc: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Subject: FW: Response received Re: File# 3013457 Correspondence from the Marketed Health
Products Directorate_Magnetsigns

Good morning Dayana,

I hope you are excellent and thank you for the discussion yesterday! Please see below,
Magnetic Signs, the sponsor of the Ivermectin billboard in Wrinkler Manitoba, [REDACTED]
[REDACTED]

The MHPD would like to hereby ask that ROEB Manitoba verifies whether the billboard in
Wrinkler Manitoba has indeed been removed.

Let me know whether you need further information.

Have a pleasant day!

Alain G. Musende, PhD
Manager, Section for Transparency and Advertising Regulatory Surveillance/
Section de la surveillance réglementaire en matière de transparence et publicité
Marketed Health Products Directorate/
Direction des produits de santé commercialisés
Government of Canada | Gouvernement du Canada
alain.musende@canada.ca
Tel: Cell: (613) 302-4856 / Office:: Cell: (613) 954-6780
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario, A.L. 1906D
Ottawa, Canada K1A 0K9

From: [REDACTED]
Sent: 2021-09-13 7:35 AM
To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>
Subject: RE: File# 3013457 Correspondence from the Marketed Health Products Directorate [REDACTED]

Good morning;

[REDACTED] has absolutely no messaging whatsoever with regard to Ivermectin.

[REDACTED] management is now fully aware of Health Canada's rules with regard to advertising and will conduct itself accordingly to ensure no more inadvertent advertising mistakes are made.

Requester agreed to
Remove 3rd Party Info

From: IllegalMarketingIllegal (HC/SC) [<mailto:illegalmarketingillegal@hc-sc.gc.ca>]
Sent: September 12, 2021 1:33 PM
To: [REDACTED]
Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate [REDACTED]

File# 3013457

Dear [REDACTED]

Thank you very much for your prompt acknowledgement.

Could [REDACTED] confirm that it has ceased any advertising of Ivermectin in all media for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19?

Moreover, could [REDACTED] advise us by September 14, 2021, on the steps it has taken to cease the contravening advertising described in Health Canada's regulatory letter?

We look forward to hearing from you at your earliest opportunity.

Kindest regards,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca

From: [REDACTED]
Sent: 2021-09-08 3:48 PM
To: IllegalMarketingIllegal (HC/SC) <illegalmarketingillegal@hc-sc.gc.ca>
Cc: 'drug-device-marketing@hc-sc.gc.ca.'
Subject: RE: File# 3013457 Correspondence from the Marketed Health Products Directorate [REDACTED]

received

Requester agreed to
Remove 3rd Party Info

From: IllegalMarketingIllegal (HC/SC) [mailto:illegalmarketingillegal@hc-sc.gc.ca]

Sent: September 8, 2021 1:22 PM

To: [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate [REDACTED]

File# 3013457

Dear [REDACTED]

Health Canada would like to resend you the attached regulatory letter pertaining to "Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin" or [REDACTED] signs in the Winkler, Manitoba area.

Upon calling [REDACTED] today, [REDACTED] kindly informed us that the e-mail address [REDACTED] listed on the Magnetsigns Web site [REDACTED] has been updated

We request that you immediately acknowledge receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Sincerely,

Requester agreed to
Remove 3rd Party Info

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: illegalmarketingillegal@hc-sc.gc.ca

From: IllegalMarketingIllegal (HC/SC)

Sent: 2021-08-31 2:55 PM

To: [REDACTED]

Subject: File# 3013457 Correspondence from the Marketed Health Products Directorate [REDACTED]

File# 3013457

To Whom It May Concern,

Please find attached a correspondence from the Marketed Health Products Directorate – File# 3013457 regarding "Unauthorized Claims Related to Coronavirus Disease 2019 (COVID-19) for Ivermectin."

Health Canada requests that [REDACTED] immediately acknowledges receipt of this correspondence by e-mail to drug-device-marketing@hc-sc.gc.ca.

Thank you,

Marketed Health Products Directorate
Section of Transparency & Advertising Regulatory Surveillance
Fax: 613-960-9754
Email: drug-device-marketing@hc-sc.gc.ca