

Also, just to let you know, our Chief Medical Officer (Dr. Supriya Sharma) is getting interested in the emerging literature on this product, and it would be great to be able to tell her when to expect PHAC's review of the literature...

Thank you so much!

P

From: Waddell, Lisa (PHAC/ASPC) <lisa.waddell@canada.ca>
Sent: 2021-06-21 2:48 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Lingohr, Erika (PHAC/ASPC) <erika.lingohr@canada.ca>
Cc: OCSO Evidence / BCSC Données Probantes (PHAC/ASPC) <phac.ocsoevidence-bcscdonneesprobantes.aspc@canada.ca>
Subject: RE: FYI - Ivermectin info from June 3

Thanks for this Phillippe,

I will have a look at that site.

As of a couple weeks ago, I do remember seeing some studies on prophylaxis. I will consider these for inclusion as well.

Cheers,
lisa

Lisa Waddell BSc. MSc. PhD.
Knowledge Synthesis Team Lead / Chef d'équipe de synthèse des connaissances
National Microbiology Laboratory / Laboratoire national de microbiologie
Public Health Agency of Canada (PHAC) / Agence de la santé publique du Canada (ASPC),
Government of Canada / Gouvernement du Canada
Tel. / Tél.: 226-979-7174
Lisa.Waddell@canada.ca

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-06-21 2:38 PM
To: Lingohr, Erika (PHAC/ASPC) <erika.lingohr@canada.ca>; Waddell, Lisa (PHAC/ASPC) <lisa.waddell@canada.ca>
Cc: OCSO Evidence / BCSC Données Probantes (PHAC/ASPC) <phac.ocsoevidence-bcscdonneesprobantes.aspc@canada.ca>
Subject: RE: FYI - Ivermectin info from June 3

Hey Erika, Hey Lisa,

I very much appreciate your involvement – yes, I think the proposed scoping question “**Is there evidence that Ivermectin is an effective or efficacious treatment for COVID-19?**” is appropriate – just

to note, some of the uses that have been flagged to us were about using ivermectin as a prophylaxis, but I don't know personally how much this is addressed in literature.

One website that we keep seeing come up over and over is [REDACTED]
[REDACTED] If any consideration of the studies cited by this website could be part of your review, this would help potentially debunk what we believe may be misleading information.

Thank you once again for your help, looking forward to seeing your conclusions,

P

Requester agreed to
Remove 3rd Party Info

From: Lingohr, Erika (PHAC/ASPC) <erika.lingohr@canada.ca>

Sent: 2021-06-21 2:26 PM

To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>

Cc: Waddell, Lisa (PHAC/ASPC) <lisa.waddell@canada.ca>; OCSO Evidence / BCSC Données Probantes (PHAC/ASPC) <phac.ocsoevidence-bcscdonneesprobantes.aspc@canada.ca>

Subject: RE: FYI - Ivermectin info from June 3

Good afternoon;

I have connected with our Knowledge Synthesis lead Lisa Waddell (cc'd above), re your interest in an Evidence Brief assessing the efficacy of Ivermectin for off-label therapeutic use for COVID-19 infection. She has kindly indicated that her team should be able to take this on given the increasing public interest.

Can you please confirm that your interest is only about treatment of infection?

Proposed Scoping Question: " **Is there evidence that Ivermectin is an effective or efficacious treatment for COVID-19?**"

- This would include RCT evidence on efficacy and potentially some real world data on effectiveness. There would be no limits on severity of COVID-19 infection, instead this would be part of the approach to subgrouping. E.g. there was little evidence that Ivermectin improved outcomes in severe cases, but there were some very new studies indicating it may speed up recovery in mild cases.

With confirmation the team will start looking into how much literature there is on this with the hopes of providing you with a completed product early next week.

Kind regards;

Erika

-on behalf of the OCSO and the PHAC Evidence Group

Erika J. Lingohr

(she | elle)

PHAC Evidence / ASPC Données Probantes
phac.ocsoevidence-bcscdonneesprobantes.aspc@canada.ca

Office of the Chief Science Officer | Bureau du conseiller scientifique en chef
Public Health Agency of Canada | Agence de la santé publique du Canada
Erika.Lingohr@Canada.ca | Tel : (519) 400-8032 (Cell)

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-06-21 1:39 PM
To: Lingohr, Erika (PHAC/ASPC) <erika.lingohr@canada.ca>
Subject: RE: FYI - Ivermectin info from June 3

Ok that's very useful to know, thank you Erika! Yes any information on the timelines of the Cochrane review would be most helpful,
Thank you again!
P

From: Lingohr, Erika (PHAC/ASPC) <erika.lingohr@canada.ca>
Sent: 2021-06-21 12:41 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: FYI - Ivermectin info from June 3

Afternoon Philippe;
As discussed we had prepared a quick overview on Ivermectin for internal awareness – that you kindly provided clinical info on.
Find the early June info here for awareness.

Note that Cochrane has registered a protocol for a systematic review on Ivermectin, but I'm not aware of the ETA at present. I will connect with the PHAC program experts for details, and the possibility of preparing a rapid evidence review.

Erika

IVERMECTIN OVERVIEW

1. SUMMARY:

Ivermectin is a broad-spectrum anti-parasitic agent authorized and approved by HC for human and veterinary applications to treat parasitic infections. At this time, HC has not authorized its use for the treatment of COVID-19 nor has it received any requests for clinical trials. The WHO currently advises against the use of ivermectin for COVID-19 outside of clinical trials, stating the current evidence is inconclusive. The manufacturer, Merck, also issued a statement against the use of ivermectin for the treatment of COVID-19.

2. CURRENT ACTIVITIES

- PHAC has not prepared an evidence review on Ivermectin, but has scanned the available evidence, with some of the detailed listed below (additional review specific info available from the Secretariat upon request).

- Noting increased interest in this potential therapeutic, the PHAC COVID-19 Therapeutics group will be monitoring the related clinical trials more closely moving forward.
- HC Therapeutics directorate is also monitoring this space and are receiving increased inquiry on this therapeutic; and have confirmed they have not yet received or approved any clinical trial proposals.

3. PERSPECTIVES ON EFFICACY

Evidence regarding ivermectin's efficacy remains unclear with many regulatory agencies (ie. WHO, EMA, FDA) not recommending the use of ivermectin for COVID-19 outside of clinical trials.

CANADIAN

- The Canadian Agency for Drugs and Technologies in Health (CADTH; statement issued on February 08, 2021); Alberta Health Services (statement issued on February 02, 2021) ; as well as British Columbia's COVID-19 Therapeutics Committee/COVID-19 Therapeutics Review and Advisory Working Group (statement issued on May 25, 2021) have all concluded that there is no clear benefit associated with ivermectin treatment among patients with COVID-19. As of June 3, 2021, no statement has been issued by INESSS.
- On May 28, 2021, Ontario's COVID-19 Science Advisory Table issued a statement titled Ivermectin to Prevent Disseminated Strongyloides Infection in Patients with COVID-19. While stipulating ivermectin is currently not recommended as a treatment or preventative for COVID-19, the statement acknowledges patients with COVID-19 who receive therapies that alter immune system function may require ivermectin for the purposes of treating a pre-existing parasitic infection and to avoid severe complications of worsening parasitic infection.

INTERNATIONAL

- In South American countries, ivermectin is being prescribed routinely for COVID-19 infections; however, it is difficult to ascertain clinical benefit from use outside the context of randomized controlled trials.
- On March 31, 2021, the WHO issued a statement on ivermectin advising against its use outside of clinical trials, stating the current clinical evidence was inconclusive
- On March 22, 2021 the EMA issued an advisory notice against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials.
- On February 11, 2021 the NIH COVID-19 Treatment Guidelines Panel issued a statement concluding there is insufficient evidence to recommend either for or against the use of ivermectin for the treatment of COVID-19.

4. EVIDENCE REVIEWS/SYSTEMATIC EVIDENCE REVIEWS

- Cochrane is preparing a systematic review, but there are not updates from that group at present. Ivermectin for preventing and treating COVID-19 (Protocol).
- COVID-NMA last updated mid May
 - Ivermectin vs. placebo, (14 RCTs) none of the outcomes indicated a benefit of treatment.
 - Ivermectin vs Lopinavir-Ritonavir - 1 RCTs none of the outcomes indicated a benefit of treatment.

- Ivermectin vs Hydroxychloroquine - 4 RCTs none of the outcomes indicated a benefit of treatment.
 - Ivermectin 100 mcg/kg vs Ivermectin 200 mcg/kg - 1 RCTs none of the outcomes indicated a benefit of treatment.
 - Ivermectin 12 mg vs Ivermectin 24 mg - 1 RCTs none of the outcomes indicated a benefit of treatment.
 - Ivermectin 200 mcg/kg vs Ivermectin 400 mcg/kg - 1 RCTs none of the outcomes indicated a benefit of treatment.
 - Ivermectin 6mg vs Ivermectin 12mg - 1 RCTs none of the outcomes indicated a benefit of treatment.
 - Ivermectin+Doxycycline vs Hydroxychloroquine+Azithromycin - 1 RCTs
 - Ivermectin+Doxycycline vs Standard care/Placebo - 3 RCTs, Clinical improvement at 28 days was significant in 1 RCT (RR=0.63, .44-.87)
 - Ivermectin+Doxycycline vs Ivermectine - 1 RCTs none of the outcomes indicated a benefit of treatment.
- Other systematic reviews and quality evidence analyses are detailed below. The most recent reviews do report some potentially beneficial effects, but the certainty is still considered very low. Note that all of the trials to date have been documented in Asia, S. America and Spain, and there is no input from the Canadian context. Recent systematic review highlights include:
 - The British Medical Journal's living systematic review and network meta-analysis analysed 16 randomized trials and based on their findings they rated the effects of ivermectin on viral clearance, mechanical ventilation and mortality as uncertain, meaning it is uncertain ivermectin treatment has an important impact on any patient-important outcome.
 - A meta-analysis based on 18 randomized trials of ivermectin in COVID-19 have found that ivermectin treatment reduced mortality, time to clinical recovery, and time to viral clearance.
 - A recent meta-analysis that has not undergone peer-revision, evaluating 10 randomized trials found that ivermectin did not reduce all-cause mortality, length of hospital stay or viral clearance in COVID-19 patients.

5. SIGNIFICANT CLINICAL TRIALS IN PROGRESS

Most trials are currently taking place in South America, where ivermectin is routinely prescribed for COVID-19 patients.

On-going

- NCT04834115 Universidad Nacional de Asunción sponsored, single-centre, Phase 3, triple blind study evaluating ivermectin treatment to placebo in preventing hospitalizations in **symptomatic or asymptomatic outpatients**. Allocation concealment not specified. Estimated enrollment of 400 with 200 participants randomized to treatment. No Canadian sites. **Study end date: May 30, 2021.**
- NCT04530474 Temple University sponsored, single-centre, Phase 3, triple blind study evaluating ivermectin treatment to placebo in preventing hospitalizations in **symptomatic outpatients**. Allocation concealment not specified. Estimated enrollment of 200, with 100 participants randomized to ivermectin treatment arm. No Canadian sites. **Primary end date: June 30, 2021.**

- [NCT04894721](#) Ministry of Public Health, Argentina sponsored, single center, Phase 2/3, triple blind study evaluating ivermectin to placebo in **post-exposure prophylaxis of close contacts of COVID-19 cases**. Allocation concealment not specified. Estimated enrollment of 750 with 500 participants randomized to treatment arm. No Canadian sites. **Primary end date: May 30, 2021.**

Not yet recruiting

- [NCT04885530](#) ACTIV-6 NIH Trial, Phase 3, double-blind study evaluating ivermectin for the treatment of **symptomatic COVID-19 outpatients**. Allocation concealment not specified. Estimated enrolment of 15,000 participants with 7,500 randomized to ivermectin treatment arm. No Canadian sites. **Primary end date: December 2022. Not yet recruiting.**
- [NCT04768179](#) Makerere University sponsored, Phase 2/3, Open-label study evaluating ivermectin + aspirin treatment compared to placebo in treating **hospitalized patients with moderate COVID-19**. Allocation concealment not specified. Estimated enrollment of 490, with 163 participants randomized to ivermectin+aspirin treatment arm (2 dosage groups). No Canadian sites. **Primary end date: June 30, 2021. Not yet recruiting.**
- [NCT04886362](#) Ayudas Diagnosticas sponsored, Phase 2/3, quadruple blind study evaluating ivermectin treatment compared to placebo in treating **outpatients with mild COVID-19**. Allocation concealment prior to randomization. Estimated enrollment of 966, with 483 participants randomized to treatment arm. No Canadian sites. **Primary end date: September 2021. Not yet recruiting.**

-on behalf of the OCSO and the PHAC Evidence Group

Erika J. Lingohr

(she | elle)

PHAC Evidence / ASPC Données Prochantes

phac.ocsoevidence-bcsdonneesprochantes.aspc@canada.ca

Office of the Chief Science Officer | Bureau du conseiller scientifique en chef

Public Health Agency of Canada | Agence de la santé publique du Canada

Erika.Lingohr@Canada.ca | Tel : (519) 400-8032 (Cell)

From: Massey, Ranjeet (HC/SC)
Sent: 2021-09-28 12:17 PM
To: Bak, Celina (HC/SC); Kearns-Justin, Dayna (HC/SC); Zayoun, Toufic (HC/SC)
Cc: Rajwani, Salima (HC/SC)
Subject: RE: Heads up: Ivermectin Signage Concern

Importance: High
Follow Up Flag: Follow up
Flag Status: Completed

Hi Team,
Sorry for the delay in getting back to you.

In speaking with Linsey she'd like us to stick with the facts around our standard process and expectations around going onsite to verify the billboard is not there. (That includes **not** saying that MHPD should be doing the drive by lol).

With that context please draft a response to send to MHPD that should:

- Note what our standard process is. (That we accept written attestation/confirmation)
- Note something along the lines of "That being said, we know that there are sensitivities specific to COVID surrounding this file however there has been no CV referral received from MHPD.
- At this time we believe that written attestation/confirmation is sufficient
- **Remove** any reference or suggestion that MHPD should drive by themselves
- Remain diplomatic and cooperative (not that you wouldn't be like this in your response lol) in case the door in fact get opened to us having to do the drive by

If you could share the response with me after sent that would be great.
Thanks,
R

From: Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Sent: Friday, September 24, 2021 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 (██████████) 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 ██████████ 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]

Requester agreed to
Remove 3rd Party Info

- 
- 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: Mineau, Philippe (HC/SC)
Sent: 2021-09-13 11:39 AM
To: Soo, Evelyn (HC/SC); Stewart, John Patrick (HC/SC)
Cc: Randall, Bruce (HC/SC)
Subject: RE: HPEC Sept 13

I tried to look up GPHN, where the reference to this new “strange” treatment is coming from, but wasn’t able to find anything useful? It could be this antiviral, Parvulan, as suggested in the article Evelyn has found?

So far, we’ve received correspondence on suggested “alternative” treatments:

- Vitamin D
- Zinc
- Ivermectin
- Hydroxychloroquine
- Budesonide (Pulmicort)
- Doxycycline
- Fluvoxamine

Requester agreed to
Remove 3rd Party Info

Hope this helps!
P

From: Soo, Evelyn (HC/SC) <evelyn.soo@hc-sc.gc.ca>
Sent: 2021-09-13 11:23 AM
To: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Cc: Randall, Bruce (HC/SC) <bruce.randall@hc-sc.gc.ca>
Subject: RE: HPEC Sept 13

Could this be it?

<https://www.reuters.com/business/healthcare-pharmaceuticals/italy-warns-against-misuse-herpes-drug-covid-19-treatment-2021-09-10/>

From: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>
Sent: 2021-09-13 11:09 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Cc: Randall, Bruce (HC/SC) <bruce.randall@hc-sc.gc.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@hc-sc.gc.ca>

Subject: FW: HPEC Sept 13

Importance: High

Hi Phil can you check with Evelyn, Carole and others to see if they are aware of the use of another unauthorized health Product to treat or prevent COVID.

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: 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>; Copley, Julia (HC/SC) <julia.copley@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 we need them

From: Lin, Mimi (HC/SC)
Sent: 2021-08-30 9:50 AM
To: Bellefeuille, Aldege (HC/SC); Nahum, Marilyne (HC/SC); BMS ORM Risk / BSM BGR Risque (HC/SC); Dinakaran, Deborah (HC/SC); Badenduck, Lucas (HC/SC)
Cc: Schmidt, Stephanie (HC/SC); Lejmi Mrad, Rim (HC/SC); Kearns-Justin, Dayna (HC/SC)
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

From: [Mineau, Philippe \(HC/SC\)](#)
Sent: 2021-07-08 9:28 AM
To: [Keeping, Elizabeth \(HC/SC\)](#)
Subject: RE: Ivermectin

Ok thanks!
P

From: Keeping, Elizabeth (HC/SC) <elizabeth.keeping@canada.ca>
Sent: 2021-07-08 9:28 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: Ivermectin

Hey Phil,

Not actual media lines – we have just been using these two bullets:

To date, Health Canada has not received any drug submission or clinical trial application for ivermectin for COVID-19 treatment or prevention.

Health Canada is closely monitoring all potential therapeutic treatments for COVID-19, including international clinical trials.

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-07-08 9:26 AM
To: Keeping, Elizabeth (HC/SC) <elizabeth.keeping@canada.ca>
Subject: FW: Ivermectin

Morning Beth!
Just wondering, do you know if we have holding lines / media lines related to ivermectin for COVID-19?
Thanks!

From: Lostracco, Anthony (HC/SC) <anthony.lostracco@canada.ca>
Sent: 2021-07-08 8:11 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: Ivermectin

Hi Philippe

Do you know if any media lines were developed about Ivermectin?

Anthony

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-06-21 3:02 PM
To: Lostracco, Anthony (HC/SC) <anthony.lostracco@canada.ca>
Subject: RE: Ivermectin

Requester agreed to
Remove 3rd Party Info

Hey Anthony,

Just to follow-up with you via email:

I had contacted you on Friday to discuss ivermectin, as we currently still receive a lot of correspondence on this drug product in relation to COVID-19. Some of this correspondence has been from professors of pharmacology, [REDACTED]

[REDACTED]

There seems to be increasing amounts of publications around this drug product in the literature, though the quality of the evidence still does not seem strong. We do know that in South American countries, ivermectin is being prescribed routinely for COVID-19 infections.

I wanted to let you know that I have been in touch with PHAC's group leading evidence reviews of emerging literature, and they are going to be taking a closer look at the literature on ivermectin – we should hear back from them in the coming weeks. I'll share their findings with you when they become available.

Thank you again for your time,

P

From: Lostracco, Anthony (HC/SC)
Sent: 2021-06-18 2:46 PM
To: Mineau, Philippe (HC/SC)
Subject: FW: Ivermectin

From: Burnett, Rodrigue (HC/SC) <rodrigue.burnett@canada.ca>
Sent: 2021-05-05 4:07 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

Requester agreed to
Remove 3rd Party Info

Hi Vivian,

•

•

•

•

•

Let me know if you have any other questions.

Thanks,
Rod

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) <rodrigue.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

Phone Conference ID: [REDACTED]

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

From: Chang, Vivian (HC/SC)
Sent: 2021-05-05 5:59 PM
To: Burnett, Rodrigue (HC/SC)
Cc: MacKay, Ian (HC/SC); Lostracco, Anthony (HC/SC)
Subject: RE: Ivermectin

Thanks Rod, for the comprehensive information. We won't share the details here but will refer the inquirer to Merck for on-label treatment supply. [REDACTED]

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

Requester agreed to
Remove 3rd Party Info

Hi Vivian,

[REDACTED]

[REDACTED]

Let me know if you have any other questions.

Thanks,
Rod

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) <rodrigue.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

Join on your computer or mobile app

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Or call in (audio only)

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

Phone Conference ID XXXXXXXXXX

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

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From: MacKay, Ian (HC/SC)
Sent: 2021-05-05 4:20 PM
To: Burnett, Rodrigue (HC/SC)
Cc: Chang, Vivian (HC/SC)
Subject: Re: Ivermectin

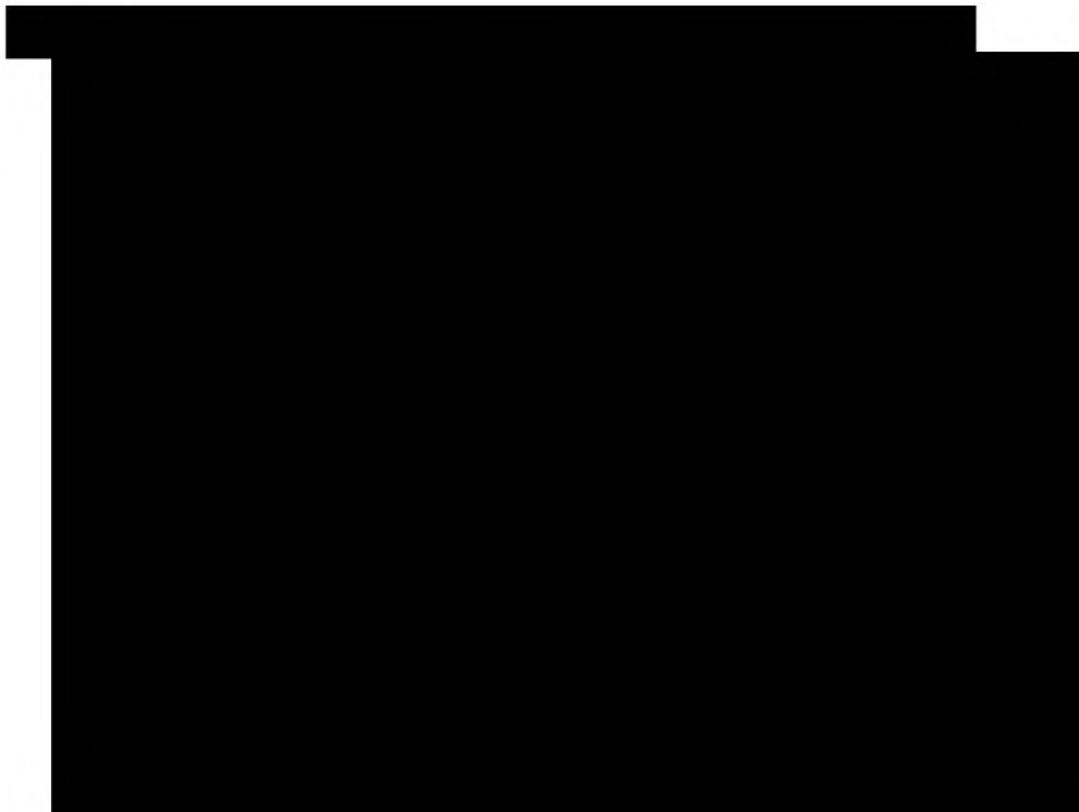
Thanks Rod. Helpful.

Sent from my iPhone

Requester agreed to
Remove 3rd Party Info

On May 5, 2021, at 4:12 PM, Burnett, Rodrigue (HC/SC) <rodrigue.burnett@canada.ca> wrote:

Hi Vivian,



Let me know if you have any other questions.

Thanks,
Rod

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) <rodrigue.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

Join on your computer or mobile app

[Click here to join the meeting](#)

Or call in (audio only)

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

Phone Conference ID: [REDACTED]

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

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

<Merck Canada Statement on STROMEKTOL® (ivermectin) use During the COVID-19 Pandemic.pdf>

From: [Mineau, Philippe \(HC/SC\)](#)
Sent: 2021-02-15 2:54 PM
To: [Keeping, Elizabeth \(HC/SC\)](#); [Randall, Bruce \(HC/SC\)](#)
Subject: RE: ivermectin

Works for me...
P

From: Keeping, Elizabeth (HC/SC) <elizabeth.keeping@canada.ca>
Sent: 2021-02-15 2:53 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Subject: RE: ivermectin

Thanks Philippe.

Could we make it a little shorter – something like this?

To date, Health Canada has not received any drug submission or clinical trial application for ivermectin for COVID-19 treatment or prevention.

Health Canada is closely monitoring all potential therapeutic treatments for COVID-19, including international clinical trials.

B

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-02-15 2:47 PM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Keeping, Elizabeth (HC/SC) <elizabeth.keeping@canada.ca>
Subject: RE: ivermectin

Hey Beth, how about something like this to respond on Twitter?

Health Canada has not received any clinical trial application for ivermectin and COVID-19, and no manufacturer has made an application for this drug to be authorized for the treatment or prevention of COVID-19. However, Health Canada is aware that such clinical trials may be planned or underway internationally and is closely monitoring all potential therapeutic treatments for COVID-19.

Our full ADMO pre-approved lines are:

- Ivermectin (brand name STROMEKTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically

intestinal strongyloidiasis and onchocerciasis. STROMEOTL 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 authorized.
- 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 authorized 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 authorized 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](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 authorized by the U.S. Food and Drug Administration or the European Medicines Agency for the prevention or treatment of COVID-19.

From: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Sent: 2021-02-15 2:34 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Keeping, Elizabeth (HC/SC) <elizabeth.keeping@canada.ca>
Subject: FW: ivermectin

Hi Phil,

Do you want to share our material with Beth?

Beth, Phil is back and has resumed as Sr Advisor. We have lines that we've been using on enquiries outside of media. They may not have the comms lens but are a bit more detailed.

The other B

From: Keeping, Elizabeth (HC/SC) <elizabeth.keeping@canada.ca>
Sent: 2021-02-15 2:31 PM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Zubkova, Ekaterina (HC/SC) <ekaterina.zubkova@canada.ca>
Subject: ivermectin

Hi Folks,

In terms of ivermectin – which is being promoted internationally for COVID treatments, I don't think we have any clinical trials for it.

Would we just say this?

B

Health Canada authorized Stromectol (ivermectin) to treat patients with parasite infections that may be acquired when travelling. It has not been authorized for any other indications.

From: Lorincz, Jessica (HC/SC) <jessica.lorincz@canada.ca>
Sent: 2021-02-15 2:27 PM
To: Kealey, Ashton (HC/SC) <ashton.kealey@canada.ca>; COVIDvaccineComms / VaccincontrelaCOVIDcommunications (HC/SC) <hc.covidvaccinecomms-vaccincontrelacovidcomms.sc@canada.ca>; Deschambault, Josee (HC/SC) <josee.deschambault@canada.ca>
Cc: Delichy, Eric (HC/SC) <eric.delichy@canada.ca>; Beahen, Megan (HC/SC) <megan.beahen@canada.ca>; Demaine, Erika (HC/SC) <erika.demaine@canada.ca>; Keeping, Elizabeth (HC/SC) <elizabeth.keeping@canada.ca>
Subject: RE: COVID Vaccine SM questions - Feb 15 am iverme

Hi Ashton, I hope your afternoon is going well,

Please note, I will defer to **Elizabeth** (on CC) to questions surrounding ivermectin.

Additionally I am looping in **Josée** to connect with our friends in travel regarding Q1.

Thank you kindly,

From: Kealey, Ashton (HC/SC) <ashton.kealey@canada.ca>
Sent: 2021-02-15 11:01 AM
To: COVIDvaccineComms / VaccincontrelaCOVIDcommunications (HC/SC) <hc.covidvaccinecomms-vaccincontrelacovidcomms.sc@canada.ca>

Cc: Lorincz, Jessica (HC/SC) <jessica.lorincz@canada.ca>; Delichy, Eric (HC/SC) <eric.delichy@canada.ca>

Subject: COVID Vaccine SM questions - Feb 15 am iverme

Hi there,

We have received these questions on COVID Vaccines this morning. Please note: we have received several comments on ivermectin.

[REDACTED]

@GovCanHealth Where do Canadian living abroad get a COVID vaccination? Does Canada have a plan for Canadian living abroad? Register anywhere?

[REDACTED]

@GovCanHealth @PattyHajdu @celliottability are we at least looking at this???

Thank you,

Ashton Kealey
(he | il)

Communications Officer, Social Media, Public Affairs Branch
Health Canada and the Public Health Agency of Canada, Government of Canada
ashton.kealey@canada.ca/ Tel: 343-543-2975

Agent de Communications, Médias sociaux, Direction des affaires publiques
Santé Canada et de l'Agence de la santé publique du Canada, Gouvernement du Canada
ashton.kealey@canada.ca/ Tél: 343-543-2975

From: Pham, Co (HC/SC) <co.pham@canada.ca>
Sent: 2021-02-08 11:01 AM
To: MacKay, Ian (HC/SC)
Subject: RE: ivermectin for COVID-19

It made the national news last night too. CBC's The National had it on and said that the Ivermectin manufacturer stated that their data to no support the use of ivermectin for COVID.

-----Original Message-----

From: MacKay, Ian (HC/SC) <ian.mackay@canada.ca>
Sent: 2021-02-08 10:57 AM
To: Pham, Co (HC/SC) <co.pham@canada.ca>
Subject: Re: ivermectin for COVID-19

Requester agreed to
Remove 3rd Party Info

Wow. I also happened to see the video of a crit care doc who passionately was pushing ivermectin at a Senate hearing in the US in December. [REDACTED]
[REDACTED] He was invited to the hearing by republicans to advance this idea that the answer to COVID is hiding in plain sight. [REDACTED]
[REDACTED]
[REDACTED]

Just saw that in meantime YouTube has taken down the video and of course now that has fed into the conspiracy theory etc.

Same kind of things at play here as with HCQ. Fascinating cultural and political battles here if they weren't so serious and consequential.

IM

Sent from my iPhone

> On Feb 4, 2021, at 11:25 PM, Pham, Co (HC/SC) <co.pham@canada.ca> wrote:
>

From: Lin, Mimi (HC/SC)
Sent: 2021-09-01 9:56 AM
To: Zayoun, Toufic (HC/SC)
Subject: RE: Ivermectin Pa posted

You're welcome!!

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Sent: 2021-09-01 9:34 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: RE: Ivermectin Pa posted

Thanks for the heads up Mimi!

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Sent: 2021-09-01 7:56 AM
To: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>
Subject: Ivermectin Pa posted

Good morning Dayna and Toufic,

The Ivermectin PA was posted last evening:

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

Thanks!

Mimi

Sent from my iPhone

From: Kearns-Justin, Dayna (HC/SC)
Sent: 2021-08-26 9:18 AM
To: Lin, Mimi (HC/SC); Zayoun, Toufic (HC/SC)
Cc: Simard, Chris (HC/SC)
Subject: RE: Ivermectin referral

Oh? I had asked CTU to follow up but luckily it hadn't been actioned yet. I guess we'll wait to see what Alain comes back with.

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Sent: 2021-08-25 10:32 PM
To: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Cc: Simard, Chris (HC/SC) <chris.simard@hc-sc.gc.ca>
Subject: Ivermectin referral

Hi All,

Steph at MHPD STARS provided me a heads-up that she's working on a summary of recent ivermectin advertising complaints that include a couple of billboard advertisements. She anticipates having this completed for Alain by tomorrow. She asked us to hold off on following up with the complainant as Alain should be reaching out to us afterwards and likely retracting this referral.

More to come.

Mimi

From: [prescription.drug.enquiries / renseignements.drogue.ordonnance \(HC/SC\)](#)
Sent: 2021-02-09 10:58 AM
To: [Punch, Vincent \(HC/SC\)](#); [Arnold, Sidney \(HC/SC\)](#)
Cc: [McLean, Martin \(HC/SC\)](#); [Geoffroy, Emile \(HC/SC\)](#)
Subject: RE: Ivermectin-COVID-19 question FW: IDU-2021-63 Correction: How can Ivermectin supply be increased so doctors can prescribe off-label

Super, thanks for confirming.

Pamela

From: Punch, Vincent (HC/SC) <vincent.punch@canada.ca>
Sent: 2021-02-09 10:54 AM
To: [Arnold, Sidney \(HC/SC\)](#) <sidney.arnold@canada.ca>; [prescription.drug.enquiries / renseignements.drogue.ordonnance \(HC/SC\)](#) <hc.prescription.drug.enquiries-renseignements.drogue.ordonnance.sc@canada.ca>
Cc: [McLean, Martin \(HC/SC\)](#) <martin.mclean@canada.ca>; [Geoffroy, Emile \(HC/SC\)](#) <emile.geoffroy@canada.ca>
Subject: FW: Ivermectin-COVID-19 question FW: IDU-2021-63 Correction: How can Ivermectin supply be increased so doctors can prescribe off-label

Hi Pamela,

FYI - This was redirected to the ROEB for reply.

Thanks.

Vincent Punch, PhD

A/Associate Director
Bureau of Gastroenterology Infection and Viral Diseases
Therapeutic Products Directorate
Health Canada, Government of Canada
vincent.punch@canada.ca / 613-404-6204

Directeur associé par intérim
Bureau de la gastroentérologie et des maladies infectieuses et virales
Direction des produits thérapeutiques
Santé Canada, Gouvernement du Canada
vincent.punch@canada.ca / 613-404-6204

From: [Burnett, Rodrigue \(HC/SC\)](#) <rodrigue.burnett@canada.ca>
Sent: 2021-02-04 4:08 PM
To: [Punch, Vincent \(HC/SC\)](#) <vincent.punch@canada.ca>

Cc: Deol, Mandy (HC/SC) <mandy.deol@canada.ca>; Lostracco, Anthony (HC/SC) <anthony.lostracco@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>

Subject: RE: Ivermectin-COVID-19 question FW: IDU-2021-63 Correction: How can Ivermectin supply be increased so doctors can prescribe off-label

Hi Vincent,

Thank you for your email. DSU will respond to this person regarding the shortage concerns.

Thanks,
Rodrigue

From: Lostracco, Anthony (HC/SC) <anthony.lostracco@canada.ca>

Sent: 2021-02-04 3:24 PM

To: Burnett, Rodrigue (HC/SC) <rodrigue.burnett@canada.ca>

Subject: FW: Ivermectin-COVID-19 question FW: IDU-2021-63 Correction: How can Ivermectin supply be increased so doctors can prescribe off-label

Hi Rod,

Is this something you could look into?

Anthony

From: Punch, Vincent (HC/SC) <vincent.punch@canada.ca>

Sent: 2021-02-04 3:18 PM

To: Lostracco, Anthony (HC/SC) <anthony.lostracco@canada.ca>

Cc: Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>

Subject: FW: Ivermectin-COVID-19 question FW: IDU-2021-63 Correction: How can Ivermectin supply be increased so doctors can prescribe off-label

Hi Anthony,

I am hoping to redirect this enquiry to ROEB, given that it pertains to a drug shortage issue.

Recently, we've become inundated with inquiries on the drug Ivermectin. This has followed a significant amount of media attention on a US senate hearing in December at which a group of physicians testified to the potential use of this drug in preventing/treating COVID-19.

Ivermectin is not authorized for COVID-19 in Canada (or the US) but this media coverage, plus a recently upgraded "neutral" stance on this product by the US National Institute of Health, has prompted a great deal of interest in the Canadian regulatory status. We are hearing from more and more Canadians who want to know how they can access this drug, particularly when their doctors refuse to prescribe it.

We received a follow-up question from one of our correspondents, regarding a shortages issue with the product (see below). This person claims that the College of Physicians and Surgeons of Ontario

(CSPO) told him that there was a potential shortage issue preventing physicians from prescribing the drug off-label. The drug shortages website currently lists a shortage for the brand name product STROMEKTOL. (<https://www.drugshortagescanada.ca/shortage/131914>).

Would you be able to respond to this person?

Thanks,

Vincent Punch, PhD

A/Associate Director | Directeur associé par intérim

Bureau of Gastroenterology Infection and Viral Diseases | Bureau de la gastroentérologie et des
maladies infectieuses et virales

Therapeutic Products Directorate | Direction des produits thérapeutiques

Health Canada | Santé Canada

613-404-6204

vincent.punch@canada.ca

From: Arnold, Sidney (HC/SC) <sidney.arnold@canada.ca>

Sent: 2021-02-03 3:32 PM

To: Punch, Vincent (HC/SC) <vincent.punch@canada.ca>

Subject: RE: Ivermectin-COVID-19 question FW: IDU-2021-63 Correction: How can Ivermectin supply be increased so doctors can prescribe off-label

From: [REDACTED]

Sent: 2021-02-02 7:29 PM

To: [prescription.drug.enquiries / renseignements.drogue.ordonnance \(HC/SC\)](mailto:prescription.drug.enquiries@canada.ca)

<hc.prescription.drug.enquiries-renseignements.drogue.ordonnance.sc@canada.ca>

Subject: IDU-2021-63 Fwd: Correction: How can Ivermectin supply be increased so doctors can prescribe off-label

Good Morning,

Melanie from OCP gave me your contact information.

I would like doctors in Ontario to be able to prescribe Ivermectin off-label for the prevention and treatment of COVID-19. How can the supply in Canada be increased?

Countries around the world are making Ivermectin available to its citizens. I don't understand why the same can't be done in Canada. Extraordinary measures are being taken for vaccines. I think it is reasonable to allow doctors to prescribe Ivermectin for the prevention and treatment of COVID-19. Ivermectin has been used for decades and its patent has expired, allowing any drug company to produce it.

I spoke with [REDACTED] from the CPSO. She informed me that doctors can prescribe off-label, but in the case of Ivermectin they cannot prescribe prophylactically because of potential supply shortages.

[REDACTED] Given the mounting evidence, it seems obvious to me that Ivermectin will become one of the keys to getting this pandemic under control, so that we can start living again.

Thank you for taking the time to address my question. I look forward to hearing from you.

Regards,

[REDACTED]

From: Punch, Vincent (HC/SC) <vincent.punch@canada.ca>
Sent: 2021-02-03 3:30 PM
To: Arnold, Sidney (HC/SC) <sidney.arnold@canada.ca>; McLean, Martin (HC/SC) <martin.mclean@canada.ca>; Geoffroy, Emile (HC/SC) <emile.geoffroy@canada.ca>
Cc: [prescription.drug.enquiries](mailto:prescription.drug.enquiries@canada.ca) / [renseignements.drogue.ordonnance](mailto:renseignements.drogue.ordonnance@canada.ca) (HC/SC) <hc.prescription.drug.enquiries-renseignements.drogue.ordonnance.sc@canada.ca>
Subject: RE: Ivermectin-COVID-19 question FW: IDU-2021-63 Correction: How can Ivermectin supply be increased so doctors can prescribe off-label

Hi Sid,

Could you please share the most recent enquiry from [REDACTED] That would help me better understand what are options are.

Thanks.

Vincent Punch, PhD

A/Associate Director | Directeur associé par intérim
Bureau of Gastroenterology Infection and Viral Diseases | Bureau de la gastroentérologie et des
maladies infectieuses et virales
Therapeutic Products Directorate | Direction des produits thérapeutiques
Health Canada | Santé Canada
613-404-6204
vincent.punch@canada.ca

From: Arnold, Sidney (HC/SC) <sidney.arnold@canada.ca>
Sent: 2021-02-03 2:45 PM
To: McLean, Martin (HC/SC) <martin.mclean@canada.ca>; Geoffroy, Emile (HC/SC) <emile.geoffroy@canada.ca>; Punch, Vincent (HC/SC) <vincent.punch@canada.ca>
Cc: [prescription.drug.enquiries](mailto:prescription.drug.enquiries@canada.ca) / [renseignements.drogue.ordonnance](mailto:renseignements.drogue.ordonnance@canada.ca) (HC/SC) <hc.prescription.drug.enquiries-renseignements.drogue.ordonnance.sc@canada.ca>
Subject: RE: Ivermectin-COVID-19 question FW: IDU-2021-63 Correction: How can Ivermectin supply be increased so doctors can prescribe off-label

Afternoon Martin and Vincent:

[REDACTED] by BGIVD Enquiries (below) – he basically wants to get a supply of ivermectin for himself and family. His family physician has refused to write a prescription for off-label use. He is unwilling to accept that he will be unable to secure a supply through normal channels. I am asking Vincent to provide options on whether BGIVD should respond (again) given the new enquiry seems to be related to supply [REDACTED] rather than the pharmacological aspects of ivermectin.

Regards

Sid

Requester agreed to
Remove 3rd Party Info

From: Arnold, Sidney (HC/SC) <sidney.arnold@canada.ca>

Sent: 2021-01-14 8:59 AM

To: [REDACTED]

Cc: TPD General / Général DPT (HC/SC) <hc.tpdgeneral-generalcpt.sc@canada.ca>; BGIVD Enquiries (HC/SC) <hc.bgivd.enquiries.sc@canada.ca>

Subject: RE: Status of Ivermectin to treat COVID

Thank you for your inquiry on ivermectin for the prevention of COVID-19.

Health Canada closely tracks all potential therapeutic treatments and vaccines in development in Canada and abroad, including products that are being used outside of their authorized indications (off-label use), as potential treatments for COVID-19.

The role of Health Canada is to approve drugs and vaccines for use in Canada based on the review of their safety, efficacy and quality of information that is submitted by pharmaceutical companies looking to sell their drugs and vaccines in Canada. To date, Health Canada has not received from a pharmaceutical company a drug submission, nor a clinical trial application for ivermectin, for the prevention or treatment for COVID-19. Therefore, the effectiveness of ivermectin as a therapeutic option for COVID-19 has not been evaluated by Health Canada at this time because of the above. 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>.

Health Canada has approved remdesivir (Veklury) and the antibody regimen, bamlanivimab, for the treatment of patients with COVID-19, as well as the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 vaccine for the prevention of COVID-19. A list of approved treatments can be found on Health Canada's website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/authorization/list-drugs.html>.

For drugs that have potential to be helpful in treating COVID-19, Health Canada encourages pharmaceutical companies to conduct clinical trials – Health Canada itself does not 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. Further studies from pharmaceutical companies are needed to determine whether ivermectin might be helpful in preventing or treating COVID-19.

Health Canada has approved ivermectin for human use in the treatment of inflammatory lesions of rosacea (Rosiver) and various parasitic infections (Stromectol). 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. Healthcare practitioners, such as family physicians, may, or may not, 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 however falls under the practice of medicine and is regulated at the provincial and territorial level, not at the federal level.

Thank you again for your inquiry and we hope you find this information useful.

BGIVD Enquiries

From: [REDACTED]
Sent: 2021-01-10 12:18 PM
To: Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>
Subject: Status of Ivermectin to treat COVID

Hello,

Before Christmas, I watched a US Senate hearing re: latest developments in treating COVID (links at end of email).

According to [REDACTED], their Ivermectin treatment protocol should be the gold standard for COVID treatment.

I spoke with my family doctor, who would not prescribe.

1. Could you please let me know how I go family and my elderly parents?

Requester agreed to
Remove 3rd Party Info

2. What is the status of the research here in Canada.

Thank you for your time.

Regards,

[REDACTED]

The hearing:

<https://www.c-span.org/video/?507035-1/medical-response-covid-19>

The evidence:

<https://covid19criticalcare.com/wp-content/uploads/2020/12/FLCCC-Alliance-Call-for-Action-News-Release-Press-Conference-Follow-Up.pdf>

<https://covid19criticalcare.com/wp-content/uploads/2020/12/FLCCC-PressConferencePresentation-Dec4-Houston.pdf>

<https://covid19criticalcare.com/wp-content/uploads/2020/11/FLCCC-Ivermectin-in-the-prophylaxis-and-treatment-of-COVID-19.pdf>

From: McLean, Martin (HC/SC) <martin.mclean@canada.ca>

Sent: 2021-02-03 2:23 PM

To: Geoffroy, Emile (HC/SC) <emile.geoffroy@canada.ca>

Cc: prescription.drug.enquiries / renseignements.drogue.ordonnance (HC/SC)
<hc.prescription.drug.enquiries-renseignements.drogue.ordonnance.sc@canada.ca>; Arnold, Sidney
(HC/SC) <sidney.arnold@canada.ca>

Subject: Re: Ivermectin-COVID-19 question FW: IDU-2021-63 Correction: How can Ivermectin supply be increased so doctors can prescribe off-label

Hi all, our fearless PMC (Sid, copied above) may already have some standard text drafted up for these Ivermectin enquiries.

Sid, sorry to throw more chaos at you, is there a template that you've been using for these that could apply here also? Just to make sure we're giving out consistent messaging and not duplicating work... 😊

Thanks!
Martin

Sent from mobile

On Feb 3, 2021, at 2:02 PM, Geoffroy, Emile (HC/SC)
<emile.geoffroy@canada.ca> wrote:

Oh boy. BGIVD approved ivermectin for human use so perhaps they could put together a response about the approved uses/indications. I see the FDA has an FAQ re: COVID and

ivermectin, but Health Canada doesn't. I've cc'ed Martin in case he's seen these types of enquiries in BGIVD already.

Emile

From: prescription.drug.enquiries / renseignements.drogue.ordonnance (HC/SC)
<hc.prescription.drug.enquiries-renseignements.drogue.ordonnance.sc@canada.ca>
Sent: 2021-02-03 10:27 AM
To: Geoffroy, Emile (HC/SC) <emile.geoffroy@canada.ca>
Subject: Ivermectin-COVID-19 question FW: IDU-2021-63 Correction: How can Ivermectin supply be increased so doctors can prescribe off-label

Hi Emile,

Flagging an ivermectin COVID-19 question to you. I was thinking of sending it to the hc.covid19.regulatory.response-reponse.reglementaire.covid19.sc@canada.ca inbox but should run this by you first.

Thanks,

Pamela

From: [REDACTED]
Sent: 2021-02-02 7:29 PM
To: prescription.drug.enquiries / renseignements.drogue.ordonnance (HC/SC)
<hc.prescription.drug.enquiries-renseignements.drogue.ordonnance.sc@canada.ca>
Subject: IDU-2021-63 Fwd: Correction: How can Ivermectin supply be increased so doctors can prescribe off-label

Good Morning,

[REDACTED] gave me your contact information.

I would like doctors in Ontario to be able to prescribe Ivermectin off-label for the prevention and treatment of COVID-19. How can the supply in Canada be increased?

Countries around the world are making Ivermectin available to its citizens. I don't understand why the same can't be done in Canada. Extraordinary measures are being taken for vaccines. I think it is reasonable to allow doctors to prescribe Ivermectin for the prevention and treatment of COVID-19. Ivermectin has been used for decades and its patent has expired, allowing any drug company to produce it.

I spoke with [REDACTED] the CPSO. She informed me that doctors can prescribe off-label, but in the case of Ivermectin they cannot prescribe prophylactically because of potential supply shortages.

[REDACTED] Given the mounting evidence, it seems obvious to me that Ivermectin will become one of the keys to getting this pandemic under control, so that we can start living again.

Thank you for taking the time to address my question. I look forward to hearing from you.

Regards,

[REDACTED]

----- Forwarded message -----

From: [REDACTED]
Date: Tue, Feb 2, 2021 at 4:49 PM
Subject: Re: Correction: How can Ivermectin supply be increased so doctors can prescribe off-label
To: [REDACTED]

Hi [REDACTED]

Thank you for your email. I will contact Health Canada.

It has been an interesting journey. Health Canada sent me an email that off-label prescriptions are handled by the Ontario Ministry of Health. The Ontario Ministry of Health told me my doctor is not able to prescribe Ivermectin, not because of off-label regulations, but because of supply issues. They asked me to contact you. Now I am back to Health Canada. Hopefully they will be my last stop.

Take care,

Jim Naar

On Tue, Feb 2, 2021 at 4:16 PM [REDACTED]
[REDACTED] wrote:

Hi [REDACTED]

Thank you for your email which was forwarded to [REDACTED]

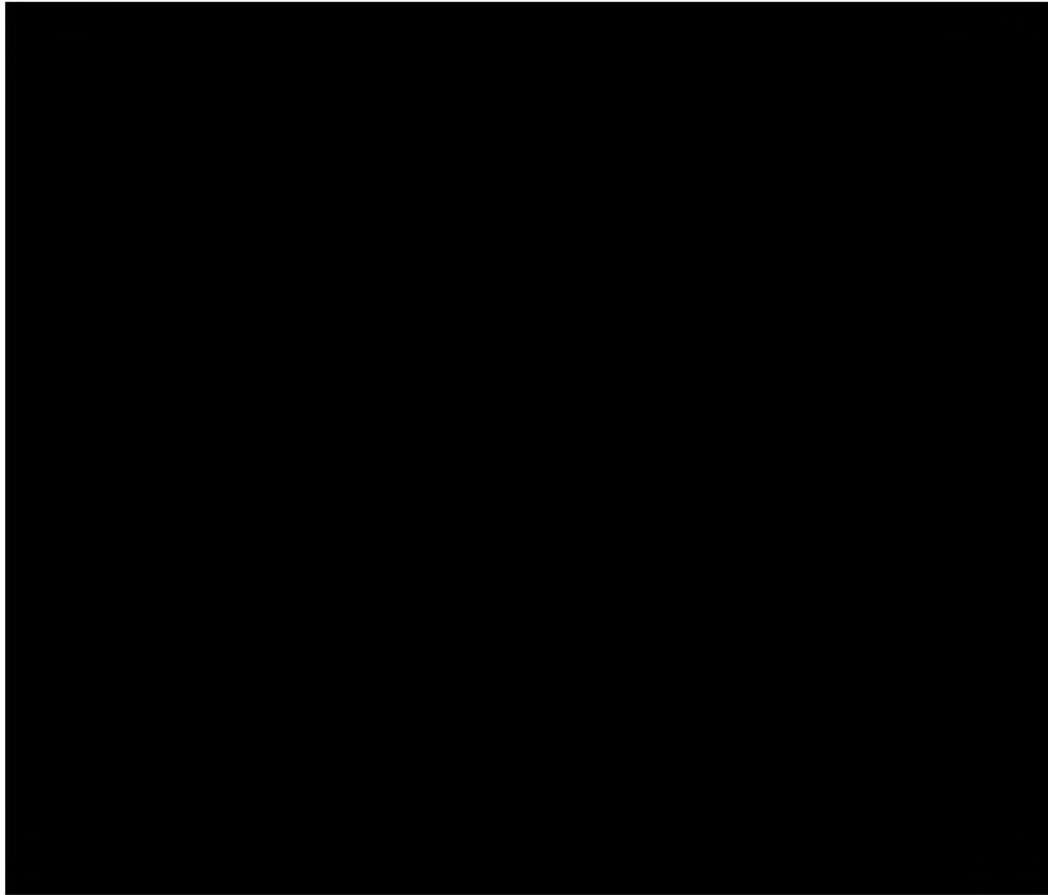
[REDACTED]

The drug supply chain is overseen at the national level by Health Canada. When a critical national drug shortage arises, Health Canada works with multiple stakeholders across the country to coordinate information sharing and identify mitigation strategies. For more information and access to additional resources, please visit Drug

Shortages in Canada. Information specifically about drugs for COVID-19 can be found on Health Canada's website along with an overview of the Exceptional importation and sale of drugs in relation to COVID-19.

To contact Health Canada, you may wish to try the Therapeutic Products Directorate of the Health Products and Food Branch: hc.prescription.drug.enquiries-renseignements.drogue.ordonnance.sc@canada.ca

Regards,



From: [REDACTED]

Sent: Tuesday, February 2, 2021 5:46 AM

To: [REDACTED]

Subject: Re: Correction: How can Ivermectin supply be increased so doctors can prescribe off-label

[EXTERNAL EMAIL] DO NOT CLICK links or attachments unless you
recognize the sender and know the content is safe.

Good Morning,

When can I expect a response?

Thank you, and have a good day.

On Sat, Jan 30, 2021 at 4:44 PM [REDACTED] wrote:

Hi Again,

I just wanted to clarify that I did not mean to say that Ivermectin has been used to treat COVID-19 for decades, but that Ivermectin has been used for decades, to treat 100's of millions people.

Thanks again for your time.

Regards,

On Sat, Jan 30, 2021 at 8:46 AM [REDACTED] wrote:

Hello,

Hope things are going well considering all that is going on.

I would like doctors in Ontario to be able to prescribe Ivermectin off-label for the prevention and treatment of COVID-19. How can the supply in Canada be increased?

I spoke with [REDACTED] from the CPSO. She informed me that doctors can prescribe off-label, but in the case of Ivermectin they cannot because of potential supply shortages. I asked how supply gets increased. She directed me to you.

[REDACTED] Given the mounting evidence, it seems obvious to me that Ivermectin will become one of the keys to getting this pandemic under control, so that we can start living again.

Requester agreed to
Remove 3rd Party Info

Countries around the world are making Ivermectin available to its citizens. I don't understand why the same can't be done in Canada. Extraordinary measures are being taken for vaccines. I think it is reasonable to allow doctors to prescribe Ivermectin, which has been used for decades, for the prevention and treatment of COVID-19.

Thank you for taking the time to address my question. I look forward to hearing from you.

Regards,

A black rectangular box redacting the signature of the sender.

From: Mineau, Philippe (HC/SC)
Sent: 2021-05-28 4:39 PM
To: Phillips, Allison (HC/SC)
Subject: RE: [REDACTED]

Ok thank you so much Allison,
P

From: Phillips, Allison (HC/SC) <allison.phillips@canada.ca>
Sent: 2021-05-28 4:38 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: [REDACTED]

Hello Philippe

[REDACTED]

Allison Phillips
(she | elle)
Counsel / Avocate
Legal Services / Services Juridiques
Health Canada / Santé Canada
Ottawa ON
Telework – Télétravail : 613-818-8406
allison.phillips@canada.ca

Solicitor-client privileged

From: Dufresne, Robert (HC/SC) <robert.dufresne@canada.ca>
Sent: 2021-05-26 5:43 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Phillips, Allison (HC/SC) <allison.phillips@canada.ca>
Subject: RE: [REDACTED]

Bonjour Philippe,

[REDACTED]

Regards,

Robert

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-05-26 3:30 PM
To: Dufresne, Robert (HC/SC) <robert.dufresne@canada.ca>
Subject: [REDACTED]

Hi there Robert,

[REDACTED]

P

Context:

[REDACTED]

ATIA - 19(1)

ATIA - 23

From: Mineau, Philippe (HC/SC)
Sent: 2021-06-07 11:45 AM
To: Phillips, Allison (HC/SC)
Cc: Dufresne, Robert (HC/SC)
Subject: RE: [REDACTED]

Hi there Allison,

[REDACTED]

All the best,
P

From: Phillips, Allison (HC/SC) <allison.phillips@canada.ca>
Sent: 2021-06-02 1:41 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Dufresne, Robert (HC/SC) <robert.dufresne@canada.ca>
Subject: RE: [REDACTED]

Hello Philippe

[REDACTED]

Allison Phillips
(she | elle)
Counsel / Avocate
Legal Services / Services Juridiques
Health Canada / Santé Canada
Ottawa ON
Telework – Télétravail : [REDACTED]

ATIA - 19(1)

ATIA - 23

allison.phillips@canada.ca

Solicitor-client privileged

From: Phillips, Allison (HC/SC)
Sent: 2021-06-01 12:31 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: [REDACTED]

Hello Philippe

[REDACTED]

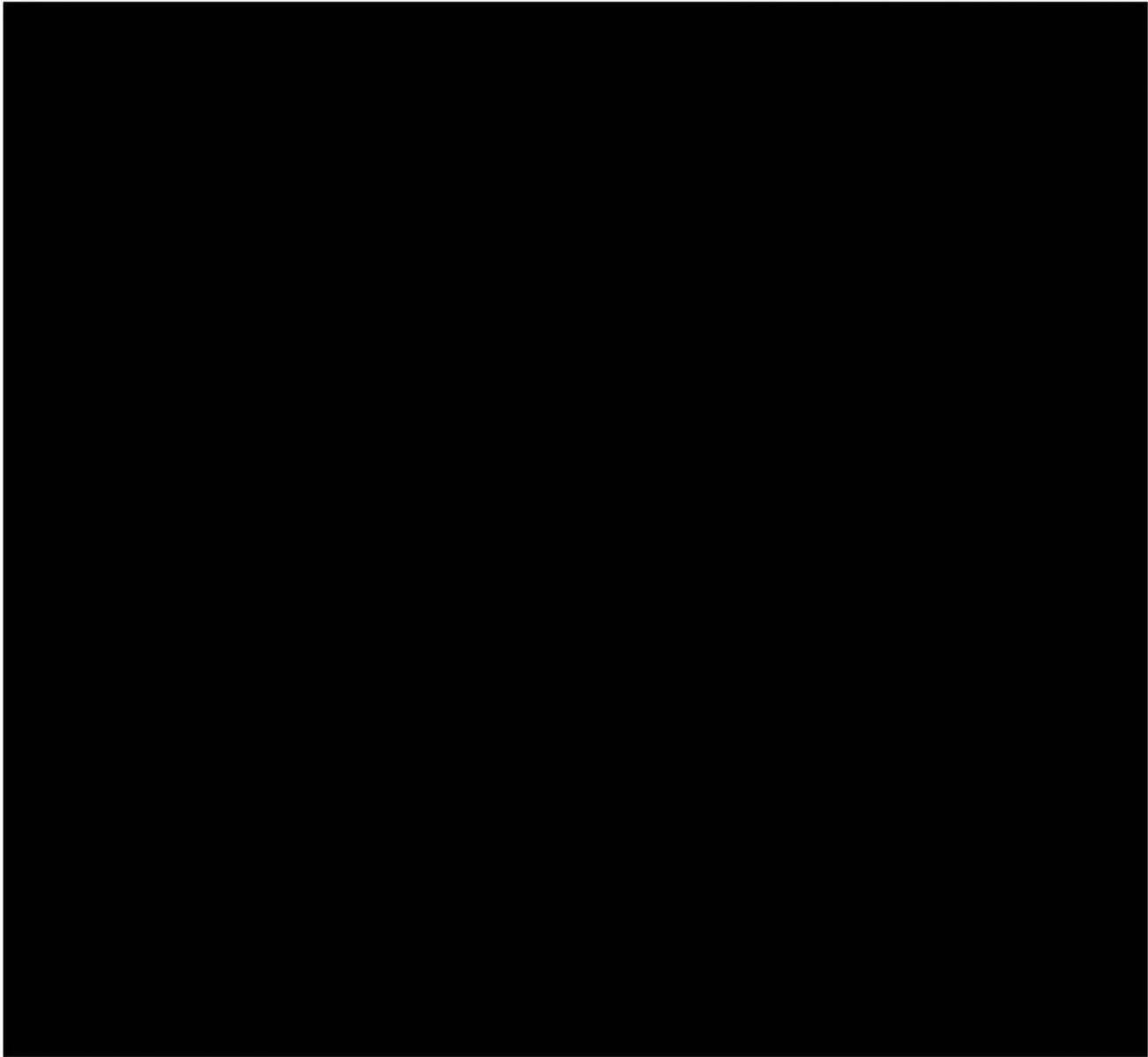
Allison Phillips
(she | elle)
Counsel / Avocate
Legal Services / Services Juridiques
Health Canada / Santé Canada
Ottawa ON
Telework – Télétravail : [REDACTED]
allison.phillips@canada.ca

Solicitor-client privileged

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-05-31 4:36 PM
To: Phillips, Allison (HC/SC) <allison.phillips@canada.ca>
Subject: RE: [REDACTED]

Hi there Allison,

[REDACTED]




Hope this helps!

P


From: Phillips, Allison (HC/SC) <allison.phillips@canada.ca>

Sent: 2021-05-31 10:21 AM

To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>

Subject: RE: 


Hello Philippe






Allison Phillips
(she | elle)
Counsel / Avocate
Legal Services / Services Juridiques
Health Canada / Santé Canada
Ottawa ON
Telework – Télétravail : 
allison.phillips@canada.ca

Solicitor-client privileged


From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-05-28 4:39 PM
To: Phillips, Allison (HC/SC) <allison.phillips@canada.ca>
Subject: RE: 



P

From: Phillips, Allison (HC/SC) <allison.phillips@canada.ca>
Sent: 2021-05-28 4:38 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: 

Hello Philippe



Allison Phillips
(she | elle)
Counsel / Avocate
Legal Services / Services Juridiques
Health Canada / Santé Canada
Ottawa ON
Telework – Télétravail : 
allison.phillips@canada.ca

Solicitor-client privileged

From: Dufresne, Robert (HC/SC) <robert.dufresne@canada.ca>
Sent: 2021-05-26 5:43 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Phillips, Allison (HC/SC) <allison.phillips@canada.ca>
Subject: RE: [REDACTED]

Bonjour Philippe,

[REDACTED]

Regards,

Robert

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-05-26 3:30 PM
To: Dufresne, Robert (HC/SC) <robert.dufresne@canada.ca>
Subject: [REDACTED]

Hi there Robert,

[REDACTED]

P

Context:

[REDACTED]

Is(Are) exempted and/or excluded pursuant to section(s)
est(sont) exemptée(s) et/ou exclus en vertu de(s)(l')article(s)

23

The head of a government institution may refuse to disclose any record requested under this Act that contains information that is subject to solicitor-client privilege

Le responsable d'une institution fédérale peut refuser la communication de documents contenant des renseignements protégés par le secret professionnel qui lie un avocat à son client

Requester agreed to
Remove 3rd Party Info

From: Kearns-Justin, Dayna (HC/SC)
Sent: 2021-08-24 10:08 AM
To: Zayoun, Toufic (HC/SC)
Subject: RE: OPRAA for action due ASAP: [REDACTED] - Ivermectin
signage concern [REDACTED]

As discussed, some thoughts:

-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 with [REDACTED] then no action
recommended

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*. Although the [REDACTED] is mentioned for more information, we cannot establish that the billboard is associated [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

Requester agreed to
Remove 3rd Party Info

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: [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]

Requester agreed to
Remove 3rd Party Info

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] and, as such, doesn't really fall under the jurisdiction of [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 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] 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,

[REDACTED]



Requester agreed to
Remove 3rd Party Info

From: [Mineau, Philippe \(HC/SC\)](#)
Sent: 2021-02-04 1:43 PM
To: [Randall, Bruce \(HC/SC\)](#)
Subject: RE: re: Input for Ivermectin

It was very minor – it was for this line: Evidence from ~~adequately powered~~ well-designed studies is needed to determine whether ivermectin might be helpful in preventing or treating COVID-19.

P

From: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Sent: 2021-02-04 1:41 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: FW: re: Input for Ivermectin

Do you know what the change was?

From: Racicot, Christa (HC/SC) <christa.racicot@canada.ca> **On Behalf Of** HPFB Briefing / Informations DGPSA (HC/SC)
Sent: 2021-02-04 10:07 AM
To: HC.F TPD Briefing / Informations DPT F.SC <hc.tpdbriefing-informationsdpt.sc@canada.ca>
Subject: re: Input for Ivermectin

Hi Jackie,

I'm not sure if what you provided for MECS#21-000464-133 is a standard response but if it is, there was one minor change for your records.

Thanks

Christa Racicot
Question Period Co-ordinator and Editor
Assistant Deputy Minister's Office
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
Email/Courriel : christa.racicot@canada.ca

From: McLean, Martin (HC/SC)
Sent: 2021-06-22 3:21 PM
To: Arnold, Sidney (HC/SC)
Cc: BGIVD Enquiries (HC/SC)
Subject: RE: Redirect - FW: For action - FW: Change status from prescription to non-prescription

Hey Sid, reply in red text below. I thought about this one for a while and I think for now it's best to keep it fairly simply and just refer them to the guidance otherwise the response starts to get pretty long and messy. It'll be easier to give them all the info they're looking for if they come back with more specific questions that the guidance doesn't answer or provide enough clarity on. Thanks!

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: Adlani, Souad (HC/SC) <souad.adlani@canada.ca> **On Behalf Of** TPD General / Général DPT (HC/SC)
Sent: 2021-05-27 1:47 PM

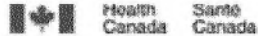
To: BGIVD Enquiries (HC/SC) <hc.bgivd.enquiries.sc@canada.ca>

Subject: FW: Redirect - FW: For action - FW: Change status from prescription to non-prescription

For bureau direct reply – Please be sure to b.c.c. this email address when sending your response which is due by June 7 , 2021.

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



De : Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>

Envoyé : 2021-05-27 13:39

À : TPD General / Général DPT (HC/SC) <hc.tpdgeneral-generalcpt.sc@canada.ca>

Objet : RE: Redirect - FW: For action - FW: Change status from prescription to non-prescription

Je suis d'accord, ici on propose de changer le statut d'ivermectin pour qu'il soit disponible sans prescription.

C'est donc pour BGIVD!

P

From: Adlani, Souad (HC/SC) <souad.adlani@canada.ca> **On Behalf Of** TPD General / Général DPT (HC/SC)

Sent: 2021-05-27 11:28 AM

To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>

Subject: TR: Redirect - FW: For action - FW: Change status from prescription to non-prescription

Rebonjour Philippe,

Je ne pense pas que la réponse standard Ivmectin serait suffisante. Qu'est-ce que tu en penses?

Merci!

De : MHPD / DPSC (HC/SC) <mhpd-dpsc@canada.ca>

Envoyé : 2021-05-27 10:17

À : TPD General / Général DPT (HC/SC) <hc.tpdgeneral-generalcpt.sc@canada.ca>

Objet : Redirect - FW: For action - FW: Change status from prescription to non-prescription

Hi,

As requested below. Redirecting for direct reply.

Thanks.

From: Lapointe2, Marc (HC/SC) <marc.lapointe2@canada.ca>
Sent: 2021-05-17 10:20 AM
To: MHPD / DPSC (HC/SC) <mhpd-dpsc@canada.ca>
Subject: RE: For action - FW: Change status from prescription to non-prescription

Please redirect to TPD.

Marc Lapointe
Marketed Pharmaceuticals Bureau
Marketed Health Products Directorate

From: MHPD / DPSC (HC/SC) <mhpd-dpsc@canada.ca>
Sent: 2021-05-13 9:58 AM
To: HC.F MHPD MPB ASSISTANTS F.SC <hc.mhpdmpbassistants.sc@canada.ca>
Subject: For action - FW: Change status from prescription to non-prescription

For direct reply.

From: Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>
Sent: 2021-04-27 2:33 PM
To: 'Kanji Nakatsu' [REDACTED]
Cc: [REDACTED]
Subject: RE: Change status from prescription to non-prescription

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: Kanji Nakatsu [REDACTED]
Sent: 2021-04-22 1:57 PM
To: Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>

Cc: [REDACTED]

Subject: Change status from prescription to non-prescription

Dear Health Canada:

[REDACTED] has determined that Canadians require greater
access to ivermectin to prevent COVID-19. [REDACTED]

[REDACTED]

[REDACTED] Accordingly, we have petitioned
the Government of Canada to make this drug more available by making it a non-prescription
medication: see petition e-3265. [REDACTED]

[REDACTED]

Thank you, [REDACTED]
Kanji Nakatsu,

[REDACTED]

Requester agreed to
Remove 3rd Party Info

From: Mineau, Philippe (HC/SC)
Sent: 2021-06-03 3:57 PM
To: Lingohr, Erika (PHAC/ASPC)
Subject: RE: Seeking evidence on Ivermectin

Much appreciated, thank you!
P

From: Lingohr, Erika (PHAC/ASPC) <erika.lingohr@canada.ca>
Sent: 2021-06-03 3:57 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: Seeking evidence on Ivermectin

Thank you very much, this is very helpful!
I'll pass along any additional info I receive in case its of use on your end.

Regards;

Erika

Erika J. Lingohr
Erika.Lingohr@Canada.ca | Tel : (519) 400-8032 (Cell)

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-06-03 2:26 PM
To: Lingohr, Erika (PHAC/ASPC) <erika.lingohr@canada.ca>
Cc: PHAC.F OCSO_ESGSecretariat / BCSC_SecrétariatGSE F.ASPC <phac.ocso_esgsecretariat-bcsc_secretariatgse.aspc@canada.ca>
Subject: RE: Seeking evidence on Ivermectin

Hey Erika,

So we still haven't received or approved any clinical trials on ivermectin, nor have we undertaken any evidence scans as we have not received a submission.

However I did ask some of our staff to do a quick review of some of the protocols that are being promoted online so that we could better respond to enquiries, and the results were the paragraphs found in the attached. It's not a comprehensive review, but it's a little summary that you may find helpful in dealing with your own correspondence. The attached is DG-approved by TPD.

Hope this helps!
P

From: Lingohr, Erika (PHAC/ASPC) <erika.lingohr@canada.ca>
Sent: 2021-06-03 10:55 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: PHAC.F OCSO_ESGSecretariat / BCSC_SecrétariatGSE F.ASPC <phac.ocso_esgsecretariat-bcsc_secretariatgse.aspc@canada.ca>
Subject: Seeking evidence on Ivermectin

Good morning Philippe;

We appear to be receiving a few more inquiries related to **Ivermectin** ourselves.

I've been asked to flag any relevant clinical trials and or evidence summaries on the topic, and related PHAC teams are supporting this search (see current overview below)

As you noted last week HC has been receiving increased interest in this – can I request that you share any key pieces you've identified with us so that we're reviewing the same info?

Should we begin receiving more formal inquiries for response I will reconnect to coordinate the best strategy.

Many thanks;

Erika

-on behalf of the OCSO and Emerging Science Group Secretariat

Erika J. Lingohr
(she | elle)

OCSO Emerging Science Secretariat / Secrétariat des sciences émergentes
phac.ocso_esgsecretariat-bcsc_secretariatgse.aspc@canada.ca
Public Health Agency of Canada | Agence de la santé publique du Canada
Erika.Lingohr@Canada.ca | Tel: (519) 400-8032 (Cell)

From: Lingohr, Erika (PHAC/ASPC)
Sent: 2021-06-03 9:02 AM
Cc: PHAC.F OCSO_ESGSecretariat / BCSC_SecrétariatGSE F.ASPC <phac.ocso_esgsecretariat-bcsc_secretariatgse.aspc@canada.ca>
Subject: FOR INPUT: Seeking evidence on Ivermectin

Good morning;

The CPHO has received inquiry relating to the use of Ivermectin as a therapeutic for COVID-19, and is currently looking for relevant evidence.

We last engaged your input on this therapeutic late April and your input was used to inform the following response statement:

“Ivermectin is a broad-spectrum anti-parasitic agent authorized and approved by HC for human and veterinary applications to treat parasitic infections. At this time, HC has not authorized its use for the treatment of COVID-19. On March 31, 2021, the WHO issued a statement on ivermectin advising against its use outside of clinical trials, stating the current evidence was inconclusive. The manufacturer, Merck, also issued a statement against the use of ivermectin for the treatment of COVID-19.”

“In summary, there is currently no robust evidence at this time to suggest that ivermectin, colchicine, or vitamin D supplementation provides clinical benefit for the treatment or prevention of COVID-19, particularly in the Canadian context. Please be assured that PHAC is actively monitoring emerging evidence of clinical efficacy and safety on novel and repurposed therapeutics for COVID-19; and makes recommendations based on findings from high quality evidence on an ongoing basis.”

Lisa (Knowledge Synthesis)/ Joseph (Therapeutics)

- **Are you aware of any recent, high quality evidence reviews that can also be shared on this topic?** (See the early April review by COVIDEND below)
- **Any additional input/thoughts on the efficacy?**
- **Any relevant clinical trials in progress that we should be keeping our eyes on?**
- **Any significant updates to the messaging above should we subsequently be asked to provide**

COVID-END summary of quality evidence summaries on the topic as of April 8: “What is the best-available evidence about the use of colchicine and ivermectin for COVID-19” that found:

- the effects of using ivermectin as a prophylactic treatment for COVID-19 are uncertain (McMaster/BMJ; site last checked 5 April 2021);
- the effects of ivermectin to treat COVID-19 patients are also uncertain (McMaster/BMJ; site last checked 5 April 2021);
- the effects of using ivermectin with iota-carrageenan as a prophylactic treatment for COVID-19 are uncertain (McMaster/BMJ; site last checked 5 April 2021);
- adding ivermectin to standard care may reduce all-cause mortality and may have little or no difference on clinical improvement, whereas the risk of adverse events is uncertain (COVIDNMA; site last checked 5 April 2021);
- the effects of adding ivermectin + doxycycline to standard care are uncertain (COVID-NMA; site last checked 5 April 2021);
- synthesis findings are pending for an evaluation of ivermectin + doxycycline vs hydroxychloroquine + azithromycin (COVID-NMA; site last checked 5 April 2020); and

- results from the only four RCTs classified as having a low risk of ivermectin may not significantly reduce mortality and probably does not improve time to symptom resolution (PAHC/L*VE; site last checked 8 April 2021)

Thanks in advance for your input;

Erika

-on behalf of the OCSO and the PHAC Evidence Group

Erika J. Lingohr

(she | elle)

PHAC Evidence / ASPC Données Probantes

phac.ocsoevidence-bcscdonneesprobantes.aspc@canada.ca

Office of the Chief Science Officer | Bureau du conseiller scientifique en chef

Public Health Agency of Canada | Agence de la santé publique du Canada

Erika.Lingohr@Canada.ca | Tel : (519) 400-8032 (Cell)

From: St-Amand, Carole (HC/SC)
Sent: 2021-05-10 12:04 PM
To: McRae, Kim (HC/SC)
Cc: Hollett, Linsey (HC/SC); Godard, Kim (HC/SC); McLaughlin, Jenny (HC/SC);
Mahdi, Jonathan (HC/SC)
Subject: RE: TO ACTION: DM Bilat Note

Hi Kim,

See edits below in your email.

I'm providing an entry for Ivermectin but Linsey had indicated to Jon/myself this morning that she would like more info on this product from our shortages team and would raise it with Stefania tomorrow once she had more info. I will leave it to you to decide if it should be held back or not.

Ivermectin (Covid-related) - *NEW

Ivermectin is an anti-parasitic, used to treat Strongyloides, a parasitic infection. Strongyloides infects 1 in 9 people from certain geographic regions (South-East Asia, South and Central America, sub-Saharan Africa and the Philippines). Most infections are asymptomatic and most people do not know they are infected.

Merck, the sole MAH, is reporting a shortage of Ivermectin with an estimated end date of December 31, 2021 due to increase in demand. There have been media reports regarding Ivermectin as a potential treatment for COVID-19. On March 31, 2021, the WHO issued a [statement](#) indicating that the current evidence on the use of ivermectin to treat COVID-19 patients is inconclusive. [REDACTED]

[REDACTED]

[REDACTED]

From: McRae, Kim (HC/SC) <kim.mcrae@canada.ca>
Sent: 2021-05-10 10:27 AM
To: St-Amand, Carole (HC/SC) <carole.st-amand@canada.ca>; Mahdi, Jonathan (HC/SC) <jonathan.mahdi@canada.ca>

ATIA-14(a)

Cc: Hollett, Linsey (HC/SC) <linsey.hollett@canada.ca>; Al-Hakim, Rosol (HC/SC) <rosol.al-hakim@canada.ca>

Subject: RE: TO ACTION: DM Bilat Note

Importance: High

Hi Carole,

Stefania has asked for a couple updates to the DM bilat note (flagged in blue highlight). Can you provide ASAP?

1. Propofol (**UPDATE**)

[REDACTED] of an urgent need for 50ml format propofol for the treatment of COVID-19 patients. The Critical Drug Reserve only has the 20ml format currently available. [REDACTED]

ROEB reached out to [REDACTED] regarding the availability of foreign supply. [REDACTED]

ROEB has reached out to other Market Authorization Holders for updates on supply. Among others, [REDACTED]

As of April 26th [REDACTED]

[REDACTED] all PTs are aware of this product being available and no others will be purchasing, indicating they have sufficient supplies.

NEED LATEST INFO [REDACTED]

2. Ongoing COVID-19 situation in India (**NEW**)

A number of initiatives are currently underway to assess the potential impact of the COVID-19 situation in India on the Canadian drug supply. Group Purchasing Organizations (GPOs) and the [REDACTED] are surveying their vendors/ members to gain additional intelligence. A short list of drugs of immediate concern has been developed (Tier 3, CDR, etc.) and information on DEL holders is being compiled. A DEL Bulletin will be sent to DEL holders reminding them of their reporting obligations related to shortages and encouraging a particular focus on anticipated shortages.

Requester agreed to
Remove 3rd Party Info

In the immediate term, work is underway to identify and address supply risks related to those critical drugs on our shortlist. Based on the information received from DEL holders, additional outreach will be undertaken for those companies on the short list of critical drugs. The information collected will also inform actions required to secure additional supply if necessary.

In the short-medium term, work will continue with GPOs and industry associations to share information in order to gain a better sense of what the overall potential impact on Canadian drug supply may be. We will monitor any responses or industry outreach generated by the DEL bulletin and work [REDACTED] on a longer-term plan to address identified risks. I will keep you apprised of developments. [REDACTED]

[REDACTED]

Thanks,
Kim

From: St-Amand, Carole (HC/SC) <carole.st-amand@canada.ca>
Sent: 2021-05-07 5:13 PM
To: McRae, Kim (HC/SC) <kim.mcrae@canada.ca>
Cc: Hollett, Linsey (HC/SC) <linsey.hollett@canada.ca>; Al-Hakim, Rosol (HC/SC) <rosol.al-hakim@canada.ca>
Subject: RE: TO ACTION: DM Bilat Note

Hi Kim

Please find attached the HPCD input for the DM bilat note.

Have a good weekend,

Carole

From: McRae, Kim (HC/SC) <kim.mcrae@canada.ca>
Sent: 2021-05-05 1:38 PM
To: Proulx, Julien (HC/SC) <julien.proulx@canada.ca>; Glen, Melissa (HC/SC) <melissa.glen@canada.ca>; Cameron, Shelley (HC/SC) <shelley.cameron@canada.ca>; Groison, Katherine (HC/SC) <katherine.groison@canada.ca>; Fontaine, Maryse (HC/SC) <maryse.fontaine@canada.ca>; Denault, Ronald (HC/SC) <ronald.denault@canada.ca>; Butz, Vicky (HC/SC) <vicky.butz@canada.ca>; St-Amand, Carole (HC/SC) <carole.st-amand@canada.ca>; Mahdi, Jonathan (HC/SC) <jonathan.mahdi@canada.ca>; Lind, Rebecca (HC/SC) <rebecca.lind@canada.ca>; Al-Hakim, Rosol (HC/SC) <rosol.al-hakim@canada.ca>; Sklepowich, Mariana (HC/SC) <mariana.sklepowich@canada.ca>; O'Leary, Rick (HC/SC) <rick.oleary@canada.ca>; Akins, Janet (HC/SC) <janet.akins@canada.ca>; Adams, Courtney (HC/SC) <kourtney.adams@canada.ca>
Cc: McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@canada.ca>; McEnaney, Jennifer (HC/SC)

<jennifer.mcenaney@canada.ca>; Huang, Catherine (HC/SC) <catherine.huang@canada.ca>; Power2, Katherine (HC/SC) <katherine.power2@canada.ca>

Subject: TO ACTION: DM Bilat Note

Importance: High

Greetings!

Please find attached a draft outline of this weeks DM bilat note. I have also attached the note that was sent up last time for info.

Stefania's next bilat with Harpreet is on Thursday, May 13th. A few new items have been added, so please read carefully.

Our note will be due to DMO Monday at noon. In order to provide time to pull together all the updates and for Stefania to review, please send your DG-approved input to myself (kim.mcrae@canada.ca) and copy the generic ROEB ADMO account (hc.roebadmo-bsmadgoral.sc@canada.ca) **no later than noon on Friday.**

Don't hesitate to reach out if you have any questions at all.

Thanks,
Kim

From: Schmidt, Stephanie (HC/SC)
Sent: 2021-09-01 1:47 PM
To: Kearns-Justin, Dayna (HC/SC); Zayoun, Toufic (HC/SC); Lin, Mimi (HC/SC)
Cc: Lejmi Mrad, Rim (HC/SC); Roy, Christophe (HC/SC); Musende, Alain (HC/SC)
Subject: RE: Update RE: Retraction of Referral to ROEB RE: OPRAA for action due ASAP: [REDACTED]
[REDACTED] - Ivermectin signage concern [REDACTED]

Hello Dayna,

This works very well for us!

That is correct: we anticipate a response by September 02, 2021

We will keep you informed as to what develops.

Many thanks, and until soon,
Stephanie

Requester agreed to
Remove 3rd Party Info

From: Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Sent: 2021-09-01 1:25 PM
To: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@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>; Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Subject: RE: Update RE: Retraction of Referral to ROEB RE: OPRAA for action due ASAP: [REDACTED]
[REDACTED] Ivermectin signage concern [REDACTED]

Hi Stephanie,

Thanks for sharing the information below. Would it be possible to wait for a response to the letter STARS sent to Magnetsigns? This information would be helpful to determine the need for ROEB to follow on the confirmation of the signage removal, and what that potential follow up would entail.

Based on the letter, a response is expected by tomorrow, correct?

If in agreement, we'll wait for another update from you after tomorrow.

Thanks,
Dayna

From: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>
Sent: 2021-09-01 10:29 AM
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>; Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Subject: Update RE: Retraction of Referral to ROEB RE: OPRAA for action due ASAP: [REDACTED]
[REDACTED] Ivermectin signage concern [REDACTED]

Hello Toufic, Dayna, Mimi, and ROEB Colleagues,

I would like to share some additional information with you about the Ivermectin signage concern we discussed last week.

We have since drafted and sent a regulatory letter to [REDACTED] the representative for Magnetsigns in Winkler, Manitoba (see attached, for your reference). Magnetsigns appears to be the company responsible for the Ivermectin signs in this province, but we remain unaware of the actual entity that ordered them. We are expecting an acknowledgement imminently and will inform you of any correspondence we receive.

Moreover, Alain was expecting a return call from [REDACTED] but had not received one by the time [REDACTED]. Another agent at Magnetsigns [REDACTED]

If possible, could ROEB confirm that the billboards in Winkler and area have been removed?

Please let us know if you have any additional questions.

Many thanks to you all for your collaboration.

Sincerely,
Stephanie

Requester agreed to
Remove 3rd Party Info

From: Schmidt, Stephanie (HC/SC)

Sent: 2021-08-30 10:27 AM

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

Subject: Retraction of Referral to ROEB RE: OPRAA for action due ASAP; [REDACTED]
[REDACTED] - Ivermectin signage concern [REDACTED]

Hello Toufic, Dayna, Mimi, and ROEB Colleagues,

Thank you for your time last week in discussing this issue.

We have since uncovered additional information in past complaints about the signage company responsible for the "Ivermectin and COVID-19" billboards in Manitoba.

Alain [REDACTED] contacted the company late last week.

As such, we would like to retract our referral to your group, as we 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.

Please let us know if you require any additional information.

With kind regards,
Stephanie

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 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

Requester agreed to
Remove 3rd Party Info

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

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 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] 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 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.

██████████ 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: Mineau, Philippe (HC/SC)
Sent: 2021-09-01 11:02 AM
To: Lin, Mimi (HC/SC); Bellefeuille, Aldege (HC/SC)
Cc: Badenduck, Lucas (HC/SC); BMS ORM Risk / BSM BGR
Risue (HC/SC); Dinakaran, Deborah (HC/SC); MacKay, Ian
(HC/SC); Chang, Vivian (HC/SC); Peate, Jaspyn (HC/SC);
Legare, Carole (HC/SC); Keene, Daniel (HC/SC); Chagnon,
Helene (HC/SC); hc.compliance.vet.conformite.sc@canada.ca;
Kearns-Justin, Dayna (HC/SC)
Subject: RE: URGENT: For Approval - PA - Do not use ivermectin for
treatment of COVID-19

I believe the PA is now live? I saw the tweet went out yesterday... (1) Health Canada and PHAC on Twitter: "#ADVISORY: #Canadians should never consume veterinary products because of potential serious risks to health. Ivermectin, an antiparasitic agent, has not been approved for use against #COVID19 and may cause serious health problems. <https://t.co/iOBtKgBIfV>" / Twitter

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Sent: 2021-08-30 2:47 PM
To: 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 Risue (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>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Chagnon, Helene (HC/SC) <helene.chagnon@hc-sc.gc.ca>; hc.compliance.vet.conformite.sc@canada.ca; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19

Hi Aldege,

Please see attached our Director Approved version of the PA. We added revisions into TPD's version (as requested).

Could you please confirm you will be seeking DG approval from VDD and my DG (HPCD)?

Thank you!

Mimi

From: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Sent: 2021-08-30 1:18 PM
To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@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 Risue

(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 Approval - PA - Do not use ivermectin for treatment of COVID-19

Hi there Aldege and Mimi,

Please see proposed TPD changes, to reflect a couple of points (TPD DG-approved):

- we are aware some doctors are prescribing ivermectin (stromectol) off-label for COVID-19 – therefore this PA should be careful to steer away from the practice of medicine
- we want to emphasize that Clinical Trials are the most appropriate route to access investigational drugs
- we want to emphasize that should a submission come in, it would be treated in the very same way as any other COVID-19 submission

Let us know what you think,

Cheers,

P

<< File: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200 (002)_TPDDGO.docx >>

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.

<< File: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200.docx >>

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-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

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-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: 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-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: 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

From: Lin, Mimi (HC/SC)
Sent: 2021-08-30 1:03 PM
To: Kearns-Justin, Dayna (HC/SC)
Subject: RE: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19
Attachments: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200 OCT (002) ML.docx

Hi Dayna,

I'm not sure how fast this is going to fly through approvals but Carole in TPD provided some great changes. I made slight revisions.

Should we seek our Director's approval on this one or wait for TPD DG input as their DGO is reviewing.

Thanks!

Mimi

From: Legare, Carole (HC/SC) <carole.legare@hc-sc.gc.ca>
Sent: 2021-08-30 12:46 PM
To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; 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>; Keene, Daniel (HC/SC) <daniel.keene@hc-sc.gc.ca>
Subject: RE: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19

Philippe,

Suggested changes (mostly reordering what is in the PA) in the attached document.
I think the emphasis should be on self-medicating. Human ivermectin would not be available without a prescription.

Carole << File: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200 OCT.docx >>

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.

<< File: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200.docx >>

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Sent: 2021-08-30 11:58 AM
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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!

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

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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>;
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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

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Sent: 2021-08-30 11:25 AM
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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.

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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!

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Sent: 2021-08-30 10:25 AM

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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-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>

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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

From: Lin, Mimi (HC/SC)
Sent: 2021-08-30 2:54 PM
To: Bellefeuille, Aldege (HC/SC)
Cc: Badenduck, Lucas (HC/SC); BMS ORM Risk / BSM BGR Risque (HC/SC); Dinakaran, Deborah (HC/SC); MacKay, Ian (HC/SC); Chang, Vivian (HC/SC); Peate, Jaspyn (HC/SC); Legare, Carole (HC/SC); Keene, Daniel (HC/SC); Mineau, Philippe (HC/SC); Chagnon, Helene (HC/SC); hc.compliance.vet.conformite.sc@canada.ca; Kearns-Justin, Dayna (HC/SC)
Subject: RE: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19

Hi Aldege,

I'm not sure who CPAB's VDD DGO contact is. Unfortunately I have not heard back from my working level colleagues at VDD.

Thanks!

Mimi

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Sent: 2021-08-30 2:49 PM
To: 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>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Chagnon, Helene (HC/SC) <helene.chagnon@hc-sc.gc.ca>; hc.compliance.vet.conformite.sc@canada.ca; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
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Hello Mimi: I've not worked with VDD so who should I send to? Thanks.

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Sent: 2021-08-30 2:47 PM
To: 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>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Chagnon, Helene (HC/SC) <helene.chagnon@hc-sc.gc.ca>; hc.compliance.vet.conformite.sc@canada.ca; Kearns-Justin, Dayna

(HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>

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

Hi Aldege,

Please see attached our Director Approved version of the PA. We added revisions into TPD's version (as requested).

Could you please confirm you will be seeking DG approval from VDD and my DG (HPCD)?

Thank you!

Mimi

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

Sent: 2021-08-30 1:18 PM

To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@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: RE: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19

Hi there Aldege and Mimi,

Please see proposed TPD changes, to reflect a couple of points (TPD DG-approved):

- we are aware some doctors are prescribing ivermectin (stromectol) off-label for COVID-19 – therefore this PA should be careful to steer away from the practice of medicine
- we want to emphasize that Clinical Trials are the most appropriate route to access investigational drugs
- we want to emphasize that should a submission come in, it would be treated in the very same way as any other COVID-19 submission

Let us know what you think,

Cheers,

P

<< File: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200 (002)_TPDDGO.docx >>

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

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

From: Mineau, Philippe (HC/SC)
Sent: 2021-08-30 2:53 PM
To: Bellefeuille, Aldege (HC/SC); Lin, Mimi (HC/SC)
Cc: Badenduck, Lucas (HC/SC); BMS ORM Risk / BSM BGR
Risqué (HC/SC); Dinakaran, Deborah (HC/SC); MacKay, Ian
(HC/SC); Chang, Vivian (HC/SC); Peate, Jaspyn (HC/SC);
Legare, Carole (HC/SC); Keene, Daniel (HC/SC); Chagnon,
Helene (HC/SC); hc.compliance.vet.conformite.sc@canada.ca;
Kearns-Justin, Dayna (HC/SC)
Subject: RE: URGENT: For Approval - PA - Do not use ivermectin for
treatment of COVID-19

VDD approval would come from their DG Marilena Bassi,
P

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Sent: 2021-08-30 2:49 PM
To: 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 Risqué
(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>;
Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Chagnon, Helene (HC/SC)
<helene.chagnon@hc-sc.gc.ca>; hc.compliance.vet.conformite.sc@canada.ca; Kearns-Justin, Dayna
(HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19

Hello Mimi: I've not worked with VDD so who should I send to? Thanks.

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Sent: 2021-08-30 2:47 PM
To: 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 Risqué
(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>;
Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Chagnon, Helene (HC/SC)
<helene.chagnon@hc-sc.gc.ca>; hc.compliance.vet.conformite.sc@canada.ca; Kearns-Justin, Dayna
(HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19

Hi Aldege,

Please see attached our Director Approved version of the PA. We added revisions into TPD's version (as requested).

Could you please confirm you will be seeking DG approval from VDD and my DG (HPCD)?

Thank you!

Mimi

From: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Sent: 2021-08-30 1:18 PM
To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@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: RE: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19

Hi there Aldege and Mimi,

Please see proposed TPD changes, to reflect a couple of points (TPD DG-approved):

- we are aware some doctors are prescribing ivermectin (stromectol) off-label for COVID-19 – therefore this PA should be careful to steer away from the practice of medicine
- we want to emphasize that Clinical Trials are the most appropriate route to access investigational drugs
- we want to emphasize that should a submission come in, it would be treated in the very same way as any other COVID-19 submission

Let us know what you think,

Cheers,

P

<< File: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200 (002)_TPDDGO.docx >>

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.

<< File: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200.docx >>

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-bsmbgrisque@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-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.lejmimirad@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>
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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-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>
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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!

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Sent: 2021-08-30 10:25 AM

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

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Sent: 2021-08-30 9:50 AM

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

Importance: High

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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.

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

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Sent: 2021-08-30 9:27 AM
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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.

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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

From: McLean, Martin (HC/SC)
Sent: 2021-08-30 12:46 PM
To: Soo, Evelyn (HC/SC)
Subject: Re: URGENT: For Approval - PA - Do not use ivermectin for treatment
of COVID-19

TY. I read it on mobile and it seems OK. I'd maybe add using ivermectin to "prevent" rather than just "treat" in a few spots but otherwise it seems OK. I've heard reports out of the US about people taking really high doses of horse paste ivermectin as a prophylactic. Not sure if we've had that issue here in Canada though

Sent from mobile device

On Aug 30, 2021, at 12:40 PM, Soo, Evelyn (HC/SC) <evelyn.soo@hc-sc.gc.ca> wrote:

It is ok, I have looked at it and will send back comments. Tx
Evelyn

From: McLean, Martin (HC/SC) <martin.mclean@hc-sc.gc.ca>
Sent: 2021-08-30 12:37 PM
To: Soo, Evelyn (HC/SC) <evelyn.soo@hc-sc.gc.ca>
Subject: Re: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19

Will look and get back ASAP, [REDACTED]
hopefully done soon

Sent from mobile device

On Aug 30, 2021, at 12:29 PM, Soo, Evelyn (HC/SC)
<evelyn.soo@hc-sc.gc.ca> wrote:

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](tel:613-941-2588) / Cel: [613-854-5378](tel: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>
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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-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>
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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-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

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!

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Sent: 2021-08-30 10:25 AM

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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>

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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

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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.lejmimirad@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.lejmimirad@hc-sc.gc.ca>

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

<ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200
(002)_TPDDGO.docx>

From: Mineau, Philippe (HC/SC)
Sent: 2021-08-30 1:22 PM
To: Legare, Carole (HC/SC)
Subject: RE: URGENT: For Review - PA - Do not use ivermectin for
treatment of COVID-19

Ok merci Carole,

We know some doctors have been prescribing off-label, so we made some more extensive edits to the PA to stay away from the practice of medicine... Because we had a bunch of extra content to add to the PA, it affected the reordering of the paragraphs as well. Merci encore!

P

From: Legare, Carole (HC/SC) <carole.legare@hc-sc.gc.ca>
Sent: 2021-08-30 1:16 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Subject: FW: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

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. We collaborated with DSU at the time.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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-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>
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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

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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>
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Hello All:

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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>

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Importance: High

Good morning Aldege,

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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,
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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: MacKay, Ian (HC/SC)
Sent: 2021-08-30 12:10 PM
To: Vivian Chang
Subject: Re: URGENT: For Review - PA - Do not use ivermectin for
treatment of COVID-19

Check the facts [REDACTED]

Requester agreed to
Remove 3rd Party Info

Hi folks. I'm not back at work yet but thought I should weigh in on this given the
significance of the story in the US and beyond.

Mectizan is approved for sale in Canada and 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]

It's also worth noting that we heard many stories over many years of 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

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-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

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

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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>

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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.

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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>

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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

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Sent: 2021-08-30 10:25 AM

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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.

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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!

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Sent: 2021-08-30 9:31 AM

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justin@hc-sc.gc.ca>

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To: [Bellefeuille, Aldege \(HC/SC\)](#); [Nahum, Marilyne \(HC/SC\)](#); [BMS ORM Risk / BSM BGR Risque \(HC/SC\)](#); [Dinakaran, Deborah \(HC/SC\)](#); [Badenduck, Lucas \(HC/SC\)](#); [Chagnon, Helene \(HC/SC\)](#); hc.compliance.vet.conformite.sc@canada.ca
Cc: [Schmidt, Stephanie \(HC/SC\)](#); [Lejmi Mrad, Rim \(HC/SC\)](#); [Kearns-Justin, Dayna \(HC/SC\)](#)
Subject: RE: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Thanks Aldege!

I've added our VDD colleagues to keep them informed.

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Sent: 2021-08-30 11:51 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>
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Subject: RE: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Thanks, Mimi. We can adjust the messaging.

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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>
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A2021000997](mailto:bmsormrisk-</p></div><div data-bbox=)

bmsbgrisque@hc-sc.gc.ca; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>;
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Santé Canada / Gouvernement du Canada

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

From: Mineau, Philippe (HC/SC)
Sent: 2021-08-30 11:58 AM
To: Lin, Mimi (HC/SC); Bellefeuille, Aldege (HC/SC)
Cc: Badenduck, Lucas (HC/SC); BMS ORM Risk / BSM BGR
Risque (HC/SC); Dinakaran, Deborah (HC/SC); MacKay, Ian
(HC/SC); Chang, Vivian (HC/SC); Peate, Jaspyn (HC/SC);
Legare, Carole (HC/SC); Keene, Daniel (HC/SC)
Subject: RE: URGENT: For Review - PA - Standard response Do not
use ivermectin for treatment of COVID-19
Attachments: COVID - Ivermectin - Direct Reply.docx

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

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>

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-bmsbgrisque@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>

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>

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

From: [Mineau, Philippe \(HC/SC\)](#)
Sent: 2021-06-14 10:29 AM
To: [Randall, Bruce \(HC/SC\)](#)
Subject: RE: URGENT ACTION REQUEST - Petition 432-01030

Ok sounds good, I'll add the following paragraph (used in previous correspondence) and move up for ADMO review:

Furthermore, there are serious risks associated with ivermectin interacting with other commonly used medications, such as blood-thinners, which raises concerns about whether it would be safe in a non-prescription setting where a physician isn't providing oversight over potential risks and complications. Therefore, at this time, it would be inappropriate to remove this product from the Prescription Drug List.

P

From: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Sent: 2021-06-11 5:35 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: URGENT ACTION REQUEST - Petition 432-01030

At this time, Health Canada does not intend to change the status of ivermectin from prescription to non-prescription. Such status changes are generally initiated by a manufacturer filing an application to Health Canada to seek a switch from prescription to Over-The-Counter status. Such applications must be supported by evidence to demonstrate that the drug and its conditions of use remain safe and effective in a self-care environment. As ivermectin has not been authorized as a prescription drug for use in COVID-19, its suitability for use as a self-care product has not been established. Furthermore, no manufacturers of ivermectin has made an application for this drug to be changed to non-prescription status.

Thanks Phil, in the above I would suggest that we indicate why at this time it's approved use and safety profile do not make it suitable in the OTC space either.

Thanks,
Bruce

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-06-11 2:27 PM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Subject: FW: URGENT ACTION REQUEST - Petition 432-01030

Hey Bruce, for approval (due to PPIAD Wednesday next week),

This is the response to the parliamentary petition on ivermectin. Evelyn added reference to the McMaster recommendations on ivermectin, as further shoring up of our story,

Let me know what you think,

Cheers!

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

From: [Soo, Evelyn \(HC/SC\)](#)
Sent: 2021-06-11 12:41 PM
To: [Mineau, Philippe \(HC/SC\)](#); [McLean, Martin \(HC/SC\)](#)
Cc: [Renart-McGowan, Isabel \(HC/SC\)](#); [Randall, Bruce \(HC/SC\)](#); [Kukulski, Filip \(HC/SC\)](#)
Subject: RE: URGENT ACTION REQUEST - Petition 432-01030
Attachments: 432-01030 HC Response_ES_FK.docx

Hi Philippe

Please find attached our proposed response to the Parliamentary Petition for ivermectin.

We would be happy to answer any questions you may have. On another note, given the increase in questions/enquiries on ivermectin, are we able to revisit the possibility of a HC statement on this?

Cheers

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).

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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

From: Legare, Carole (HC/SC)
Sent: 2021-06-10 4:04 PM
To: Soo, Evelyn (HC/SC)
Subject: RE: URGENT ACTION REQUEST - Petition 432-01030
Attachments: [REDACTED] STROMECTOL® (ivermectin) use
During the COVID-19 Pandemic.pdf

Hi Evelyn,

We have not received any application for the use of ivermectin in a clinical trial. The SAP has received a few calls from patients and physicians who were unaware that it was now marketed. We know that some pharmacies had stocked up on ivermectin because of the pandemic, which has put a strain on the supply. [REDACTED]

The COVID-END website from McMaster provides evidence-based recommendations and their conclusion on the effect of ivermectin (17th report from the top) is that depending on the endpoint, it makes no difference or the effect is uncertain. <https://www.mcmasterforum.org/networks/covid-end/resources-specific-to-canada/for-decision-makers/scan-evidence-products>
Finally, a recent publication in the BMJ concluded "research related to ivermectin in COVID-19 has serious methodological limitations resulting in very low certainty of the evidence"
<https://ebm.bmj.com/content/early/2021/05/26/bmjebm-2021-111678>

Hope this helps

Carole

Requester agreed to
Remove 3rd Party Info

From: Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>
Sent: 2021-06-10 3:17 PM
To: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Subject: FW: URGENT ACTION REQUEST - Petition 432-01030

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
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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

Simard, Chris (HC/SC)

From: Kearns-Justin, Dayna (HC/SC)
Sent: 2021-08-25 4:36 PM
To: Zayoun, Toufic (HC/SC)
Cc: Simard, Chris (HC/SC)
Subject: RE: DIRECTOR Caretaker Sensitivity File - OPRAA for action due ASAP: [REDACTED]
[REDACTED] - Ivermectin signage concern [REDACTED] - August 24, 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 website [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.

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.
- HPCEU to flag to CPAB the potential of a PA (if needed)

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 on the [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 advertising

Anything else?

Requester agreed to
Remove 3rd Party Info

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]



- 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 [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.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 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

Requester agreed to
Remove 3rd Party Info

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

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)

ATIA - 19(1)

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@hc-sc.gc.ca / renseignements.droque.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 [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]
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

ATIA - 19(1)



From: [Kukulski, Filip \(HC/SC\)](#)
Sent: 2021-07-08 8:00 AM
To: [Soo, Evelyn \(HC/SC\)](#)
Subject: RE: For expert review: Ivermectin evidence brief
Attachments: COVID-19_Ivermectin_EvidenceBrief_Ref_2021_06_23_Clean - FK.docx

Hi Evelyn,

I have read the document and agree with the review conclusions. I only have a few minor comments (please see attached file).

Thank you for the opportunity to comment on this.

Filip

From: Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>
Sent: 2021-07-07 5:34 PM
To: Kukulski, Filip (HC/SC) <filip.kukulski@canada.ca>
Subject: Fwd: For expert review: Ivermectin evidence brief

Can you take a look also at this?

Thanks so much
Evelyn

Evelyn C Soo, PhD
Director, Health Products and Food Branch
Health Canada / Government of Canada
evelyn.soo@canada.ca / Tel: [613-941-2588](tel:613-941-2588) / Cel: [613-854-5378](tel: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](tel:613-941-2588) / Tél. cell: [613-854-5378](tel:613-854-5378)

Begin forwarded message:

From: "Cornelisse, Mette (PHAC/ASPC)" <mette.cornelisse@canada.ca>
Date: July 7, 2021 at 5:04:23 PM EDT
To: "Soo, Evelyn (HC/SC)" <evelyn.soo@canada.ca>
Cc: "Mineau, Philippe (HC/SC)" <philippe.mineau@canada.ca>, "Janicki, Rachelle (PHAC/ASPC)" <rachelle.janicki@canada.ca>, "Lingohr, Erika (PHAC/ASPC)" <erika.lingohr@canada.ca>
Subject: For expert review: Ivermectin evidence brief

Good afternoon,

As part of my team's role in the COVID response, we are involved with the Emerging Science Group and coordinate expert reviews of new evidence briefs written by the team. An evidence brief on ivermectin has been developed, as Erika noted below, we thought you may be well positioned to review this one.

We would greatly appreciate your feedback on this evidence brief. If you are able to provide comments by EOD Thursday, it would be much appreciated, so we can include it in Friday's weekly evidence tracker.

Apologies in advance for the short turn around time. Please let me know if you will be able to provide feedback within this timeframe.

Thanks so much!

Mette

From: Wang, Ming-Dong (HC/SC) on behalf of DAT / EAD (HC/SC)
Sent: 2021-03-24 2:46 PM
To: Ferrier, Sylvie (HC/SC); DAT / EAD (HC/SC)
Cc: Sleno, Rory (HC/SC)
Subject: RE: Priority: IQVIA data request for ivermectin

Hi Sylvie:

Rory has provided quarterly info, I just added the annual info, and the market share info calculated based on the number of total prescriptions

I agree with your following statement, yes, IQVIA data does not include the data information for veterinary drugs.

Do you know if IQVIA collects prescription/purchasing data for veterinary drugs (with DIN)? Knowing where CDH & CompuScript extrapolates their data from (pharmacies and hospitals), I would think they do not have this data but I welcome your thoughts (and alternative exposure databases) for this question.

Ming-Dong

From: Ferrier, Sylvie (HC/SC) <sylvie.ferrier@canada.ca>
Sent: 2021-03-24 1:54 PM
To: DAT / EAD (HC/SC) <hc.dat-ead.sc@canada.ca>
Cc: Sleno, Rory (HC/SC) <rory.sleno@canada.ca>
Subject: Priority: IQVIA data request for ivermectin

Requester agreed to
Remove 3rd Party Info

Good afternoon,

Please see attached IQVIA request for ivermectin use in Canada.

A turnaround time of <24 hrs is requested as this data is related to an ongoing evaluation of a potential safety concern with ivermectin use in COVID-19.

Please do not hesitate to contact me if you have any questions or require any other information.

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: [Soo, Evelyn \(HC/SC\)](#)
Sent: 2021-06-11 12:41 PM
To: [Mineau, Philippe \(HC/SC\)](#); [McLean, Martin \(HC/SC\)](#)
Cc: [Renart-McGowan, Isabel \(HC/SC\)](#); [Randall, Bruce \(HC/SC\)](#); [Kukulski, Filip \(HC/SC\)](#)
Subject: RE: URGENT ACTION REQUEST - Petition 432-01030
Attachments: 432-01030 HC Response_ES_FK.docx

Hi Philippe

Please find attached our proposed response to the Parliamentary Petition for ivermectin.

We would be happy to answer any questions you may have. On another note, given the increase in questions/enquiries on ivermectin, are we able to revisit the possibility of a HC statement on this?

Cheers

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

From: Sun, Rong (HC/SC)
Sent: 2021-09-08 10:36 AM
To: Duguay, David (HC/SC)
Cc: HC.F MHPD Action Requests F.SC; Sleno, Rory (HC/SC)
Subject: Re: Action MPB asap: For Review: Social Media Plan – Ivermectin

Thank you, David and Rory. With Kelly now.

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.*

From: Duguay, David (HC/SC)
Sent: 2021-08-30 1:25 PM
To: Sleno, Rory (HC/SC); Ferrier, Sylvie (HC/SC)
Cc: Irfan, Nashwa (HC/SC)
Subject: RE: CV-2021-441: CV search request

Great, thanks Rory, we can keep this information if/when needed for media lines.
David

From: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>
Sent: 2021-08-30 1:19 PM
To: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>
Subject: RE: CV-2021-441: CV search request

I would say so. 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.

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 1:07 PM
To: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>
Subject: RE: CV-2021-441: CV search request

Thanks Rory for the update. Can we interpret this as “no Canadian cases of ADRs reported to CanadaVigilance with the use of ivermectin for COVID-19”?
David

From: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>
Sent: 2021-08-30 12:29 PM
To: Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>; Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>

sc.gc.ca>

Subject: FW: CV-2021-441: CV search request

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).

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: Longo, Maria (HC/SC) <maria.longo@hc-sc.gc.ca>

Sent: 2021-08-30 12:16 PM

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

Cc: Morrison, Heather (HC/SC) <heather.morrison@hc-sc.gc.ca>; Canada Vigilance (HC/SC) <canadavigilance@hc-sc.gc.ca>

Subject: FW: CV-2021-441: CV search request

Rory Sleno,

Please find attached a response on behalf of the **Canada Vigilance Program**. In order to avoid large email files, your search results are saved on the **Y:drive** at the path(s) below.

IMPORTANT: Please do not move or delete *any* of the search results provided from the folders on the ARIS Y:drive.

In response to your request dated **Aug. 30, 2021** a search of the **Canada Vigilance Program Database** was conducted.

The parameters of the **Canada Vigilance Program Database** search was as follows:

1. Reports received for **ivermectin** as a **suspected** role ;
2. **all reported adverse reactions** ;
3. Reports received and entered into the database from **Jan.1, 1965** to **Aug. 29 2021**

The summary of each of this search can be found at

[Y:\HC\HPFB\MHPD\MHPSEIB-ARIS\HEALTH RISK PROTECTION HC6\ENQUIRIES\1. Search Request Line-Listing\2. Active Ingredient E-K\Ivermectin\CV-2021-441](#)

Duplicate reports are reports related to the same patient and event received from more than one source (e.g. pharmacist and consumer). Therefore, the sum of all reports in the line listing may exceed the total number of individual patient cases.

In order to assist with the identification of duplicates please refer to the Duplicates Page of your PDF document. For an explanation of these duplicates, please refer to the **duplicate tab WI** document Y:\HC\HPFB\MHPD\MHPSEIB-ARIS\HEALTH RISK PROTECTION HC6\ENQUIRIES\1. Search Request Line-Listing\Caveat and Work Instructions\Duplicate tab WI_20140613.docx

- Please direct anyone using this information to the document **Interpretation of Adverse Reaction Line Listing Summaries** found at Y:\HC\HPFB\MHPD\MHPSEIB-ARIS\HEALTH RISK PROTECTION HC6\ENQUIRIES\1. Search Request Line-Listing\Caveat and Work Instructions\Interpretation Guide\Interpretation Line Listing_final_en 20140613.pdf

- Should you require a copy of adverse reaction reports, please send your request to the following e-mail address and include the AER numbers you require: hc.canada.vigilance.ar.request-requete.ei.sc@canada.ca

Please do not hesitate to contact me should you have any questions.

Maria

Maria Longo BscPharm, RPh

Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Health Products Surveillance and Epidemiology Bureau | Bureau de la surveillance des produits de santé et de l'épidémiologie

MHPD IDirection des produits de santé commercialisés

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

Health Canada | Santé Canada

Jeanne Mance Building | Immeuble Jeanne Mance 8th floor, Room/Pièce 806D

200 Eglantine Driveway

Pré Tunney's Pasture

Ottawa, Ontario K1A 0K9, A.L. 1908C

Facsimile | Télécopieur (613) 957-0335

From: Morrison, Heather (HC/SC) <heather.morrison@hc-sc.gc.ca>

Sent: 2021-08-30 11:43 AM

To: Longo, Maria (HC/SC) <maria.longo@hc-sc.gc.ca>

Cc: Canada Vigilance (HC/SC) <canadavigilance@hc-sc.gc.ca>; Ungureanu, Nicoleta Hosszu (HC/SC) <nicoleta.hosszuungureanu@hc-sc.gc.ca>

Subject: FW: CV-2021-441: CV search request

Hi Maria,

Can you please run this search today for Rory? Due date will be August 31, 2021. There is a communication being released today so I think they want to be prepared.

Please run the search up until yesterday even if not QC'd.

Please let me know if you have any questions/concerns.

Take care,
Heather

From: Canada Vigilance (HC/SC) <canadavigilance@hc-sc.gc.ca>
Sent: 2021-08-30 10:53 AM
To: hc.mhpdhpseb-coordinators.sc@canada.ca
Cc: Morrison, Heather (HC/SC) <heather.morrison@hc-sc.gc.ca>; Ungureanu, Nicoleta Hosszu (HC/SC) <nicoleta.hosszuungureanu@hc-sc.gc.ca>
Subject: CV-2021-441: CV search request

Hello ARMIS,

The CV# assigned is **CV-2021-441**.
The request is urgent, with a due date of September 1, 2021.

Thanks

Shun

From: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>
Sent: 2021-08-30 10:36 AM
To: Canada Vigilance (HC/SC) <canadavigilance@hc-sc.gc.ca>
Cc: Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>
Subject: CV search request

Hello,

Please find enclosed a CV research request form for an urgent search with respect to ivermectin (to support a risk communication).

Please include all case reports up to today for all AE.

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: Stankevitch, Tatiana (HC/SC)

Sent:

2021-09-15 10:42 AM

To: Mariadevasan, Andrew (HC/SC)

Subject:

RE: DIRECTOR Concurrence: CSF - Public
Enquiry - Central - Sep 14, 2021

Follow Up Flag:

Follow up

Flag Status:

Flagged

Hi Andrew,

FYI: Please send a brief summary up of the call to me and Bobbie once completed in light of the recent media attention.

Thanks,
Tatiana

From: Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>

Sent: 2021-09-15 9:26 AM

To: Stankevitch, Tatiana (HC/SC) <tatiana.stankevitch@hc-sc.gc.ca>

Cc: Mariadevasan, Andrew (HC/SC) <andrew.mariadevasan@hc-sc.gc.ca>

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

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](https://www.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: Mariadevasan, Andrew (HC/SC)
Sent: 2021-09-15 3:07 PM
To: Chiu, Bobbie (HC/SC); Stankevitch, Tatiana (HC/SC)
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Bobbie and Tatiana,

Central answered the public enquiry on the afternoon of September 15, 2021.

Enquirer: [REDACTED]

Summary of the Outcome:

- [REDACTED] confirmed she heard the two products could be acquired in Canada for personal use. [REDACTED] confirmed she lived in the United States of America.
- Inspector AM confirmed Canadian residents would need to consult with their physician in regards to obtaining the product. Inspector AM confirmed both products would be classified as prescription drugs in Canada and would require a prescription.
- Inspector AM confirmed she should seek the advice of the United States Food and Drug Administration for information on both products.
- [REDACTED] amicably ended the call upon hearing that Canadian residents required a prescription for personal use. (Additionally, call ended as I did not provide information on how to obtain product in the United States)

Aside: Information on the advisory was not provided as COVID-19 was not mentioned and individual lived in the United States.

Thanks,
Andrew

From: Chiu, Bobbie (HC/SC) <bobbie.chiu@hc-sc.gc.ca>
Sent: 2021-09-15 12:42 PM
To: Stankevitch, Tatiana (HC/SC) <tatiana.stankevitch@hc-sc.gc.ca>
Cc: Mariadevasan, Andrew (HC/SC) <andrew.mariadevasan@hc-sc.gc.ca>
Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

Hi,

Please go ahead with responding to the enquirer.

Please provide a summary of the outcome.

Thanks,
Bobbie

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Cc: Mariadevasan, Andrew (HC/SC) <andrew.mariadevasan@hc-sc.gc.ca>
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.

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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.

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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>

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Hi Ranjeet,

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Subject: RE: DIRECTOR Concurrence: CSF - Public Enquiry - Central - Sep 14, 2021

Importance: High

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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>

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Hi Ranjeet,

Central received a public enquiry in the form of a voice mail message in the afternoon of Sep 14, 2021.

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 - Information in *Ivermectin not authorized to prevent or treat COVID-19; may cause serious health problems* and the link below can be shared
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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: Sleno, Rory (HC/SC)
Sent: 2021-09-02 8:10 PM
To: Irfan, Nashwa (HC/SC); Ferrier, Sylvie (HC/SC); Duguay, David (HC/SC)
Subject: RE: Ivermectin - Advisory
Attachments: Ivermectin and COVID-19_2021-08-31.docx

Hi Nash,

Please find enclosed the up-to-date document I had presented at prioritization on Tuesday.

- 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 spring 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 [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.
 - [REDACTED]

Sylvie/David – Please make additions/modifications as you see fit.

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

Sent: 2021-09-02 7:07 PM

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

Subject: Fwd: Ivermectin - Advisory

Hi Rory and Sylvie,

Could you kindly provide me with the screening document you did for ivermectin as well as some high level bullets on what we did and found (including the info from poison control centres)?

Possible by 10 am tomorrow please?

Thx

Nash

Sent from my iPhone

Begin forwarded message:

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

Date: September 2, 2021 at 6:46:10 PM EDT

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

Cc: "Sommerer, Sophie (HC/SC)" <sophie.sommerer@hc-sc.gc.ca>

Subject: FW: Ivermectin - Advisory

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>

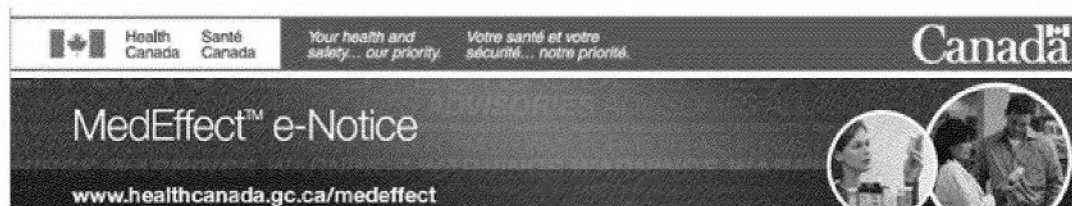
(the phrase we discussed - You are not a horse. You are not a cow.- comes from the FDA's tweet on this issue https://mobile.twitter.com/US_FDA/status/1429050070243192839)

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 page.
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

This message was automatically generated. If you have comments or questions about the program, please contact us at mhpd_dpssc@hc-sc.gc.ca.

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<http://www.hc-sc.gc.ca/dhp-mps/medeff/subscribe-abonnement/index-eng.php>

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Health professional or public advisories are made available on Health Canada's Web site on an ad hoc basis as a service to health professionals, consumers, and other interested parties. These advisories may be prepared in collaboration with Directorates of Health Canada's Health Products and Food Branch, which includes pre-market and post-market areas, as well as market authorization holders and other stakeholders.

From: [Sleno, Rory \(HC/SC\)](#)
Sent: 2021-09-03 8:27 AM
To: [Irfan, Nashwa \(HC/SC\)](#); [Ferrier, Sylvie \(HC/SC\)](#)
Cc: [Duguay, David \(HC/SC\)](#); [Soltys, Kathy \(HC/SC\)](#)
Subject: RE: Ivermectin update

I'll send a formal request today.

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: Irfan, Nashwa (HC/SC) <nashwa.irfan@hc-sc.gc.ca>
Sent: 2021-09-03 8:17 AM
To: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>
Cc: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>; Soltys, Kathy (HC/SC) <kathy.soltys@hc-sc.gc.ca>
Subject: FW: Ivermectin update

Hi Rory and Sylvie,

Thanks again for the summary and bullets provided yesterday..

Please see email from Kelly below re: follow up from the PCC...I believe that we had decided at SP no need to further do anything in that regard, but given Senior Management is interested, could we please do a follow up (understand that we will likely not get the results soon)..

Thanks
N

From: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Sent: 2021-09-03 7:17 AM
To: Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; Irfan, Nashwa (HC/SC) <nashwa.irfan@hc-sc.gc.ca>
Cc: Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
Subject: FW: Ivermectin update

Thanks again Nashwa, I have shared the info with Marilena and Manon.

Can we follow up with the poison control centres that have not yet responded back?
Best, Kelly

From: Robinson, Kelly (HC/SC)
Sent: 2021-09-03 7:13 AM
To: Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>
Cc: Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>
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 [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.

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

Requester agreed to
Remove 3rd Party Info

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

From: [Morrison, Heather \(HC/SC\)](#)
Sent: 2021-09-08 3:43 PM
To: [Duguay, David \(HC/SC\)](#)
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

Thank you, David.

Heather

From: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>
Sent: 2021-09-08 3:38 PM
To: Morrison, Heather (HC/SC) <heather.morrison@hc-sc.gc.ca>
Subject: FW: 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 Heather,
Sorry, should have copied you on the response below.
Thanks,
David

From: Duguay, David (HC/SC)
Sent: 2021-09-08 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. The

ATIA - 19(1)

ATIA - 21(1)(a)

reporter may seek information from the Canadian Poison Control Centres for cases associated with ivermectin across Canada. [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 HPSEB Management / DPSC BSPSE Gestionnaires F.SC <hc.mhpdhpsebmanagement-dpscbbspsegestionnaires.sc@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] 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 from 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

From: Duguay, David (HC/SC)
Sent: 2021-09-21 8:34 AM
To: Sleno, Rory (HC/SC); Ferrier, Sylvie (HC/SC)
Subject: RE: PC Data Ask - Ivermectin Data Request (Due: Sept. 30)

Thanks to both of you!
David

From: Bogeljic, Bojana (HC/SC) <bojana.bogeljic@hc-sc.gc.ca> **On Behalf Of** Toxicovigilance (HC/SC)
Sent: 2021-09-20 3:38 PM
To: [REDACTED]

Cc: HC.F SCU Team / Equipe UCS F.SC <hc.scuteam-equipeucs.sc@hc-sc.gc.ca>; Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>; Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>
Subject: PC Data Ask - Ivermectin Data Request (Due: Sept. 30)
Importance: High

Good afternoon,

This email is further to our discussion on Sept. 15th, where we reviewed the tables and agreed to move forward with the Ivermectin (COVID-19 Related) Data Request.

For further details, please find attached the final data request form and mock tables, and below an at-a-glance summary.

Request title	Ivermectin (COVID-19 Related) (Jan. 1st, 2020 to Sept. 15th, 2021)
Requestor	Marketed Health Products Directorate (MHPD)
Note	There are two tables: <ul style="list-style-type: none">• Table 1 – A to E (COVID-19 related ivermectin exposure cases from Jan. 2020 - Sept. 15, 2021, inclusive dates)• Table 2 – Additional Information (3 Questions)

	Please note: <ul style="list-style-type: none">• In all tables: Filter out cases where Outcome = Confirmed non exposure
Due date	Sept. 30 th , 2021 (1.5 weeks)

Thank you,

Bojana Bogeljc

Senior Advisor, Program Development/ Conseillère principale, Élaboration de programme
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

Telephone/téléphone: (613) 404-8960

E-mail/courriel: bojana.bogeljc@hc-sc.gc.ca

From: McLean, Martin (HC/SC)
To: Arnold, Sidney (HC/SC)
Cc: Durno, Laura (HC/SC); Soo, Evelyn (HC/SC); BGIVD Enquiries (HC/SC)
Subject: RE: Redirect - FW: For action - FW: Change status from prescription to non-prescription
Date: 2021-05-27 6:33:54 PM
Attachments: image001.png

Hey Sid, I think it's still us as lead given the Q is about Rx vs. OTC status but, to your point, it might not hurt to run a draft reply by BPS before sending anything back. Right now the only oral ivermectin product available is the innovator/Merk... a generic could come in for that product and apply for Rx to OTC switch but I'm not sure if this can be done via ANDS, I'd need to get BPS input on that. The "generic" may have to file as an innovator in order to do that. More to come, this one is on my list... for now [REDACTED]

Martin McLean

Associate Director
Bureau of Gastroenterology, Infection and Viral Diseases
Therapeutic Products Directorate / Health Products and Food Branch
Health Canada / Government of Canada
martin.mclean@canada.ca / Tel: 613-297-6818

Directeur associé
Bureau de la gastroentérologie et des maladies infectieuses et virales
Direction des produits thérapeutiques / Direction générale des produits de santé et des aliments
Santé Canada / Gouvernement du Canada
martin.mclean@canada.ca / Tél.: 613-297-6818

From: Arnold, Sidney (HC/SC) <sidney.arnold@canada.ca>
Sent: 2021-05-27 2:38 PM
To: McLean, Martin (HC/SC) <martin.mclean@canada.ca>
Cc: Durno, Laura (HC/SC) <laura.durno@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>; BGIVD Enquiries (HC/SC) <hc.bgivd.enquiries.sc@canada.ca>
Subject: RE: Redirect - FW: For action - FW: Change status from prescription to non-prescription

Good Afternoon;

I think this enquiry should go to BPS given the request for ivermectin to go non-prescription/generic. [REDACTED] has petitioned the House of Commons and so why has DGO not decided to play a role in responding?

Anyone's thoughts?

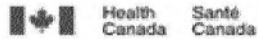
Sid

From: Adlani, Souad (HC/SC) <souad.adlani@canada.ca> **On Behalf Of** TPD General / Général DPT (HC/SC)
Sent: 2021-05-27 1:47 PM
To: BGIVD Enquiries (HC/SC) <hc.bgivd.enquiries.sc@canada.ca>
Subject: FW: Redirect - FW: For action - FW: Change status from prescription to non-prescription

For bureau direct reply – Please be sure to b.c.c. this email address when sending your response which is due by June 7 , 2021.

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



De : Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Envoyé : 2021-05-27 13:39
À : TPD General / Général DPT (HC/SC) <hc.tpdgeneral-generalcpt.sc@canada.ca>
Objet : RE: Redirect - FW: For action - FW: Change status from prescription to non-prescription

Je suis d'accord, ici on propose de changer le statut d'ivermectin pour qu'il soit disponible sans prescription.

C'est donc pour BGIVD!

P

From: Adlani, Souad (HC/SC) <souad.adlani@canada.ca> **On Behalf Of** TPD General / Général DPT (HC/SC)
Sent: 2021-05-27 11:28 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: TR: Redirect - FW: For action - FW: Change status from prescription to non-prescription

Rebonjour Philippe,

Je ne pense pas que la réponse standard Ivmectin serait suffisante. Qu'est-ce que tu en penses?

Merci!

De : MHPD / DPSC (HC/SC) <mhpd-dpsc@canada.ca>
Envoyé : 2021-05-27 10:17

À : TPD General / Général DPT (HC/SC) <hc.tpdgeneral-generalcpt.sc@canada.ca>

Objet : Redirect - FW: For action - FW: Change status from prescription to non-prescription

Hi,

As requested below. Redirecting for direct reply.

Thanks.

From: Lapointe2, Marc (HC/SC) <marc.lapointe2@canada.ca>

Sent: 2021-05-17 10:20 AM

To: MHPD / DPSC (HC/SC) <mhpd-dpsc@canada.ca>

Subject: RE: For action - FW: Change status from prescription to non-prescription

Please redirect to TPD.

Marc Lapointe
Marketed Pharmaceuticals Bureau
Marketed Health Products Directorate

From: MHPD / DPSC (HC/SC) <mhpd-dpsc@canada.ca>

Sent: 2021-05-13 9:58 AM

To: HC.F MHPD MPB ASSISTANTS F.SC <hc.mhpdmpbassistants.sc@canada.ca>

Subject: For action - FW: Change status from prescription to non-prescription

For direct reply.

From: Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>

Sent: 2021-04-27 2:33 PM

To: 'Kanji Nakatsu' <nakatsuk@queensu.ca>

Cc: David Ross <davidarossfca@gmail.com>; BK Bhagwan Vaswani <swaney557@gmail.com>

Subject: RE: Change status from prescription to non-prescription

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 | Téléimprimeur 1 800-267-1245

Government of Canada | Gouvernement du Canada

From: Kanji Nakatsu [REDACTED]
Sent: 2021-04-22 1:57 PM
To: Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>
Cc: [REDACTED]
Subject: Change status from prescription to non-pres

Requester agreed to
Remove 3rd Party Info

Dear Health Canada:

[REDACTED] has determined that Canadians require greater access to ivermectin to prevent COVID-19. This is based on its remarkable safety record during four decades of use against parasites, and its recently documented ability to protect against contracting SARS CoV-2. Unfortunately [REDACTED]

[REDACTED] If the response is positive, should I assume that Commons staff will usher this through? If they do not initiate this change, we would be interested in pursuing this change in status either as private citizens or with a generic pharmaceutical manufacturer. Should this be the case, can you instruct us regarding the procedures to follow?

Thank you, [REDACTED]
Kanji Nakatsu,
[REDACTED]

From: [Irfan, Nashwa \(HC/SC\)](#)
Sent: 2021-08-30 2:20 PM
To: [Duguay, David \(HC/SC\)](#)
Cc: [Soltys, Kathy \(HC/SC\)](#)
Subject: RE: Update: Ivermectin publication list

Fantastic...thank you so much to you and your team! I asked DGO about a status of the PA, and they have not seen it yet...I will touch base with Melanie as well a bit later if we don't hear anything..

Thanks
Nash

From: Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>
Sent: 2021-08-30 2:17 PM
To: Irfan, Nashwa (HC/SC) <nashwa.irfan@hc-sc.gc.ca>
Cc: Soltys, Kathy (HC/SC) <kathy.soltys@hc-sc.gc.ca>
Subject: FW: Update: Ivermectin publication list

Hi Nashwa,
I believe we will be in good position to review/comment draft risk communication material when they are circulated. We have updated information on literature, Canadian case reports, human product use, foreign communications (TGA also issued a piece on Aug 23). Waiting for response from Poison Control Center.
Thanks,
David

From: Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>
Sent: 2021-08-30 1:44 PM
To: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>; Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>
Subject: RE: Update: Ivermectin publication list

Bonjour David,

- 1) From the GoC Clinical Trials Database, there are no ivermectin trials being conducted in Canada (either closed or ongoing) for COVID-19. There is 1 ongoing Canadian clinical trial for an ivermectin cream (0.3%) in subjects with atopic dermatitis. If you think this information is critical, we should verify with OCT.
- 2) There are several ongoing trials on ivermectin being conducted worldwide. As you pointed out, several small studies are ongoing on clinicaltrials.gov. There is a good analysis of the ongoing studies published in the Cochrane review (<https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD015017.pub2/full>). I also found that ivermectin was recently (June 23, 2021) added to the Oxford's PRINCIPLE trial (5000+ volunteers), but I don't have any idea when this data would be available (<https://www.principletrial.org/results>). There is also an ongoing large TOGETHER trial (in Brazil) that aims to study ivermectin (<https://www.togethertrial.com/>); I was not able to find interim data published online. It seems that the principal investigator (who is affiliated with McMaster University) presented preliminary results at a NIH symposium on August 6, 2021 concluding that ivermectin had "no effect whatsoever" on the trial's outcomes

(<https://rethinkingclinicaltrials.org/news/august-6-2021-early-treatment-of-covid-19-with-repurposed-therapies-the-together-adaptive-platform-trial-edward-mills-phd-frcp/>).

- 3) The above ongoing studies are sizeable enough to shift meta-analyses (depending on magnitude of the effect, as well), but it is difficult to confidently predict their impact without an in-depth analysis of their strengths and limitations.
- 4) Beyond existing uncertainty and lack of efficacy for COVID-19 outcomes, I would say no, the Cochrane MA doesn't present any new safety concern. The Cochrane paper concludes for inpatients: "We are uncertain whether ivermectin may increase or reduce any adverse events up to 28 days" and for outpatients: "Ivermectin may have little or no effect on any adverse events up to 28 days". It is important to note that the studies I've come across do not specifically evaluate the self-directed use of ivermectin (animal or human formulation), and may not be relevant to the potential risks being considered here.

Please let me know if you have any other questions.
Sylvie

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

Sent: 2021-08-30 1:43 PM

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

Subject: RE: Update: Ivermectin publication list

1. [REDACTED]
2. Evaluated 14 studies and nothing more to say than the TGA, "This review found no evidence to support the use of Ivermectin for treating or preventing COVID-19 infection, and **noted that the evidence base is limited**".

RS

Requester agreed to
Remove 3rd Party Info

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 1:23 PM

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

Subject: RE: Update: Ivermectin publication list

Sorry, 2 more questions:

TGA issued a communication last week (Aug 23) <https://www.tga.gov.au/media-release/risks-importing-ivermectin-treatment-covid-19>

- TGA noted an increase in prescribing of ivermectin for the treatment of COVID-19

Is there a similar issue in Canada (eg when comparing prescriptions during the pandemic vs before March 2020)?

- TGA is quoting a Cochrane systematic review
<https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD015017.pub2/full>,
any new relevant safety data from this one?

Thanks,
David

From: Duguay, David (HC/SC)
Sent: 2021-08-30 1:03 PM
To: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>; Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>
Subject: RE: Update: Ivermectin publication list

Thanks Sylvie for the update.
Are we aware of ongoing studies on ivermectin in COVID-19? In Canada?
I saw several small studies on clinicaltrials.gov, not sure how/when the results would become available and what would be the potential impact on current status from meta-analyses.
David

From: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>
Sent: 2021-08-30 12:32 PM
To: Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>; Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>
Subject: RE: Update: Ivermectin publication list

Looks good to me. Thanks for the update!

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: Ferrier, Sylvie (HC/SC) <sylvie.ferrier@hc-sc.gc.ca>
Sent: 2021-08-30 12:03 PM
To: Sleno, Rory (HC/SC) <rory.sleno@hc-sc.gc.ca>; Duguay, David (HC/SC) <david.duguay@hc-sc.gc.ca>
Subject: Update: Ivermectin publication list

Hello David and Rory,

A brief update in blue... not sure if any of it will be of use at this point...

EMA cited studies in March 2021 publication (<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 STROMECTOL 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, and I only identified 4 studies that presented AEs for the ivermectin group (highlighted in blue). 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, I am fairly confident that 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 STROMECTOL includes information on the symptoms of accidental intoxication or overdose.

Recent notable studies and actions:

- Recent randomized double-blind, placebo-controlled study of 501 patients (Vallejos, J., et al. 2021, not included in above EMA summary) published on July 2, 2021 showed no statistically significant effect on preventing hospitalization of patients with COVID-19. No serious adverse events were observed in this study.
- Ripple effect of data integrity and quality:
 - Recent correction of pre-print study Elgazzar, A., et al. 2020 (included in above EMA summary) on July 14, 2021 due to expression of concern: <https://www.researchsquare.com/article/rs-100956/v4>. This study had been viewed more than 150,00 times, cited 30 times and included in a number of meta-analyses. This action led to the retraction of the RCT meta-analysis Hill, A., et al. 2021. Another RCT meta-analysis published recently (Bryant, A., et al. 2021), which found moderate certainty evidence in support of reductions in COVID-19 deaths with ivermectin, has committed to revising its conclusion if the Elgazzar study is found to be unreliable. Both of these meta analyses do not focus on safety outcomes beyond those related to COVID-19 progression.
 - Another retracted ivermectin study Patel et al. 2020 (also included in above EMA summary) associated with electronic health records from Surgisphere (previously associated with retracted HCQ study) continues to be referenced in the media.

In our PSLs RefWorks account, I did not find any new ivermectin study suggestive of any emerging adverse events beyond those that are known or related to COVID-19 progression.

Please let me know if you have any other questions.
Sylvie

From: Ferrier, Sylvie (HC/SC) <sylvie.ferrier@canada.ca>
Sent: 2021-06-18 8:47 AM
To: Duguay, David (HC/SC) <david.duguay@canada.ca>
Subject: FW: For MPB prioritization: Ivermectin publication list

Bonjour David,

Tel que discuté, voici le résumé d'articles d'ivermectin que j'ai présenté à la rencontre de priorisation du 13 avril 2021. J'inclus aussi un document qui résume les autres éléments de notre analyse (il est aussi sauvegardé sur le Y:).

Laisse moi savoir si tu as des questions

Merci
Sylvie

From: Ferrier, Sylvie (HC/SC)
Sent: 2021-03-19 4:24 PM
To: Duguay, David (HC/SC) <david.duguay@canada.ca>
Cc: Sleno, Rory (HC/SC) <rory.sleno@canada.ca>
Subject: For MPB prioritization: Ivermectin publication list

Bonjour David,

I've completed a high-level screen of the 46 papers referenced in the EMA communication for ivermectin. My preliminary thoughts ahead of the weekend:

- 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, and I only identified 4 studies that presented AEs for the ivermectin group (highlighted in blue). 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, I am fairly confident that 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 overdose.

As discussed, I will be on training for the most part of next week but I will try to attend the prioritization meeting on Tuesday (please send me the invitation).

Thanks

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

Pinard, Mike (HC/SC)

From: Stewart, John Patrick (HC/SC)
Sent: 2021-08-23 8:15 AM
To: [REDACTED]
Cc: prescription.drug.enquiries / renseignements.drogue.ordonnance (HC/SC); [REDACTED]
[REDACTED] Robinson, Kelly (HC/SC); Sommerer, Sophie (HC/SC); Peate, Jaspyn (HC/SC)
Subject: RE [REDACTED] - Ivermectin signage concern [REDACTED]

Good morning [REDACTED]

Thank you so much for your email below.

I have forwarded it onto Kelly Robinson, the Director General of the Marketed Health Products Directorate (MHPD) and someone from her team will contact you about this matter.

Thank you for bringing this to our attention.

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 / 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.

ATIA - 19(1)

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]

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] 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: Schmidt, Stephanie (HC/SC)
Sent: 2021-08-30 10:27 AM
To: Zayoun, Toufic (HC/SC); Kearns-Justin, Dayna (HC/SC); Lin, Mimi (HC/SC)
Cc: Lejmi Mrad, Rim (HC/SC); Roy, Christophe (HC/SC); Musende, Alain (HC/SC)
Subject: Retraction of Referral to ROEB RE: OPRAA for action due ASAP: [REDACTED]
[REDACTED] - Ivermectin signage concern [REDACTED]

Hello Toufic, Dayna, Mimi, and ROEB Colleagues,

Thank you for your time last week in discussing this issue.

We have since uncovered additional information in past complaints about the signage company responsible for the "Ivermectin and COVID-19" billboards in Manitoba.

Alain, [REDACTED] contacted the company late last week.

As such, we would like to retract our referral to your group, as we 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.

Please let us know if you require any additional information.

With kind regards,
Stephanie

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]

[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 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

Requester agreed to
Remove 3rd Party Info

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@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 [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 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] 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

Advisory

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

Tweet: #ADVISORY: Reports to poison control centres concerning Ivermectin sharply increased over the summer. #Canadians should never consume animal health products, including Ivermectin because of the potential serious health dangers. [Link to PA]

Summary

Product: Ivermectin (veterinary or human versions), an antiparasitic agent (tablets, paste, oral solution, injectable solution, medicated premix or topical).

Issue: Consumers, are purchasing veterinary ivermectin to prevent or treat COVID-19.

What to do: Do not use veterinary ivermectin for the prevention or treatment of COVID-19. If you have purchased ivermectin for this purpose, discard it immediately. Consult a healthcare professional if you have used this product and have health concerns.

UPDATE (October XX, 2021): Reports to poison control centres concerning Ivermectin as a prevention or treatment for COVID-19 sharply increased over the summer months

Issue

Health Canada is once again warning Canadians not to use either the veterinary or human drug versions of Ivermectin to prevent or treat COVID-19 following multiple incident reports to poison control centres. The majority of reports were in western Canada with 23 cases being reported between July - September 15, 2021.

There is no evidence that Ivermectin works to prevent or treat Covid-19. Further, Canadians should never consume health products intended for animals because of the potential serious health dangers, including seizures, coma and even death.

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

In this light, Health Canada will continue its proactive monitoring searches, using Artificial Intelligence, to identify marketing activities involving Ivermectin as a treatment for COVID-19.

As part of its ongoing commitment to openness and transparency, Health Canada also posts a summary of health product advertising complaints as well as health product advertising incidents related to COVID-19 addressed by the Department. The incident of non-compliant billboard advertising is expected to be posted online in the coming weeks.

What you should do

- If you have used Ivermectin to prevent or treat COVID-19, call your provincial poison control centre right away.



- If you have purchased Ivermectin for the prevention or treatment of COVID-19, stop using it and discard it:
 - Follow municipal or regional guidelines on how to dispose of chemicals and other hazardous waste; or
 - Return the product to the point of sale for proper disposal.
- Consult a healthcare professional if you have used ivermectin and have health concerns.
- Report any health product adverse events to Health Canada.
- Submit a complaint to Health Canada should you have any information regarding the illegal advertising or sale of Ivermectin or any other health product using its online complaint form
- Report marketing that is false or misleading or does not meet regulatory requirements.

Issue

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.

The veterinary version of ivermectin, especially at high doses, can be dangerous for humans and may cause serious health problems such as vomiting, diarrhea, low blood pressure, allergic reactions, dizziness, seizures, coma and even death. Ivermectin products for animals have a higher concentrated dose than ivermectin products for people.

The Department is aware of multiple reports of patients in the U.S. who have required medical support and been hospitalized after using ivermectin intended for horses.

Health Canada is closely monitoring all potential therapeutic treatments for COVID-19, including treatments being studied in international clinical trials. To date, Health Canada has not received any drug submission or clinical trial application for ivermectin for the prevention or treatment of COVID-19.

For drugs that have the 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.

Should a manufacturer provide a submission to Health Canada related to the use of ivermectin to prevent or treat COVID-19, Health Canada would conduct a scientific evaluation of the evidence to determine the drug's quality, safety and effectiveness.

Health Canada will continue to monitor the situation and will take appropriate and timely action should new information become available, including any information regarding the illegal advertising or sale of ivermectin. Health Canada will also communicate any new safety information to healthcare professionals and consumers.

Health Canada has previously warned Canadians about products making false and misleading claims to treat or cure COVID-19. For information on Health Canada authorized vaccines and treatments, visit Canada.ca.

Background





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.

What you should do

- If you have purchased ivermectin for the prevention or treatment of COVID-19, stop using it and discard it:
 - Follow municipal or regional guidelines on how to dispose of chemicals and other hazardous waste; or
 - Return the product to the point of sale for proper disposal.
- Consult a healthcare professional if you have used ivermectin and have health concerns.
- Report any side effects from this product directly to Health Canada.
- Submit a complaint to Health Canada should you have any information regarding the illegal advertising or sale of ivermectin or any other health product using its online complaint form.

Media enquiries

Health Canada
(613) 957-2983
media@hc-sc.gc.ca

Public enquiries

(613) 957-2991
1-866 225-0709
hcinfo.infosc@canada.ca





Advisory

Do not use ivermectin, veterinary or human versions, to treat or prevent COVID-19

Tweet: #ADVISORY: #Canadians should not use ivermectin, an antiparasitic agent, to treat #COVID19. Ivermectin has not been approved for use against COVID-19 and may cause serious health risks. [\[Link to PA\]](#)

Summary

Product: Ivermectin (veterinary or human versions), an antiparasitic agent (tablets or topical).

Issue: Consumers, without medical supervision or guidance, are purchasing veterinary ivermectin to treat COVID-19.

What to do: If you have purchased ivermectin to prevent or treat COVID-19, stop using it immediately and discard it. Consult a health care professional if you have used this product and have health concerns.

Issue

In response to a growing interest in the off-label use of ivermectin to prevent or treat COVID-19, Health Canada is advising Canadians to stop purchasing and self-administering this drug. There is no evidence that ivermectin (veterinary or human version) is safe and effective against COVID-19. There are reports that people are purchasing the veterinary version of this product, which can be dangerous for humans and may cause serious health issues.

To date, Health Canada has not received any drug submission or clinical trial application for ivermectin as a COVID-19 treatment or prevention. Health Canada has previously warned Canadians about products making false and misleading claims to treat or cure COVID-19.

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.

Health Canada has authorized ivermectin to treat patients with certain parasite infections that Canadians may acquire when travelling in high-risk areas, or that new Canadians may have when arriving from such regions. Should a manufacturer provide a submission to Health Canada related to ivermectin as a COVID-19 treatment or prevention, Health Canada would conduct a scientific evaluation of the evidence to determine its safety and effectiveness before authorizing it in Canada for this use, as it has done with all other health products related to COVID-19.

It is important to note that ivermectin products for animals are different from ivermectin products for people. The veterinary version of ivermectin is highly concentrated because it is intended for use on large animals, which typically weigh a lot more than people. As a result, this higher concentrated dose may pose serious health risks to Canadians.

Action taken by Health Canada

Health Canada is closely monitoring all potential therapeutic treatments for COVID-19, including international clinical trials.





Health Canada will continue to monitor the situation and will take appropriate and timely action should new information become available. Health Canada will also communicate any new safety information to healthcare professionals and consumers.

What you should do:

- If you have purchased ivermectin (veterinary version), stop using it and discard it appropriately:
 - Follow municipal or regional guidelines on how to dispose of chemicals and other hazardous waste; or
 - Return the product to the point of sale for proper disposal.
- If you are feeling unwell, seek immediate medical attention.
- Report any side effects from this products directly to Health Canada.

For a list of authorized COVID-19 vaccines and treatments, visit Canada.ca.

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hcinfo.infosc@canada.ca





Advisory

Ivermectin, veterinary or human versions, is not approved by Health Canada to treat or prevent COVID-19 and may have serious health risks

Tweet: #ADVISORY: Canadians should never consume veterinary products. Ivermectin, an antiparasitic agent, has not been approved for use against #COVID-19 and may cause serious health risks.. [[Link to PA](#)]

Summary

Product: Ivermectin (veterinary or human versions), an antiparasitic agent (tablets or topical).

Issue: Consumers, without medical supervision or guidance, are purchasing veterinary ivermectin to treat COVID-19.

What to do: If you have purchased veterinary ivermectin to prevent or treat COVID-19, stop using it immediately and discard it. Consult a health care professional if you have used this product and have health concerns.

Issue

In response to a growing interest in the unauthorized use of ivermectin to prevent or treat COVID-19, Health Canada is advising Canadians to stop self-administering this drug. There is no evidence that ivermectin (veterinary or human version) is safe and effective against COVID-19. There are reports that people are purchasing the veterinary version of this product, which can be dangerous for humans and may cause serious health issues.

To date, Health Canada has not received any drug submission or clinical trial application for ivermectin for the treatment or prevention of COVID-19. Health Canada has previously warned Canadians about products making false and misleading claims to treat or cure COVID-19. In addition, Health Canada has authorized certain products to treat COVID-19 and its symptoms, a list can be found here.

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. Current evidence suggests that it is not effective in this context.

It is important to note that ivermectin products for animals are different from ivermectin products for people.

Health Canada has authorized ivermectin to treat patients with certain parasite infections that Canadians may acquire when travelling in high-risk areas, or that new Canadians may have when arriving from such regions. Should a manufacturer provide a submission to Health Canada related to ivermectin as a COVID-19 treatment or prevention, Health Canada would conduct a scientific evaluation of the evidence to determine its quality, safety and effectiveness before authorizing it in Canada for this use, as it has done with all other health products related to COVID-19.

Action taken by Health Canada

Health Canada is closely monitoring all potential therapeutic treatments for COVID-19, including international clinical trials. Ivermectin (brand name STROMEKTOL) is a prescription drug product,





which is already authorized for sale in Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis and should only be used under the supervision of a healthcare professional.

Health Canada will continue to monitor the situation and will take appropriate and timely action should new information become available. Health Canada will also communicate any new safety information to healthcare professionals and consumers.

What you should do:

- If you have purchased ivermectin (veterinary version), stop using it and discard it appropriately:
 - Follow municipal or regional guidelines on how to dispose of chemicals and other hazardous waste; or
 - Return the product to the point of sale for proper disposal.
- If you are feeling unwell, seek immediate medical attention.
- Report any side effects from this products directly to Health Canada.

For a list of authorized COVID-19 vaccines and treatments, visit [Canada.ca](https://canada.ca).

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hcinfo.infosc@canada.ca





Advisory

Do not self-medicate with ivermectin, to treat or prevent COVID-19

Tweet: #ADVISORY: #Canadians should not use ivermectin, an antiparasitic agent, to treat #COVID19. Ivermectin has not been approved for use against COVID-19 and may cause serious health risks. [\[Link to PA\]](#)

Summary

Product: Ivermectin, an antiparasitic agent (tablets or topical).

Issue: Consumers, without medical supervision or guidance, are purchasing veterinary ivermectin to treat COVID-19.

What to do: If you have purchased ivermectin to prevent or treat COVID-19, stop using it immediately and discard it. Consult a health care professional if you have used this product and have health concerns.

Issue

In response to a growing interest in the off-label use of ivermectin to prevent or treat COVID-19, Health Canada is advising Canadians to stop purchasing and self-administering this drug.

To date, Health Canada has not received any drug submission or clinical trial application for ivermectin as a COVID-19 treatment or prevention. Health Canada has previously warned Canadians about products making false and misleading claims to treat or cure COVID-19. There is no evidence that ivermectin (veterinary or human version) is safe and effective against COVID-19.

Health Canada has authorized ivermectin to treat patients with certain parasite infections that Canadians may acquire when travelling in high-risk areas, or that new Canadians may have when arriving from such regions.

There are reports that people are purchasing the veterinary version of this product, which can be dangerous for humans and may cause serious health issues.

It is important to note that ivermectin products for animals are different from ivermectin products for people. The veterinary version of ivermectin is highly concentrated because it is intended for use on large animals, which typically weigh a lot more than people. As a result, this higher concentrated dose may pose serious health risks to Canadians.

Action taken by Health Canada

Health Canada is closely monitoring all potential therapeutic treatments for COVID-19, including international clinical trials.

Health Canada continues to monitor the situation and will take appropriate and timely action should new information become available. Health Canada will communicate any new safety information to healthcare professionals and consumers.

What you should do:

- If you have purchased ivermectin (veterinary version), stop using it and discard it appropriately:





- Follow municipal or regional guidelines on how to dispose of chemicals and other hazardous waste; or
- Return the product to the point of sale for proper disposal.
- If you are feeling unwell, seek immediate medical attention.
- Report any side effects from this products directly to Health Canada.

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Advisory

Do not use ivermectin, veterinary or human versions, to treat or prevent COVID-19

Tweet: #ADVISORY: #Canadians should not use ivermectin, an antiparasitic agent, to treat #COVID19. Ivermectin has not been approved for use against COVID-19 and may cause serious health risks. [\[Link to PA\]](#)

Summary

Product: Ivermectin (veterinary or human versions), an antiparasitic agent (tablets or topical).

Issue: Consumers, without medical supervision or guidance, are purchasing veterinary ivermectin to treat COVID-19.

What to do: If you have purchased ivermectin to prevent or treat COVID-19, stop using it immediately and discard it. Consult a health care professional if you have used this product and have health concerns.

Issue

In response to a growing interest in the off-label use of ivermectin to prevent or treat COVID-19, Health Canada is advising Canadians to stop purchasing and self-administering this drug

To date, Health Canada has not received any drug submission or clinical trial application for ivermectin as a COVID-19 treatment or prevention. Health Canada has previously warned Canadians about products making false and misleading claims to treat or cure COVID-19.

There is no evidence that ivermectin (veterinary or human version) is safe and effective against COVID-19.

Health Canada has authorized ivermectin to treat patients with certain parasite infections that Canadians may acquire when travelling in high-risk areas, or that new Canadians may have when arriving from such regions.

There are reports that people are purchasing the veterinary version of this product, which can be dangerous for humans and may cause serious health issues..

It is important to note that ivermectin products for animals are different from ivermectin products for people. The veterinary version of ivermectin is highly concentrated because it is intended for use on large animals, which typically weigh a lot more than people. As a result, this higher concentrated dose may pose serious health risks to Canadians.

Action taken by Health Canada

Health Canada is closely monitoring all potential therapeutic treatments for COVID-19, including international clinical trials.

Health Canada continues to monitor the situation and will take appropriate action should new information become available. Health Canada will communicate any new safety information to healthcare professionals and consumers.

What you should do:





- If you have purchased ivermectin (veterinary version), stop using it and discard it appropriately:
 - Follow municipal or regional guidelines on how to dispose of chemicals and other hazardous waste; or
 - Return the product to the point of sale for proper disposal.
- If you are feeling unwell, seek immediate medical attention.
- Report any side effects from this products directly to Health Canada.

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Advisory

Ivermectin, veterinary or human versions, not authorized to treat or prevent COVID-19; may pose serious health risks

Tweet: #ADVISORY: #Canadians should never consume veterinary products. Ivermectin, an antiparasitic agent, has not been approved for use against #COVID-19 and may cause serious health risks. [Link to PA]

Summary

Product: Ivermectin (veterinary or human versions), an antiparasitic agent (tablets, paste, oral solution, injectable solution, medicated premix or topical).

Issue: Consumers, without medical supervision or guidance, are purchasing veterinary ivermectin to prevent or treat COVID-19.

What to do: If you have purchased veterinary ivermectin to prevent or treat COVID-19, stop using it immediately and discard it. Consult a health care professional if you have used this product and have health concerns.

Issue

In response to a growing interest in the unauthorized use of ivermectin to prevent or treat COVID-19, Health Canada is advising Canadians to stop self-administering this drug. There is no evidence that ivermectin (veterinary or human version) is safe and effective against COVID-19.

Veterinary ivermectin can be dangerous for humans and may cause serious health issues. It is important to note that ivermectin products for animals are different from ivermectin products for people. In this light, Canadians should not be consuming products that are intended to treat animals, which have a higher concentrated dose and as such, may pose a serious risks to health.

To date, Health Canada has not received any drug submission or clinical trial application for ivermectin for the treatment or prevention of COVID-19. Health Canada has previously warned Canadians about products making false and misleading claims to treat or cure COVID-19. In addition, Health Canada has authorized certain products to treat COVID-19 and its symptoms.

For drugs that have the 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.

Should a manufacturer provide a submission to Health Canada related to ivermectin as a COVID-19 treatment or prevention, Health Canada would conduct a scientific evaluation of the evidence to determine its quality, safety and effectiveness, as it has done with all other health products related to COVID-19.

Action taken by Health Canada

Health Canada is closely monitoring all potential therapeutic treatments for COVID-19, including international clinical trials. Ivermectin (brand name STROMEKTOL) is a prescription drug product, which is already authorized for sale in Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis and should only be used under the supervision of a healthcare professional.





Health Canada will continue to monitor the situation and will take appropriate and timely action should new information become available. Health Canada will also communicate any new safety information to healthcare professionals and consumers.

What you should do:

- If you have purchased ivermectin (veterinary version), stop using it and discard it:
 - Follow municipal or regional guidelines on how to dispose of chemicals and other hazardous waste; or
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ATIA - 19(1)

ATIA - 21(1)(a)

Reply all ✓ Delete Junk Block ...

Kelly/Sophie (ASAP) // Ivermectin Media Query: Winnipeg Free Press

Regulations of agricultural ivermectin



Sun, Rong (HC/SC)

Thu 2021-09-23 5:11 PM

To: Robinson, Kelly (HC/SC); Sommerer, Sophie (HC/SC)

Cc: HC.F MHPD Action Requests F.SC

Hi Kelly/Sophie,

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

- 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 [REDACTED]

This information is provided proactively through the table of advertising incident for COVID-19, which is updated regularly weekly. ~~We do not know the sponsor of the ad but we know and Health Canada have been~~ [REDACTED] was in contact with ~~dealing with~~ the billboard company involved: Magnet Signs based in Alberta 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>.

ATIA-14(a)








 Reply all
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  Junk
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FYI - off label use of ivermectin

SR

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

Fri 2021-03-26 4:19 PM

To: Robinson2, Kelly (HC/SC) <kelly.robinson2@canada.ca>; Sommerer, Sophie (HC/SC) <sophie.somme

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 (STROMEKTOL) 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 [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

⏮ Reply all ⏹ Delete ⓧ Junk Block ...

Re: Quick q - off label use of ivermectin

SR

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

Fri 2021-03-26 7:56 PM

📧 👍 📅 ⏮ ⏪ ⏩ ⏭ ...

To: Soltys, Kathy (HC/SC) <kathy.soltys@canada.ca>

Cc: Ferrier, Sylvie (HC/SC) <sylvie.ferrier@canada.ca>; Irfan, Nashwa (HC/SC) <nashwa.irfan@canada.ca>

I second Kathy's comment. Thank you team for your quick and excellent summary on this issue. Kelly is aware too :)

Have a lovely weekend,

Rong Sun, PhD
Health Canada/Santé Canada

On Mar 26, 2021, at 4:05 PM, Soltys, Kathy (HC/SC) <kathy.soltys@canada.ca> wrote:

Thanks for the excellent summary and response, Sylvie!
Kathy

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

⏮ Reply all ⏹ Delete ⓧ Junk Block ...

FW: Quick q - off label use of ivermectin

SR

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

Fri 2021-03-26 3:09 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>; Fe

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

↩ Reply all ✓ 🗑 Delete 🚫 Junk Block ...

RE: Quick q - off label use of ivermectin

SR

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

Fri 2021-03-26 2:50 PM

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

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

Reply | Forward

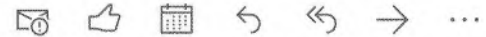
Reply all Delete Junk Block ...

FYI Ivermectin PA Update | Ivermectin



Sun, Rong (HC/SC)

Tue 2021-10-19 5:57 PM



To: Robinson, Kelly (HC/SC); Sommerer, Sophie (HC/SC); Rahim, Hamida (HC/SC); Berg, Jason (HC/SC)

FYI

Get [Outlook for iOS](#)

From: Aboueid, Suzane (HC/SC) <suzane.aboueid@hc-sc.gc.ca>

Sent: Tuesday, October 19, 2021 5:15 PM

To: Zayoun, Toufic (HC/SC); Regimbald-Krnel, Michele (HC/SC); Bak, Celina (HC/SC); Payette, Louise (HC/SC); Bellefeuille, Aldege (HC/SC); Mineau, Philippe (HC/SC); Sun, Rong (HC/SC); Tatone, Elise (HC/SC); Geduld, Jennifer (HC/SC)

Cc: Burgess, Sean (HC/SC); Legault-Thivierge, Geoffroy (HC/SC); McAllister, James (HC/SC); HC.F MHPD Action Requests F.S.C; Rajwani, Salima (HC/SC)

Subject: LINKS: PA Update | Ivermectin

Good evening,

Please find the links to the updated advisory below for sharing with your teams / DGs.

Web:

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

<https://canadiensensante.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-fra.php>

Wire links to follow.

The tweet accompanying the advisory will go out tonight and the social media campaign will commence tomorrow.

Thanks for all your help!

Suzane

Suzane Aboueid
(She | Elle)

Senior Communications Strategist
Communications and Public Affairs Branch (CPAB)
Health Canada and the Public Health Agency of Canada | Government of Canada
suzane.aboueid@canada.ca | Cell: 343-572-9292

Conseillère principale en communications stratégiques
Direction générale des communications et des affaires publiques (DGCAP)
Santé Canada et l'Agence de la santé publique du Canada | Gouvernement du Canada

↩ Reply all ▾ 🗑 Delete 🚫 Junk 🚫 Block ...

Fw: Ottawa Citizen article re: Ivermectin



Sun, Rong (HC/SC)

Wed 2021-10-13 8:47 AM

To: Soltys, Kathy (HC/SC); Rahim, Hamida (HC/SC)

FYI.

I understand ROEB and CPAB are considering another round of PA and social media. Will keep you posted if there is development on this front.

Many thanks,
RS

From: Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>

Sent: Wednesday, October 13, 2021 8:23 AM

To: Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>

Subject: FW: Ottawa Citizen article re: Ivermectin

fyi – Manon asked that we share this with you.

<https://ottawacitizen.com/news/local-news/feed-stores-take-precautions-with-ivermectin-hoax-covid-treatment>

Melissa

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

Sent: 2021-10-12 5:14 PM

To: Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>

Thanks. pls share with the team (vdd and mhp) for their awareness as well

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

** New / Nouveau manon.bombardier@hc-sc.gc.ca

From: Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>

Sent: 2021-10-12 2:21 PM

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

Reply all Delete Junk Block ...

Fw: ivermectin

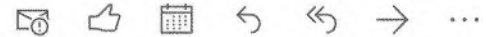


Sun, Rong (HC/SC)

Fri 2021-10-08 8:40 AM

To: Soltys, Kathy (HC/SC)

FYI only



From: Pinard, Mike (HC/SC) <mike.pinard@hc-sc.gc.ca> on behalf of Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Sent: Friday, October 8, 2021 8:36 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: FYI: ivermectin

FYI for Rong.

From: Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>
Sent: 2021-10-08 8:31 AM
To: Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>
Cc: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@hc-sc.gc.ca>; Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>; Randall, Bruce (HC/SC) <bruce.randall@hc-sc.gc.ca>; Davis, Meggan (HC/SC) <meggan.davis@hc-sc.gc.ca>; Geduld, Jennifer (HC/SC) <jennifer.geduld@hc-sc.gc.ca>; Tatone, Elise (HC/SC) <elise.tatone@hc-sc.gc.ca>; Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Subject: RE: ivermectin

Hi Manon,

Will do - - just looping in MHPD and TPD as well because this is broader than VDD...

Thanks
Marilena

From: Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>
Sent: 2021-10-08 8:10 AM
To: Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>
Subject: FW: ivermectin

Pls note. Keep me posted pls 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
** New / Nouveau manon.bombardier@hc-sc.gc.ca

Reply all
 Delete
 Junk
 Block
 ...

Re: For Action - Ivermectin Communication Information Request and Next Steps



Sun, Rong (HC/SC)

Mon 2021-10-18 11:35 AM

To: Bellefeuille, Aldege (HC/SC); Aboueid, Suzane (HC/SC); Bak, Celina (HC/SC); Payette, Louise (HC/SC);

Cc: Burgess, Sean (HC/SC); Legault-Thivierge, Geoffroy (HC/SC); McAllister, James (HC/SC); HC.F MHPD ,

ROEB_PA Update_Iverme...

68 KB



Hi Aldege,

Please see MHPD DG approved comments/edits.

Many thanks,

RS

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

Sent: Friday, October 15, 2021 9:14 AM

To: Aboueid, Suzane (HC/SC) <suzane.aboueid@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Regimbald-Krnel, Michele (HC/SC) <michele.regimbald-krnel@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Tatone, Elise (HC/SC) <elise.tatone@hc-sc.gc.ca>

Cc: Burgess, Sean (HC/SC) <sean.burgess@hc-sc.gc.ca>; Legault-Thivierge, Geoffroy (HC/SC) <geoffroy.legault-thivierge@hc-sc.gc.ca>; McAllister, James (HC/SC) <james.mcallister@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>

Subject: RE: For Action - Ivermectin Communication Information Request and Next Steps

Hello All:

Attached is the first draft to the Update to the Ivermectin PA issued in August 2021. The highlighted portion (in yellow) is the approved version on the web. Please provide any suggested changes. We are hoping to have DG approval today in order to continue moving the document over the weekend and be ready to issue on either Monday or Tuesday.

Thanks!

From: Aboueid, Suzane (HC/SC) <suzane.aboueid@hc-sc.gc.ca>

Sent: 2021-10-14 2:46 PM

To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Regimbald-Krnel, Michele (HC/SC) <michele.regimbald-krnel@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>;

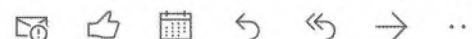
Reply all ▼ Delete Junk Block ...

Kelly/Sophie asap - Urgent PA Review ahead of DGO Approval - Ivermectin



Sun, Rong (HC/SC)

Mon 2021-10-18 10:50 AM



To: Robinson, Kelly (HC/SC); Sommerer, Sophie (HC/SC)

Cc: HC.F MHPD Action Requests F.SC

ROEB_PA Update_Iverme...

65 KB



Hi Kelly/Sophie,

The Ivermectin PA is being revised to boost awareness of the Ivermectin issue.

For MHPD, we have not received ADRs related to Ivermectin COVID use. We have dealt with a couple of complains, one is the billboard and the other is an MC's tweet. Both are listed in the "resolved" list of non-compliant advertising list online.

I have included a few comments about advertising.

Please see the revised copy, for your review **by 11:30am** please and thank you.

Many thanks,
RS

From: Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>**Sent:** Monday, October 18, 2021 10:36 AM**To:** Regimbald-Krnel, Michele (HC/SC) <michele.regimbald-krnel@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Aboueid, Suzane (HC/SC) <suzane.aboueid@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Tatone, Elise (HC/SC) <elise.tatone@hc-sc.gc.ca>**Cc:** Burgess, Sean (HC/SC) <sean.burgess@hc-sc.gc.ca>; Legault-Thivierge, Geoffroy (HC/SC) <geoffroy.legault-thivierge@hc-sc.gc.ca>; McAllister, James (HC/SC) <james.mcallister@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>**Subject:** For Action - Urgent PA Review ahead of DGO Approval - Ivermectin

Hi all,

Apologies for the delay in responding. We had some major revisions on our end and believe this lines up with the expectations from ROEB ADMO/DMO.

Please let me know by 1130 am if you are good with these revisions ahead of the clean version moving up to DGOs.

Reply all
 Delete
 Junk
 Block
 ...

Re: For Action - Ivermectin Communication Information Request and Next Steps



Sun, Rong (HC/SC)

Mon 2021-10-18 11:35 AM

To: Bellefeuille, Aldege (HC/SC); Aboueid, Suzane (HC/SC); Bak, Celina (HC/SC); Payette, Louise (HC/SC);

Cc: Burgess, Sean (HC/SC); Legault-Thivierge, Geoffroy (HC/SC); McAllister, James (HC/SC); HC.F MHPD ,

ROEB_PA Update_Iverme...

68 KB



Hi Aldege,

Please see MHPD DG approved comments/edits.

Many thanks,

RS

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

Sent: Friday, October 15, 2021 9:14 AM

To: Aboueid, Suzane (HC/SC) <suzane.aboueid@hc-sc.gc.ca>; Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Regimbald-Krnel, Michele (HC/SC) <michele.regimbald-krnel@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Sun, Rong (HC/SC) <rong.sun@hc-sc.gc.ca>; Tatone, Elise (HC/SC) <elise.tatone@hc-sc.gc.ca>

Cc: Burgess, Sean (HC/SC) <sean.burgess@hc-sc.gc.ca>; Legault-Thivierge, Geoffroy (HC/SC) <geoffroy.legault-thivierge@hc-sc.gc.ca>; McAllister, James (HC/SC) <james.mcallister@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>

Subject: RE: For Action - Ivermectin Communication Information Request and Next Steps

Hello All:

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Thanks!

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Sent: 2021-10-14 2:46 PM

To: Bak, Celina (HC/SC) <CELINA.BAK@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; Zayoun, Toufic (HC/SC) <toufic.zayoun@hc-sc.gc.ca>; Regimbald-Krnel, Michele (HC/SC) <michele.regimbald-krnel@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>;

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.
- 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. Further studies are 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->

- 2 -

[products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/notice-interim-order.html](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.

From: Keene, Daniel (HC/SC)
Sent: 2021-08-30 12:20 PM
To: Legare, Carole (HC/SC)
Subject: Suggested changes for your comment: URGENT: For
Approval - PA - Do not use ivermectin for treatment of
COVID-19
Attachments: ROEB_PA_Ivermectin and COVID-19_2021-
08_30_1200.dk.docx.docx

Importance: High

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.

<< File: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200.docx >>

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.lejmimirad@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-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

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 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

The FLCCC Alliance was organized in March, 2020 by a group of highly published, world renowned Critical Care physician/scholars – with the academic support of allied physicians from around the world – to research and develop lifesaving protocols for the prevention and treatment of COVID-19 in all stages of illness.

NIH: The COVID-19 Treatment Guidelines Panel's Statement on the Use of Ivermectin for the Treatment of COVID-19 Last Updated: January 14, 2021

Recommendation

The COVID-19 Treatment Guidelines Panel (the Panel) has determined that currently there are **insufficient data to recommend either for or against the use of ivermectin for the treatment of COVID-19**. Results from adequately powered, well-designed, and well-conducted clinical trials are needed to provide more specific, evidence-based guidance on the role of ivermectin for the treatment of COVID-19.

Rationale

Ivermectin is an antiparasitic drug that is approved by the Food and Drug Administration (FDA) for the treatment of onchocerciasis and strongyloidiasis. Ivermectin is not FDA-approved for the treatment of any viral infection. In general, the drug is well tolerated. It is currently being evaluated as a potential treatment for COVID-19.

Antiviral and Anti-Inflammatory Effects of Ivermectin

Reports from in vitro studies suggest that ivermectin acts by inhibiting the host importin alfa/beta-1 nuclear transport proteins, which are part of a key intracellular transport process that viruses hijack to enhance infection by suppressing the host antiviral response.^{1,2} In addition, ivermectin docking in vitro may interfere with the attachment of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein to the human cell membrane.³

Ivermectin has been shown to inhibit the replication of SARS-CoV-2 in cell culture. However, pharmacokinetic and pharmacodynamic studies suggest that ivermectin doses up to 100-fold higher than those approved for use in humans would be required to achieve the plasma concentrations necessary to duplicate the drug's antiviral efficacy in vitro.^{4,5} Even though ivermectin appears to accumulate in lung tissue, with the doses used in most clinical trials, predicted systemic plasma and lung tissue concentrations are much lower than 2 µM, the half-maximal inhibitory concentration (IC₅₀) against SARS-CoV-2 in vitro.^{6,7}

Ivermectin demonstrates potential anti-inflammatory properties in some in vitro studies,^{8,9} properties which have been postulated to be beneficial in the treatment of COVID-19.¹⁰

Clinical Data

Since the last revision of the Ivermectin section of the Guidelines, the results of several randomized trials and retrospective cohort studies of ivermectin use in patients with COVID-19 have been published in peer-reviewed journals or made available as preliminary, non-peer-reviewed reports. Some clinical studies showed no benefits or worsening of disease after ivermectin use,¹¹⁻¹⁴ whereas others reported shorter time to resolution of disease manifestations attributed to COVID-19,¹⁵⁻¹⁸ greater reduction in inflammatory markers,^{16,17} shorter time to viral clearance,^{11,16} or lower mortality rates in patients who received ivermectin than in patients who received comparator drugs or placebo.^{11,16,18}

However, most of the studies reported to date had incomplete information and significant methodological limitations, which make it difficult to exclude common causes of bias. The missing information and limitations include the following:

The sample size of most of the trials was small.

Various doses and schedules of ivermectin were used.

Some of the randomized controlled trials were open-label studies in which neither the participants nor the investigators were blinded to the treatment arms.

In addition to ivermectin or the comparator drug, patients also received various concomitant medications (e.g., doxycycline, hydroxychloroquine, azithromycin, zinc, corticosteroids), confounding assessment of the true efficacy or safety of ivermectin.

The severity of COVID-19 in the study participants was not always well described.

The study outcome measures were not always clearly defined.

Because of these limitations, the Panel cannot draw definitive conclusions about the clinical efficacy or safety of ivermectin for the treatment of COVID-19. Results from adequately powered, well-designed, and well-conducted clinical trials are needed to provide more specific, evidence-based guidance on the role of ivermectin for the treatment of COVID-19.

Canadian Market Authorization Status for Ivermectin:

STROMEKTOL™ ivermectin tablet, USP 3 mg Antiparasitic Agent (authorized 2016)

INDICATIONS: is indicated for the treatment of intestinal strongyloidiasis and onchocerciasis.

ACTION AND CLINICAL PHARMACOLOGY- Mechanism of Action: Ivermectin is a member of the avermectin class of broad-spectrum antiparasitic agents which have a unique mode of action.

Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite.

ROSIVER® Ivermectin Cream, 1% w/w Topical Rosacea Therapy (authorized 2015)

Indication: ROSIVER (ivermectin) Cream, 1% is indicated for the topical treatment of inflammatory lesions (papules and pustules) of rosacea in adults 18 years of age or older.

Mechanism of Action: The mechanism of action of ROSIVER in treating rosacea is unknown.

Pharmacodynamics: Anti-inflammatory properties of topical ivermectin have been observed in animal models of skin inflammation. Ivermectin is known to have endectocidal properties via selective high affinity binding to glutamate-gated anion channels and γ -aminobutyric acid-gated chloride channels. These channels occur in peripheral motor synapses of parasites, but occur only in the central nervous system in mammals. Ivermectin is normally excluded from the mammalian central nervous system by mature levels of p-glycoprotein activity

Clinical trials in Canada

COVID- NIL

Other:

- 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 Algorithmme Inc.) CLOSED
- 165720 PH1 BIO IVERMECTIN Sponsor: SubstiPharm France (submitted by Algorithmme Inc.) CLOSED
- 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

Twitter Search: Preliminary Findings

Objectives / Summary

- Twitter search of “ivermectin” use in Canada ...
- Results found no significant trends of concern ...

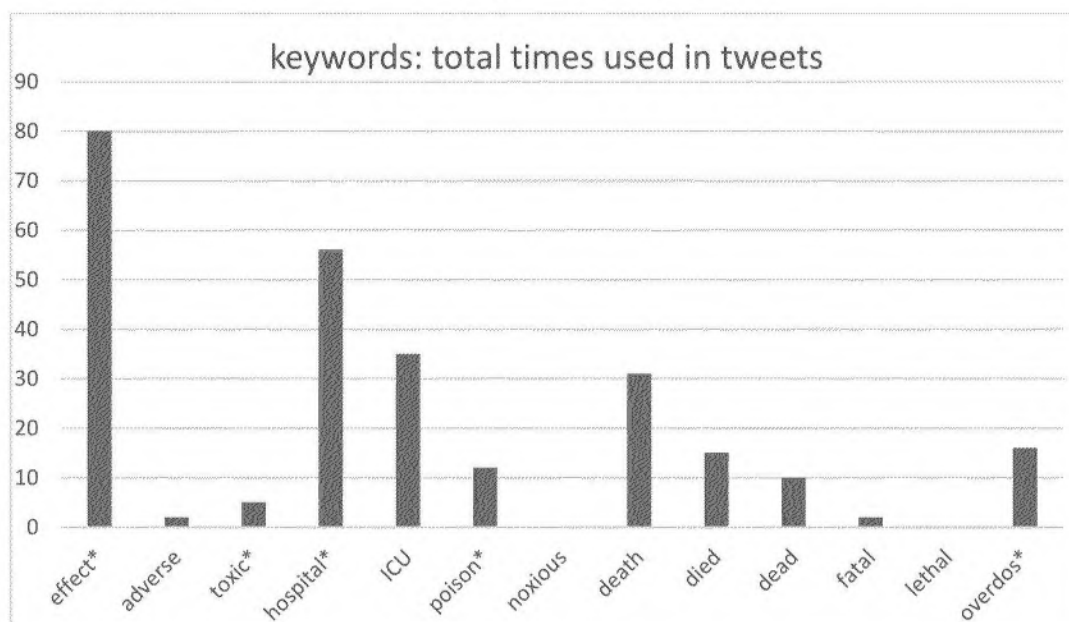
Methods:

Using Twitter developer and original Application Programming Interface (API) search strings:

- API is software that allows two applications to talk to each other (ex. use app like twitter, check the weather on your phone).
- Approved for an academic Twitter Developer account which gives access to archive search (all twitter history rather than last 7 days) and a total of 10,000,000 tweets each month.
- Using open-source codes to gather data, example:
 - o `twarc2 search --archive --limit 5000000 --start-time "2021-01-01" --end-time "2021-09-25" "lang:en (ivermectin) place_country:CA" tweets1.json`
- Key term “ivermectin,” from Canada, since January 1, 2021.

Results:

- 1,453 original tweets collected:
 - o Around 1% of Twitter users tag their location in tweets, limiting results (might be able to find a way to search by user profile location).
- Additional filters and results: “effect*” (80), “adverse” (2), “toxic*” (5), “hospital*” (56), “ICU” (35), “poison*” (12), “noxious” (0), “death” (31), “died” (15), “dead” (10), “fatal” (2), “lethal” (0), “overdos*” (16).
 - o “OD” found a lot of irrelevant results, so it wasn’t included.



From: Schmidt, Stephanie (HC/SC)
Sent: 2021-09-01 10:29 AM
To: Zayoun, Toufic (HC/SC); Kearns-Justin, Dayna (HC/SC); Lin, Mimi (HC/SC)
Cc: Lejmi Mrad, Rim (HC/SC); Roy, Christophe (HC/SC); Musende, Alain (HC/SC)
Subject: Update RE: Retraction of Referral to ROEB RE: OPRAA for action due ASAP: [REDACTED]
 [REDACTED] - Ivermectin signage concern [REDACTED]
Attachments: 3013457_Regulatory Letter-COVID-19_[REDACTED]

Follow Up Flag: Follow up
Flag Status: Completed

Hello Toufic, Dayna, Mimi, and ROEB Colleagues,

I would like to share some additional information with you about the Ivermectin signage concern we discussed last week.

We have since drafted and sent a regulatory letter to [REDACTED], the representative for Magnetsigns in Winkler, Manitoba (see attached, for your reference). Magnetsigns appears to be the company responsible for the Ivermectin signs in this province, but we remain unaware of the actual entity that ordered them. We are expecting an acknowledgement imminently and will inform you of any correspondence we receive.

Moreover, Alain was expecting a return call from [REDACTED] but had not received one by the time [REDACTED]. Another agent at Magnetsigns [REDACTED]

If possible, could ROEB confirm that the billboards in Winkler and area have been removed?

Please let us know if you have any additional questions.

Many thanks to you all for your collaboration.

Sincerely,
 Stephanie

Requester agreed to
 Remove 3rd Party Info

From: Schmidt, Stephanie (HC/SC)
Sent: 2021-08-30 10:27 AM
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>; Musende, Alain (HC/SC) <alain.musende@hc-sc.gc.ca>
Subject: Retraction of Referral to ROEB RE: OPRAA for action due ASAP: [REDACTED]
 [REDACTED] - Ivermectin signage concern [REDACTED]

Hello Toufic, Dayna, Mimi, and ROEB Colleagues,

Thank you for your time last week in discussing this issue.

We have since uncovered additional information in past complaints about the signage company responsible for the "Ivermectin and COVID-19" billboards in Manitoba. Alain, [REDACTED] contacted the company late last week.

As such, we would like to retract our referral to your group, as we 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.

Please let us know if you require any additional information.

With kind regards,
Stephanie

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 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 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 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.

Requester agreed to
Remove 3rd Party Info

[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]

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,

[REDACTED]

From: Bellefeuille, Aldege (HC/SC)
Sent: 2021-08-30 12:03 PM
To: Mineau, Philippe (HC/SC); Lin, Mimi (HC/SC)
Cc: Badenduck, Lucas (HC/SC); BMS ORM Risk / BSM BGR
Risque (HC/SC); Dinakaran, Deborah (HC/SC); MacKay, Ian
(HC/SC); Chang, Vivian (HC/SC); Peate, Jaspyn (HC/SC);
Legare, Carole (HC/SC); Keene, Daniel (HC/SC)
Subject: URGENT: For Approval - PA - Do not use ivermectin for
treatment of COVID-19
Attachments: ROEB_PA_Ivermectin and COVID-19_2021-
08_30_1200.docx

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-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

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, Marilyn (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

Tasks	Comments
Items with DO for Approval	<p><u>Update August 26, 2021</u></p> <ol style="list-style-type: none">1. HS DEL Transition Proposed Approach2. PLL Options analysis and recommendation3. NHP GMP Q/A Document
NHP-GMP Inspection Pilot	<p><u>Update August 26, 2021:</u></p> <p>Attached are updates to the project dashboard and inspection tracker. The project road map did not require an update at this time as it is a higher level document.</p> <p>Dashboard Highlights:</p> <p>Risks to consider with regards to upcoming election and ongoing, confirmed and planned inspections. Further regulatory action could be taken with NC sites who submit inadequate CAPA, confirmed inspections of importers could result in NC ratings and planned inspections are our first manufacturer inspections, which could also result in NC ratings. In addition, if confirmed/planned inspections are postponed, we would have to consider extending the pilot another 2-3 months (April/May 2022) to complete the required 36 inspections.</p> <p><u>Inspection Planning:</u></p> <p>August/September :</p> <p>3 importer inspections confirmed starting Monday next week :</p> <div><div></div>Aug. 30 –Sep. 3, 2021</div> <div><div></div>Aug. 30 –Sep. 3, 2021</div> <div><div></div>Aug. 30 –Sep. 3, 2021</div> <p>3 manufacturer inspections planned (companies not yet contacted):</p> <p>Central has the following sites to choose from, but has not selected one yet:</p> <div></div> <p>West has the following sites to choose from:</p> <div></div>

Requester agreed to Remove 3rd Party Info

[Redacted]

Inspector was planning on starting with [Redacted] They were inspected during the CMPs and are not expected to be NC.

East has the following sites to choose from:

[Redacted]

Requester agreed to
Remove 3rd Party Info

Inspector was planning on starting with [Redacted]. They manufacture drugs. [Redacted] and are not expected to be NC.

Proposed NC Site Update:

[Redacted] NC will be confirmed Aug. 27, 2021 and regulatory actions by NNHPD verified. The Exit Notice meeting with the company is not yet scheduled, but is held soon after the compliance rating is confirmed.

Confirmed NC Site Updates:

The CAPA for [Redacted] is due November 11/21. The inspector will have 20 business days to review it for acceptability.

The CAPA for [Redacted] is due September 22/21. The inspector will have 20 business days to review it for acceptability.

The inspector reviewed the CAPA for [Redacted] and is in discussion with NNHPD concerning its acceptability.

The inspector received the CAPA for [Redacted] on Aug. 23/21, but has not started the review. The inspector has 20 business days to review it for acceptability.

The inspector received and reviewed all outstanding CAPA from [Redacted] and is expecting to hear from NNHPD early next week whether it is acceptable [Redacted]

Inspection Tracker Highlights:



July/August:

3 inspections Completed

[Redacted] July 26-30 & Aug. 3-4, 2021 (proposed NC)


ATIA - 19(1)
ATIA - 21(1)(a)

HPCE Weekly Thursday Update – August 26, 2021

	<p>[REDACTED] - August 2-6 & 9-10, 2021 (proposed C)</p> <p>[REDACTED] - July 29-30 & August 3- 6, 2021 (proposed C)</p> <div>  NHP GMP Project Dashboard 26Aug2021  Dashboard Inspection Summary </div> <div>Requester agreed to Remove 3rd Party Info</div>
Update on Teva-Canada/Sivem Pharmaceuticals ULC Recall of 7 lots with Azido Impurity Levels Above the TTC	<p><u>Update on August 26, 2021</u></p> <p>Just to provide an update on this as of this pm.</p> <p>Current Status:</p> <ul style="list-style-type: none"> 2 lots, Sivem-Losartin (cross licenced products) will also be recalled in addition to the below (target initiation tomorrow by Sivem Pharmaceuticals ULC) and will be included within scope of the PA. PA has been sent to TPD to validate the name of the new mutagenic azido impurity as well as another comments on the modifications proposed by CPAB. Since the recall may expand to Sandoz products (based on the positive AMES test by Teva-Canada), DSU was consulted on potential shortages created by these upcoming Losartan recalls. Their response: <ul style="list-style-type: none"> As for the potential impact of recalls, DSU has previously stated that DSU is not concerned about shortages resulting from the possible multi-sarstan recall. Of course, there will be shortages any time there is a stop sale/recall. In this case, there are alternatives within the sartans class and drugs in the ACE-inhibitors class that patients can be switched to if their regular sartan is not available. Similar to nitrosamine impurities that first occurred in 2018, DSU is of the opinion that shortage concerns should prevent or impact market actions because of the availability of alternatives that patients could switch to relatively easily. We have also not heard significant concerns about these shortages from the PTs. <p>Next Steps:</p> <ul style="list-style-type: none"> Finalise PA and send to HPCRM DO on August 27 (am). HPCEU to ensure posting only happens after Sivem product recall has initiated. HPCEU to finalise stakeholder message on August 27 (am) to be sent out by Mary Morgan, this should be followed by an embargoes PA, once available. HPCE to reach out to Sandoz on August 30, 2021 after discussion with ORM in am, informing them of the recent AMES test results and requesting a recall of lots above TTC for new mutagenic impurity. PA and stakeholder message will follow once Sandoz agrees.
CSF Update - Public Enquiry - Central	<p><u>Update on August 26, 2021</u></p> <p>Inspector was able to reach the enquirer by phone on early afternoon of Aug 26:</p> <ul style="list-style-type: none"> The individual enquired about the labelling of drug products (OTC, PDL), in particular whether package insert must include ingredients; <ul style="list-style-type: none"> Inspector discussed and offered guidance on labelling requirements for pharmaceutical products and health product complaint form (FRM-0317); however, the individual was not interested in filing a complaint. The individual has concerns on what ingredients are in vaccines for COVID-19 that are administered in Canada. <ul style="list-style-type: none"> Inspector referred the individual to Health Canada page for more information on each vaccine, including medicinal and non-medicinal ingredients, and offered to send a link to him in a follow-up email. The individual provided email address for the follow-up email and appeared to be satisfied at the end of the phone call. <p>We propose to send a follow up email to the caller today, Aug 26. The email will be brief and will contain the link to the following:</p> <ul style="list-style-type: none"> Link to report Health Canada's COVID-19 Vaccines page: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines.html <p>Please let us know if there are any concerns with sending the follow-up email to the enquirer and close-off the enquiry.</p>
CSF Heads Up-[REDACTED]	<p><u>Update on August 25, 2021</u></p> <p>CSF - Please see below [REDACTED]</p>

	<p>East is gathering more details for us and I will share as soon as I receive them. Please see below for Stéphane’s original email.</p> <p>Background:</p> <div></div> <p>Current Situation:</p> <div></div> <p>Next Steps:</p> <div></div> <p>- Update LSU</p> <div>Requester agreed to Remove 3rd Party Info</div>
<p>Update to Caretaker Sensitivity File - OPRAA for action due ASAP</p> <p>Ivermectin signage concern</p>	<p><u>Update on August 26, 2021</u></p> <p>Current Status:</p> <ul style="list-style-type: none">Referral from MHPD on August 23, 2021 from the 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 mentionsMeeting 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. <p>Next Steps:</p> <ul style="list-style-type: none">MHPD to look into their case load to identify if other complaints have been submitted and will inform HPCE if they require assistance to identify advertiserIf MHPD agrees, CTU to gather additional details on the location of the billboard and contact details for the rental company of the billboard, for potential case creation.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. <p>Please let me know if you have any questions and/or concerns.</p>
<p>Eco-Med Pharmaceuticals - Possible Contamination of B. stabilis in 4 Licensed NHPs (RADAR 2021-004097)</p>	<p><u>Update on August 26, 2021</u></p> <ul style="list-style-type: none">PA on medical devices and NHPs posted on Aug 25: <u>Potential contamination of health products manufactured by Eco-Med Pharmaceuticals Inc. may pose health risks to Canadians - Recalls and safety alerts (healthycanadians.gc.ca)</u>Recalls will not be conducted as Eco-Med is not in operationEntities in possession of the product are being informed to stop using the products and discard them appropriatelyProduct distribution list containing full contact information was received:<ul style="list-style-type: none">44 consignees on record, but only 2 were consignees of NHPs. The other 42 were for medical devices.NNHPD has issued a notice of COVID SL Revocation to the company on August 26, 2021.Insolvency firm is not aware of the current inventory for any products stored on-site as their role currently is too safeguard the site until they are affirmed by the Court of Ontario on Tuesday August 31, 2021After Aug 31, insolvency firm will work on inventory and they are open to discussing a disposal plan.Upon further examination of the distribution list, 3 out of 44 consignees purchased NHPs instead of 2 as previously stated.

HPCE Weekly Thursday Update – August 26, 2021

	<div> Eco-Med Pharmaceuticals Inc</div>
Amending biocide regulations [REDACTED]	<div><div><u>Update on August 12, 2021</u></div><div>Issue: NNHPD have been working closely with OLRM on the CBA for biocides, [REDACTED] [REDACTED]</div><div>ROEB (PRSD, HPCRM) has some concerns with the new approach and has followed up with NNHPD regarding additional questions:<ul style="list-style-type: none">[REDACTED][REDACTED][REDACTED][REDACTED][REDACTED]</div><div>Next steps: ROEB (PRSD, HPCRM) to prepare a briefing to share with ADM [REDACTED]</div></div>
Heads Up: NuWTR Fulvic & Black Oxygen Products Recall (2021-026872 & 2021-047885)	<div><div><u>Update on August 24, 2021</u></div><div><ul style="list-style-type: none">Aug 20: Type II recall to the distributor level was recommended for all NuWTR fulvic and Black Oxygen products [REDACTED]Aug 23: MAH proposed Type II recall to consumer level and provided draft recall communication to be issued via email<ul style="list-style-type: none">[REDACTED][REDACTED][REDACTED][REDACTED][REDACTED][REDACTED][REDACTED]Sent request for NNHPD to confirm risk to health (possibly Type I risk) and whether the MAH submitted notification to discontinue the NPNs</div><div>Next Steps:<ul style="list-style-type: none">Confirm when MAH initiates the recallOnce recall is initiated, submit RAN [REDACTED]Follow-up with fulfillment centre [REDACTED]Follow-up with HPCEU regarding public communication (if required [REDACTED])</div><div>Requester agreed to Remove 3rd Party Info</div></div>

Next Steps:

Lead inspector to determine further compliance action including possibility of

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

UPDATE - Site Visit

Update on August 18, 2021

Please see the updates (in red) below on this file as of today.

Radar:

Company:

Product:

Requester agreed to
Remove 3rd Party Info

Background:

- Complaint received from RMD as RMD has been informed via a complaint [REDACTED] May 7th 2021 of two disinfectant with non compliant label
- [REDACTED] that is a concentrated product that needs to be diluted prior use.
- A diluted (ready to use) version [REDACTED] surface disinfectant [REDACTED]
- The concentration of the active ingredient (benzalkonium chloride) and the label of the product sold [REDACTED] are not compliant with the DIN.

Actions to date:

- Distributor [REDACTED] have confirmed having ceased the sale of the non-compliant product;
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

The following findings were made from the unannounced visit:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

In the absence of the QA responsible person during the on-site visit, further email communications were needed in order to get the QA related information [REDACTED]

Following receipt of additional information from the QA responsible person, [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Current Status:

- Issue a letter to the attention of the company outlining some of the observations noted during the visit and on the documents received
- [REDACTED]
- Based on NNHPD assessment take the appropriate compliance measures

Central received confirmation from CPS that they will be sending a rejection letter to the registrant. This means further follow-up will be necessary.

•
•
•
•
•

Update

Update:

The image shows a document page where the majority of the content has been redacted with a solid black box. On the far left, there is a narrow white margin. Within this margin, there are two groups of five small black dots each, arranged vertically. The top group of dots is positioned higher than the bottom group. To the right of the blacked-out area, a portion of another page is visible, showing some faint, illegible text.

• [REDACTED]


• [REDACTED]

Requester agreed to
Remove 3rd Party Info


ATIA - 16(1)(b)
ATIA - 21(1)(a)

Requester agreed to
Remove 3rd Party Info

Valisure report on sunscreen products- Questions for FDA	<p><u>Update on August 11, 2021</u></p> <p>RMD reached out to [REDACTED] irrespective of the level of benzene identified in the report. RMD has been in communication [REDACTED]</p> <p>One company [REDACTED] RMD referred this company to ROEB on August 10 and a case (RADAR #2021-051699) has been triaged to HPC-East for further follow up.</p> <p>Questions sent to the FDA on July 21 related to the Valisure report on sunscreen products. A meeting has been set for September 1, 2021 to discuss the below. HPCEU and NNHPD will meet to discuss who will lead and prepare for the meeting in mid August (tbc).</p> <ol style="list-style-type: none">1. Can you please provide more information on the risk assessment conducted by the US FDA for benzene in sunscreen products. Health Canada would like to align our actions and would like to gain a better understanding of the risk assessment and rationale.2. Has the US FDA establish a daily exposure limit for benzene?3. Has the US FDA validated or are you considering validating the methods used in the Valisure report?4. Does the US FDA plan to conduct an outreach/investigation on the companies identified in the Valisure report? Are there any plans to expand the scope to other companies with sunscreen products that may also be impacted by high levels of benzene?5. To date, the US FDA has not recalled any other products from companies identified on the Valisure report with a benzene quantity above 2ppm. Johnson & Johnson initiated a voluntary recall out of an abundance of caution. What are the proposed actions from the US FDA on this issue? Will you be recalling other products/investigating the situation further?
Update [REDACTED]	<p><u>Update on July 28, 2021</u></p> <p>[REDACTED]</p> <p>Current Status:</p> <ul style="list-style-type: none">• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED] <p>Next steps:</p> <ul style="list-style-type: none">• [REDACTED]• [REDACTED]• [REDACTED]
Plain Language Labelling	<p><u>Update on August 13, 2021</u></p> <p>The Plain Language Labelling (PLL) regulations came into effect in June 2017 for non-prescription drugs, with full compliance expected at the retail level by June 30, 2021. With the pending retail deadline, a joint critical path has been developed to guide key actions to be taken during June, July and August.</p> <p>Attached you will find ROEB-HPCRM an options analysis with a recommendation to utilize a compliance promotion approach for non-responders referred by NNHPD.</p>

	<div>  <div>Options PLL OTC_20210708_HPC</div> </div>
For Director's Office Concurrence: Hand Sanitizer DEL Transition Period End and Next Steps (August 17, 2021)	<div> <div>Update on August 18, 2021</div> <div> <p>Please see below for information regarding the Hand Sanitizer DEL Transition Period End and proposed next steps.</p> <p>HPCRM and HPIL met on August 17, 2021 to discuss next steps for the Hand Sanitizer DEL Transition Period slated to end on September 1, 2021</p> <p>Issue:</p> <ul style="list-style-type: none"> As of September 1st, 2021; all companies conducting licensable activities under the interim order exemption for a designated hand sanitizer without holding a DEL must have applied for a DEL to continue their activities. Companies that do not would be required to cease activities. HPCEU was engaged to determine potential CV actions. <ul style="list-style-type: none"> Companies that applied for a DEL during the six-month transition period (until September 1, 2021) may continue to conduct the activities without a licence while HC reviews the application (approx.. 250 days for review) Numbers of impacted companies: <ul style="list-style-type: none"> HPIL indicated that approx. 80 DINs are impacted with 21 importers and 40 domestic manufacturers. Products imported through interim measure are also implicated. Numbers of importers of drug based hand sanitizer to be confirmed. No companies have submitted a DEL application to date. <p>The following path forward was discussed/proposed:</p> <ul style="list-style-type: none"> HPIL to send reminder email to impacted companies along with additional information on how to apply for a DEL and associated fees (target; week of August 16, 2021) HPIL will issue an email post September 1, 2021 (target September 2, 2021) to all impacted companies who did not submit a DEL application informing them that the deadlines has passed and requesting them to attest they have cease all licensable activities. For importers: an import alert will be activated for all importers who does not submit a DEL application by September 1, 2021. HPCEU is proposing the following CV actions: <ul style="list-style-type: none"> HPCEU will follow-up on non responders to the attestation request For companies who attested they have ceased activities: complaint driven CV follow-up For importers: an import alert will be activated <p>Next steps:</p> <ul style="list-style-type: none"> HPIL to issue reminder email (target; week of August 16, 2021) HPIL to work on post September 1, 2021 email with attestation with input from HPCEU HPCEU to draft ROD for CV action follow-up HPCEU to draft action an plan for non responders for follow-up HPIL to refer non responders to HPCEU for CV follow-up <p>Background:</p> <ul style="list-style-type: none"> To address the hand sanitizer shortage, a DEL exemption was offered through an interim order for hand sanitizers classified as non-prescription drugs. Companies that conducted licensable activities under the interim order exemption have up to September 1st to submit their DEL applications if they wish to continue conducting activities. If they do, they can continue their activities without a DEL while HC reviews their DEL application (approx. 250 days). Companies that do not would be required to cease activities. <ul style="list-style-type: none"> A six-month transition period was given to industry to adjust to the changes. On March 18, 2020, Health Canada introduced an interim measure for the exceptional release of hard surface disinfectants and hand sanitizers to expedite access to products that may not fully meet regulatory requirements under the <i>Food and Drugs Act</i>. This interim measure enabled Health Canada to facilitate the availability of supplies of hard surface disinfectants and hand sanitizers for Canadians. </div> </div>

HPCE Weekly Thursday Update – August 26, 2021

	<ul style="list-style-type: none">On January 15, 2021, Health Canada stopped accepting new applications for all hand sanitizers through this interim measureHand sanitizers previously accepted under the interim measure continue to be allowed to be imported and/or sold by companies that received acceptance correspondence from Health Canada <p>Please let me know if you have any questions and/or concerns and if you concur with the above approach.</p>
Ethanol Update	<p><u>Update on August 26, 2021:</u></p> <p>The HS RL was last updated Tuesday August 24th with 2 entries (all from HS CMP): https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75267a-eng.php. There are no new entries for the RL this week.</p> <p>Please see attached the IMR that provides an update on the status of the CVs in the HS CMP.</p> <p>Highlights of HS CMP:</p> <ul style="list-style-type: none">All testing of 40 samples for HS CMP is complete!All assessment by NNHPD is complete!All requests to firms to mitigate risks (e.g. request recall or stop sale) have been made.1 sample in Batch #4 was identified to be resembling a beverage container. We are waiting for distribution details (e.g. whether distributed before November 27, 2020 or not) as they did not distribute any product in 2021.4 recalls are expected to take place that are pending initiation or awaiting confirmation from the firm <p>Regulatory notices and KAIs drafted/issued by NNHPD are saved here: Y:\HC\ROEB\HPCD\HPCRM\HEALTH RISK PROTECTION HC6\CASE MGMT\HS CMP</p> <div><p>Hand Sanitizer CMP IMR_Aug 26 2021 H</p></div> <div>Requester agreed to Remove 3rd Party Info</div>
New impurity in naloxone [REDACTED]	<p><u>Update on August 11, 2021:</u></p> <p>Issue:</p> <ul style="list-style-type: none">November 2020 – [REDACTED]As of June 2021 [REDACTED][REDACTED] from the impacted site and a CV case was opened in November 2020 [REDACTED] <p>Current Status:</p> <ul style="list-style-type: none">June 2021, HPCRM notified HPFB - BPS of this issueBPS noted that the impurity may be a degradation product, and possibly present in all products that contain Naloxone and povidoneBPS suggested an advisement letter be sent to [REDACTED] MAHs notifying them [REDACTED] indicating that further testing may be required as more information becomes available. However, they acknowledged, that without a definitive identification this would be difficult to communicate to stakeholders <p>Next steps:</p> <ul style="list-style-type: none">Discussions with HPFB are ongoing to determine if an advisement letter is needed given information is very limited and communicating the issue to MAHs would be difficultRequest additional information [REDACTED] and continue to monitor international notifications for updatesIdentification of the impurity and investigation [REDACTED] is still ongoing at this time.

International student reaching out to HC for information on [REDACTED] for thesis

Early heads up provided to OCS

Update on August 2, 2021

Christine brought to our attention a student inquiry (foreign student) linked to nitrosamines. Attached is her list of questions that she would like us to answer for her dissertation on [REDACTED]. Prior answering, it was decided to seek DG concurrence and Salima should bring this issue to Linsey during her bilat. TPD will also bring this issue to their DM


Details from Christine below:

Summary:

- HPCEU has received an inquiry from a student [REDACTED] conducting a dissertation on [REDACTED] in Medicinal Products- [REDACTED]
 - She has provided a list of questions and would appreciate having a representative from HC to have an interview and or complete questions as a questionnaire if a interview is not possible.
 - HPCEU already provided the Q&A document [REDACTED] and link [REDACTED] landing page.
- HPCEU has shared the questions with [REDACTED] SMEs and brought it up at this morning's CM. It was agreed we would request concurrence for DGs prior to responding to this request. Salima has already indicated she will bring it up at her bilat with Linsey this Friday.
- [REDACTED]
 - [REDACTED]

Next steps:

- HPCEU will request some additional information to the student in the meantime (i.e. were other regulators contacted and have they provided any information).
- DO/DGO (ROEB/TPD) supports responding to this request [REDACTED]
- BPS director to lead the response to the student.



Health Canada
Regulatory Authority

Requester agreed to Remove 3rd Party Info

Nitrosamines	Update August 23, 2021						
	Please see below for the nitrosamine weekly update for this week. Please let me know if you have any questions or concerns.						
	***Any suggestions/comments for these updates are welcome.						
	Lead	Date received/ Timeline	Issue/Affected product/Company	Background	The latest/Update	Current status and proposed next step	Comments/Questions
New notifications	HPC Central/H PCEU	2021-08-18	[REDACTED]	[REDACTED]	NIL	<ul style="list-style-type: none">[REDACTED]	

Prepared by HPCE

12

Last Updated on August 26, 2021
Page: 1,240 of/de 1,302
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						<div>[REDACTED]</div> <p>Next steps:</p> <ul style="list-style-type: none">• Info/package to be sent to TPD once inspector confirms missing info from the firm, including the rationale for the limit and RA was performed for the approved/marketed canadian products.	
New results	HPC Central/H PCEU	2021-08-19	<div>[REDACTED]</div>	<div>[REDACTED]</div>	<div>[REDACTED]</div>	<div>[REDACTED]</div> <p>Next steps:</p> <ul style="list-style-type: none">• [REDACTED]• [REDACTED] <p>Next steps:</p> <ul style="list-style-type: none">• Info/package to be sent to TPD once inspector sends full company response.• Determine if extension can be granted based on rationale provided and other extension requests <div style="border: 2px solid blue; padding: 5px;">Requester agreed to Remove 3rd Party Info</div>	<ul style="list-style-type: none">• PMS also requested an extension for testing till end of this year due to difficulty obtaining standards + their initial RA concluded no risk. TPD provided recommendation to test only in July 2021.• Overall extension requests can be evaluated once we received most extension requests. To be

					<div></div> <p>confirmatory testing for all approved/dormant/marketed drug products.</p> <p>In order to determine the extent of Canadian impact of presence of nitrosamines</p> <div></div> <p>HPCE issued letters to the other MAHs</p> <div></div> <p>to make them aware of the issue and request information on marketed products within expiry, risk assessment, medically necessary determination form and product testing as a high priority:</p> <ul style="list-style-type: none">• Information, risk assessment and NMD form was requested within 1 week of issuance.• Testing results <div></div> <p>and any other suspected nitrosamines identified in the risk assessment was requested within 3 months</p> <div></div> <ul style="list-style-type: none">• MAHs having only approved/dormant DINs (strides, biomed) were asked to confirm that they will provide risk			discussed .	
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Requester agreed to Remove 3rd Party Info

					assessment and testing prior to commencing sale if they have no lots currently on the market within expiry				
	MAH Letter Issuance	NIL							
	Stakeholder outreach (responses, Q&A)	TPD	2021-08-09	Stakeholder session	Virtual Stakeholder Scientific and Technical Session on Nitrosamines: Webinar is intended to provide an opportunity for industry stakeholders to present new technical developments and scientific progress, which could facilitate the risk assessment and control of nitrosamine impurities in human pharmaceuticals. Information presented at this session will inform Health Canada of industry's scientific and technical understanding on key areas as well as identify current gaps and priorities, and may support refining and developing regulatory views going forward.	Invites were sent to TPD and BRDD stakeholders on August 9, 2021 and 10, respectively.	<ul style="list-style-type: none"> Timelines: call for proposals by August 23, 2021 Accept or decline invitation: August 30, 2021 Documents: 		
							<p><<21-113867-518-Invitee list and email script for the HC October 2021 Stakeholder session on Nitrosamines v7.docx>></p> <p><<21-113867-518-HC Stakeholder Session - Nitrosamines (2021-10-20) - draft agenda v4_CT.docx>></p> <p><<21-113867-518-Email invite attachment for stakeholder session on Nitrosamines Oct 20 2021 v7.docx>></p>		

Requester agreed to Remove 3rd Party Info

						Next steps: <ul style="list-style-type: none">HPCEU to draft closing remarks for HPCD DG.TPD to review calls for proposal.	
Risk Communi cation	NIL						
Internatio nal updates	TPD	2021-08-20	NIL	See below Varencline section for more details	The U.S. FDA <u>posted</u> a webpage of varenicline testing results on August 23, 2021. <div></div> <ul style="list-style-type: none">	Current status: <ul style="list-style-type: none">From the <div></div> call in July, the FDA conducted their own testing <div></div> <div></div> <ul style="list-style-type: none"> Next Steps: <ul style="list-style-type: none">Inspector will follow-up with <div></div> to confirm whether any canadian lots were released as part of the same manufacturing lot as the lots tested by US FDA.	

Requester agreed to Remove 3rd Party Info

	Risk assessment follow-up	TPD/HPCEU	2021-08-18	NIL	<p>A letter dated of April 14, 2021, to follow up on Step 1 of our call for review in order to gauge completion levels and to gain insight into any risks identified was issued to all affected MAHs (roughly 1200 MAHs). MAHs were asked to complete an attestation letter to confirm risk assessment have been completed for all marketed, approved and dormant products (Annex 1). If risk assessments have not been completed, then the MAHs were asked to provide details and rationale for non completion (Annex 3). If risk assessments have been completed then a summary of completed risk assessments (Annex 2) was asked to be provided. These responses will be received by HPFB and all incomplete responses and non-responders will be forwarded to ROEB for compliance verification action. Timelines to receive these responses have been extended on as follows:</p> <ul style="list-style-type: none"> • Annex 1: Risk Assessment Attestation letter – extended to July 30, 2021, • Annex 2: Summary of Completed Risk Assessments – 	<p>A reminder email was sent on August 17, 2021 to approximately 500 active MAHs that have not responded to our April 14, 2021 letter requesting documents/Annexes be completed.</p> <ul style="list-style-type: none"> • Around 150 MAHs have responded that they have already responded. • TPD (BPS) is looking into the discrepancy and will give an update on numbers and next steps shortly. 	<p>Next steps:</p> <ul style="list-style-type: none"> • TPD to provide an update at next CM on discrepancy and next steps. • TPD to refer to HPCEU an updated list of non responders and MAHs who have not completed they risk assessments for C&E actions with including information on: <ul style="list-style-type: none"> a) MAHs who have marketed products b) MAHs who only have dormant DINs (i.e., are not in the marketed products list c) MAHs who only have approved but not marketed DINs (i.e., are not in the marketed products list) <p>Additional actions may be taken prior to referring to HPCEU, depending on list of non responders. More analysis on the non-responders will be required from pre-market (e.g. ensuring that we have the correct company contacts, that contacts are cross-referenced to ensure that if they represent more than one company – that is reflected etc.).</p> <p>Responses received to date: TBC</p> <p>Status of HPCEU national Action Plan (for follow-up on non responders and incomplete responses) : HPCEU is collating comments received from IOC</p>		
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				<p>extended to Sept. 1, 2021, and</p> <ul style="list-style-type: none">Annex 3: Details Regarding Incomplete Risk Assessments (if applicable) – extended to July 30, 2021.		and will provide version for DO approval by end of this week.	
APO-varenicline	TPD/HPCE U/HPC Central	2021-08-23	<p>Company: Apotex Inc</p> <p>Products: APO-Varenicline 0.5 mg DIN 02479882 APO-Varenicline 1mg DIN 02419890 APO-Varenicline 0.5mg/1mg combo DIN 02435675</p> <p>Radar #2020-067860</p>	<p>On September 23, 2020, the EMA shared information with international partners that three new nitrosamines were detected in varenicline API. The EMA also reported that an additional nitrosamine impurity, NDEA, was identified for Pfizer’s varenicline product, Champix. HPFB (TPD) confirmed a risk for formation of multiple nitrosamines for all Canadians Market Authorization Holders (MAHs) of varenicline. In line with the standard process, ROEB issued a letter to all MAHs on October 26, 2020 requesting they evaluate the risk for the presence of nitrosamines and to testing for nitrosamines where a risk is identified.</p> <p>Prior to June 2021, Health Canada had established an interim Acceptable Intake (AI) limit of 26.5 ng/day for drug products containing N-nitrosovarenicline, to guide requests for recalls. As of June 2021, international alignment was reached amongst regulatory partners and HC revised the AI limit to 37 ng/day for the N-nitrosovarenicline impurity. Medical necessity</p>	<ul style="list-style-type: none">ROEB (HPC Central) sent a no objection letter (NOL) to Apotex, indicating that Health Canada agrees with Apotex’s proposal to release Apo-varenicline onto the Canadian market with an AI concentration limit of NMT 18.5 ppm. Health Canada will not object to an interim shelf-life limit of 92.5 ppm at this time (and will be re-assessing this enforcement discretion in 6 months) with certain conditions (target timeline to send this NOL: August 17, 2021):	<p>Current Status:</p> <ul style="list-style-type: none">Three lots were tested and found to contain n-nitrosovarenicline above the AI.<	

Requester agreed to Remove 3rd Party Info

					<p>determinations were conducted by TPD for varenicline drug products.</p> <p>[Redacted]</p>	<ul style="list-style-type: none">• [Redacted]• [Redacted]• [Redacted]	<p>[Redacted]</p> <p>Next steps:</p> <ul style="list-style-type: none">• HPC Central to follow-up with Apotex [Redacted]• [Redacted]• CM to discuss the need for public comms for interim limit (i.e. update to nitro webpage, etc.)		
						<ul style="list-style-type: none">• [Redacted]• [Redacted]			

Requester agreed to Remove 3rd Party Info

	Champix	HPC East/HPC EU	2021-08-06	<p>Radar: 2020-067826</p> <p>Product and Company Description: <u>Company</u> Pfizer Canada ULC 17300 Trans-Canada Highway Kirkland, QC, JH9J 2M5</p> <p><u>API manufacturer:</u></p> <ul style="list-style-type: none"> [REDACTED] [REDACTED] <p><u>Products</u> Champix (DIN 02298309, 02291177, 02291185)</p> <ul style="list-style-type: none"> Champix is a prescription medication indicated for smoking-cessation treatment in adults, in conjunction with smoking-cessation counselling. [REDACTED] 	<p>Background On September 23, 2020, EMA notified HC that 3 new nitrosamines were detected in varenicline API. In addition to these 3 nitrosamines, another nitrosamine impurity, NDEA, was also identified as a risk for the varenicline brand name product Champix (Pfizer). Following their review of manufacturing processes, HPFB (TPD) confirmed a risk for formation of multiple nitrosamines for all Canadians Market Authorization Holders (MAHs). In line with the standard process, HC sent a letter on October 26, 2020 to all MAHs requesting them to evaluate the risk for the presence of nitrosamines in their varenicline drug product and to perform testing for nitrosamines for which a risk has been identified, including N-nitrosovarenicline.</p> <p>Prior to June 2021, Health Canada was using the internally established interim Acceptable Intake (AI) limit of 26.5 ng/day for drug products containing N-nitrosovarenicline, to guide requests for recalls. As of June 2021, since international alignment was reached amongst regulatory partners and HC initiated using an AI of 37 ng/day for the N-nitrosovarenicline impurity. Medical necessity determinations were conducted by TPD for varenicline drug products. Only the Apo-varenicline</p>	<p>Last update (from week of August 9, 2021) Pfizer confirmed in writing ON August 12, 2021 that Pfizer has not released new lots on the Canadian market and will not do so until agreement with HealthCanada is reached on an interim plan for release. Pfizer does not have an estimated date when distribution of CHAMPIX can resume in Canada with N-nitroso-varenicline (NNV) levels at or below 37ng/day</p> <p>[REDACTED]</p>	<p>Current Status:</p> <ul style="list-style-type: none"> [REDACTED] Pfizer recalled 4 lots above their proposed AI, to the retail level as a Type II [REDACTED] [REDACTED] The <u>Nitrosamines recall</u> and <u>medication affected</u> webpage were updated to include this recall on July 28, 2021 All units of affected lots within Pfizer control have been placed on hold as of May 5, 2021. Pfizer confirmed on August 6, 2021, that not new lots have been released. Pfizer's product are not considered med nec. <p>Next Steps:</p> <ul style="list-style-type: none"> ROEB (HPCD) to follow-up with Pfizer to obtain: <ul style="list-style-type: none"> Root cause investigation report. TPD to review proposal and provide input/comments. 	<p>Pfizer not releasing any lots at this time.</p>	<div>Requester agreed to Remove 3rd Party Info</div>
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			<div><div></div><div><ul style="list-style-type: none">• Lots recalled on June 8, 2021: 00019062, 00020452, 00020451, ED7397,• Lot not yet distributed: #00023749</div></div>	<div><div></div><div><div>Requester agreed to Remove 3rd Party Info</div></div></div>	<div><div></div><div><ul style="list-style-type: none">• TPD to send list of question to FDA</div></div>	
Bumetanide	HPC East	Bumetanide	<div><div></div><div><ul style="list-style-type: none">• Letter requesting risk assessment and subsequent confirmatory testing was issued</div></div>	<div><div></div><div><div></div></div></div>	<div><div></div><div><p>Current Status :</p><p>Summary of risk assessment: Based on the findings of the assessment report, the following two impurities will be subject to confirmatory testing on the drug product: N-nitrosobumetanide and NDEA. Updated risk assessment taking into account additional information regarding extrinsic factors / GMP factors, as noted by BPS, was provided and no further risk were identified.</p><p>Summary of confirmatory testing results to date:</p><ul style="list-style-type: none">• API: the impurity N-nitrosobumetanide has been detected (up to 1.18 ppm) in several batches of API, by API manufacturer. No API lots used for the manufacture of lots on the Canadian markets have been tested to date.• DP: validated results indicate that the levels of</div></div>	<div><div></div><div><p>-Once SAR is received from MAH, ORM to assess AI.</p></div></div>

[illegible]

Key Items this week:

- CM meeting planned on August 25, 2021. Topics for discussions so far:
 - Varenicline
 - Ticagrelor
 - Update on RA follow ups
- HPCEU will request to have discussion around amitriptyline (i.e. request remaining MAHs who have provided a RA concluding no risk and no further testing required that that Health Canada is still requesting confirmatory testing results)

Here is the link to our nitrosamines [CV tracking sheet](#).

[Y:\HC\ROEB\HPCD\HPCRM\HEALTH RISK PROTECTION HC6\CASE MGMT\Nitrosamines](#)

DGO Annotated Agenda:



Monthly DG update
call on nitrosamines

NISG Annotated Agenda for Next Meeting:



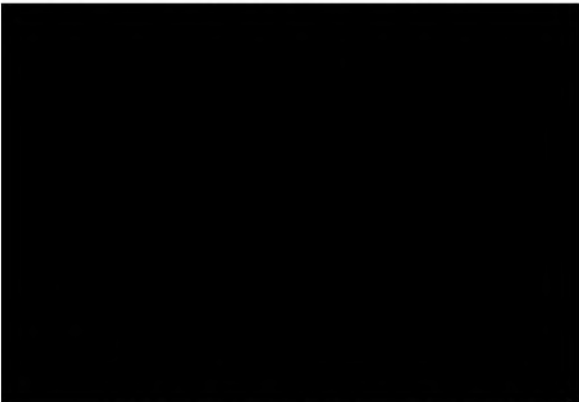
NISG Agenda Sept
29, 2021.docx

Tasks	Comments
NHP-GMP Inspection Pilot	<p><u>Update August 26, 2021:</u></p> <p>Attached are updates to the project dashboard and inspection tracker. The project road map did not require an update at this time as it is a higher level document.</p> <p>Dashboard Highlights:</p> <p>Risks to consider with regards to upcoming election and ongoing, confirmed and planned inspections. Further regulatory action could be taken with NC sites who submit inadequate CAPA, confirmed inspections of importers could result in NC ratings and planned inspections are our first manufacturer inspections, which could also result in NC ratings. In addition, if confirmed/planned inspections are postponed, we would have to consider extending the pilot another 2-3 months (April/May 2022) to complete the required 36 inspections.</p> <p><u>Inspection Planning:</u></p> <p>August/September :</p> <p>3 importer inspections confirmed starting Monday next week :</p> <div><div></div>Aug. 30 –Sep. 3, 2021</div> <div><div></div>– Aug. 30 –Sep. 3, 2021</div> <div><div></div>30 –Sep. 3, 2021</div> <p>3 manufacturer inspections planned (companies not yet contacted):</p> <p>Central has the following sites to choose from, but has not selected one yet:</p> <div></div> <p>West has the following sites to choose from:</p> <div></div>

Requester agreed to
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Inspector was planning on starting with GFR Pharma. They were inspected during the CMPs and are not expected to be NC.

East has the following sites to choose from:



Inspector was planning on starting with [redacted] They manufacture drugs. [redacted] are not expected to be NC.

Proposed NC Site Update:

[redacted] will be confirmed Aug. 27, 2021 and regulatory actions by NNHPD verified. The Exit Notice meeting with the company is not yet scheduled, but is held soon after the compliance rating is confirmed.

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Confirmed NC Site Updates:

The CAPA for [redacted] is due November 11/21. The inspector will have 20 business days to review it for acceptability.

The CAPA for [redacted] is due September 22/21. The inspector will have 20 business days to review it for acceptability.

The inspector reviewed the CAPA for [redacted] and is in discussion with NNHPD concerning its acceptability.

The inspector received the CAPA for [redacted] on Aug. 23/21, but has not started the review. The inspector has 20 business days to review it for acceptability.

The inspector received and reviewed all outstanding CAPA from [redacted] and is expecting to hear from NNHPD early next week whether it is acceptable and the suspension SL and ITS for PLs will be lifted.

Inspection Tracker Highlights:

July/August:



3 inspections Completed

[redacted] - July 26-30 & Aug. 3-4, 2021 (proposed NC)

[redacted] - August 2-6 & 9-10, 2021 (proposed C)

[redacted] - July 29-30 & August 3- 6, 2021 (proposed C)

Requester agreed to
Remove 3rd Party Info

	<div><div> NHP GMP Project Dashboard 26Aug2021</div><div> Dashboard Inspection Summary</div></div>
Heads up OOS TYMC Ruzurgi Medunik Canada	<p><u>Update on September 2, 2021</u></p> <p>As per the look-ahead update. A notification was received from MedUnik about an OOS for TYMC. The distributor Innomar was notified to stop the distribution (date being confirmed) of the batch impacted by the investigation and the lot 18038 was placed in quarantine (date being confirmed), in MedUnik warehouse. Investigation is ongoing (should be completed within 2 weeks) and MedUnik is waiting for the investigation’s results in order to proceed with the release or recall of Ruzurgi, lot 18038. No shortage concerns with having this lot in quarantine are expected and no ADRs have been reported to date. More to come.</p> <p>As you are aware this product was the one that had to reapply for a new NOC as a result of a Federal court order (data protection issue). See HPRC: https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75793a-eng.php</p> <p>More Details on Case from East:</p> <div><div><p>Radar : 2021-056938 Company : MedUnik Canada Product : Ruzurgi, lot 18038 DIN: 02503034</p></div><div><div>Requester agreed to Remove 3rd Party Info</div></div></div> <p>Issue:</p> <ul style="list-style-type: none">• RUZURGI (amifampridine) is indicated for the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) (rare disease) in patients 6 years of age and older;• A notification from MedUnik was received about an OOS for TYMC;<ul style="list-style-type: none">• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]• As part of Health Canada's requirement of testing one lot per year, the Ruzurgi lot 18038 was tested [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED] They also requested bottles of the batch impacted that was received at MedUnik and the raw data of the laboratory that reported OOS results;• The distributor [REDACTED] was notified (date being confirmed) to stop the distribution of the batch impacted by the investigation;• The lot 18038 was placed in quarantine (date being confirmed), in MedUnik warehouse;• Investigation is ongoing. MedUnik is waiting for the investigation’s result to proceed with the release or recall of Ruzurgi, lot 18038;• [REDACTED]• MedUnik will complete the investigation in 2 weeks (many incubation days);• No shortage is to be expected due to lot 18038 being quarantined;• No adverse effects received for this lot.

ATIA - 19(1)

ATIA - 21(1)(a)

HPCE Weekly Thursday Update – September 2, 2021

	<p>Next Steps</p> <ul style="list-style-type: none">Follow up with Medunik for the results and take appropriate C&E actions, as appropriate. <p>Please let us know if you have any questions and/or concerns.</p>
Heads Up: HPC East Site Visit [REDACTED]	<p><u>Update on September 2, 2021</u></p> <p>Closing the loop on this site visit as no issues were identified. More details below:</p> <ul style="list-style-type: none">Unannounced site visit conducted to firm morning of September 2nd 2021 to verify any licensable activities conducted by firm.The owner informed the inspectors that the application for a site license for importation activity was submitted several months ago [REDACTED]No packaging equipment or labels were seen on site. The owner confirmed that they do not complete any packaging and labeling activities for the NHPs.No seizure or voluntary detention took place. <p>Next Steps:</p> <ul style="list-style-type: none">Send a compliance email outlining the visit.Close the case.
International Outreach- Dr. Jason Klop Fecal Microbial Transplant File CBC Article	<p><u>Update on September 1, 2021</u></p> <p>HPC-West has drafted an email that will go out tomorrow via the Rapid Alert Generic account [REDACTED] It will contain only <u>publicly available information</u> (CBC article, website he uses, order from the naturopaths of BC to stop making FMT, our guidance docs etc). By invoking section 37 Dr. Klop attests that his product meet the regulatory requirements of Mexico.</p> <p>[REDACTED]</p>
Ivermectin Signage Concern (Caretaker Sensitivity File)	<p><u>August 30, 2021</u></p> <p>We followed up with MHPD and can confirm that they are following up with <u>signage company</u> (Magnetic Signs- [REDACTED])</p> <p>The contact information for Magnet Signs in Winkler, Manitoba, the area in which the complaints are occurring (near the border of North Dakota, USA), is:</p> <p>[REDACTED]</p> <p>[REDACTED] They will still be sending a regulatory letter to the company.</p> <p>MHPD is still having discussions on whether they should be requesting for detailed information on who paid for the billboards/advertisements. The area in which the earlier complaints are situated (excluding the most recent one from the Pharmacists' Association) are in Winkler, MB, which is quite close to the US border (North Dakota). [REDACTED]</p> <p>[REDACTED]</p> <p>PA was posted on August 31, 2021- https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php</p>

Requester agreed to Remove 3rd Party Info

HPCE Weekly Thursday Update – September 2, 2021

Haywick Industries (HS CMP)	<p><u>Update on September 2, 2021</u></p> <p>Haywick Industries hand sanitizers with deficient labels and high methanol content - contesting HC lab results and refusal to initiate recall</p> <ul style="list-style-type: none">Haywick Industries has a Covid Site Licence (SL) and 2 NPNs for PURE75 (gel: NPN 80098346; wipes: NPN 80104709) that were tested as apart of the hand sanitizer (HS) compliance monitoring project (CMP).Deficient risk statements on product labels were classified as a type II risk and a stop sale request was sent August 6 & 13. [REDACTED]On August 20, HPCD issued a request for a Type II recall retail level, after HC laboratory analysis results noted an impurity methanol concentration of 269 ppm (limit is 200 ppm)On August 25, NNHPD issued an immediate suspension of NPN 80098346, intent to suspend NPN 80104709 and intent to revoke COVID-SL.On August 27, the company responded to the recall request by disputing the HC laboratory results and requesting a new test from Health Canada.[REDACTED]Next steps were discussed internally on Aug 30 (HPCD & NNHPD). Per standard business practice, it was agreed the inspector was to respond to the company to justify the analysis performed by the HC lab, justify why a Type II risk was assigned, request the results of the 3rd party testing to be conducted by the company and confirm whether the company is intending on initiating the requested recall of the product.[REDACTED]Further C&E action will be considered, including potential public advisory, should the company not agree to the recall
HPC Central Site Visit to [REDACTED]	<p><u>Update on September 1, 2021</u></p> <p>Note the outcome of HPCRM's (HPC Central) Aug 30 site visit to [REDACTED] retail locations across Toronto (ON):</p> <ul style="list-style-type: none">[REDACTED][REDACTED][REDACTED][REDACTED][REDACTED]A compliance letter will be issued early next week.The border target/lookout will be requested by the end of this week
Update on Teva-Canada/Sivem Pharmaceuticals ULC Recall of 7 lots with Azido Impurity Levels Above the TTC and Next Steps	<p><u>Update on August 30, 2021</u></p> <p>UPDATE: Type I recall (to retail) of Losartan due to azido impurity</p> <ul style="list-style-type: none">On August 26, 2021 Teva Canada initiated a Type I recall to retail level for 5 lots of their Teva-Losartan products due to AMES testing demonstrating levels of the azido impurity above the Threshold of toxicological concern (TTC) of 1.5 ug/day (15 ppm) to be mutagenic.Sivem Pharmaceuticals ULC also initiated a type I recall for 2 lots of their cross licensed product, Sivem-Losartan, August 27, 2021.The <u>ongoing Public Advisory (PA)</u> was updated August 28 to include all 7 lots; a stakeholder message was issued by HPCD on August 27.Previously, this impurity was identified above the TTC in 3 SANDOZ losartan products; however, HC was waiting for AMES test from Sandoz. Now that results are available, based on ORM's recommendation HPCRM will now reach out to Sandoz to request a recall.[REDACTED]Since the recall may expand to Sandoz products (based on the positive AMES test by Teva-Canada), DSU was consulted on potential shortages created by these upcoming Losartan recalls and confirmed there are no shortage concerns as there are alternatives available. <p>Next Steps:</p> <ul style="list-style-type: none">HPCE to reach out to Sandoz after discussion with TPD (target TBC), informing them of the recent AMES test results and requesting a recall of lots above TTC for new mutagenic impurity. An update to the PA and stakeholder message will follow once Sandoz agrees.

Requester agreed to
Remove 3rd Party Info

Update on August 25, 2021

CSF - Please see below

NOTE:

For more information, see HPCR's detailed summary below.

Requester agreed to
Remove 3rd Party Info

Flaggering this to you as a caretaker file- Eric Tessier from HPC East received a summons to appear in court with respect to a compliance letter sent to Actumus Inc. in 2018. More details below:

- •
•

-

- RADAR #2018-020464-Complaint received regarding the advertising of a detox product for babies attention:

-

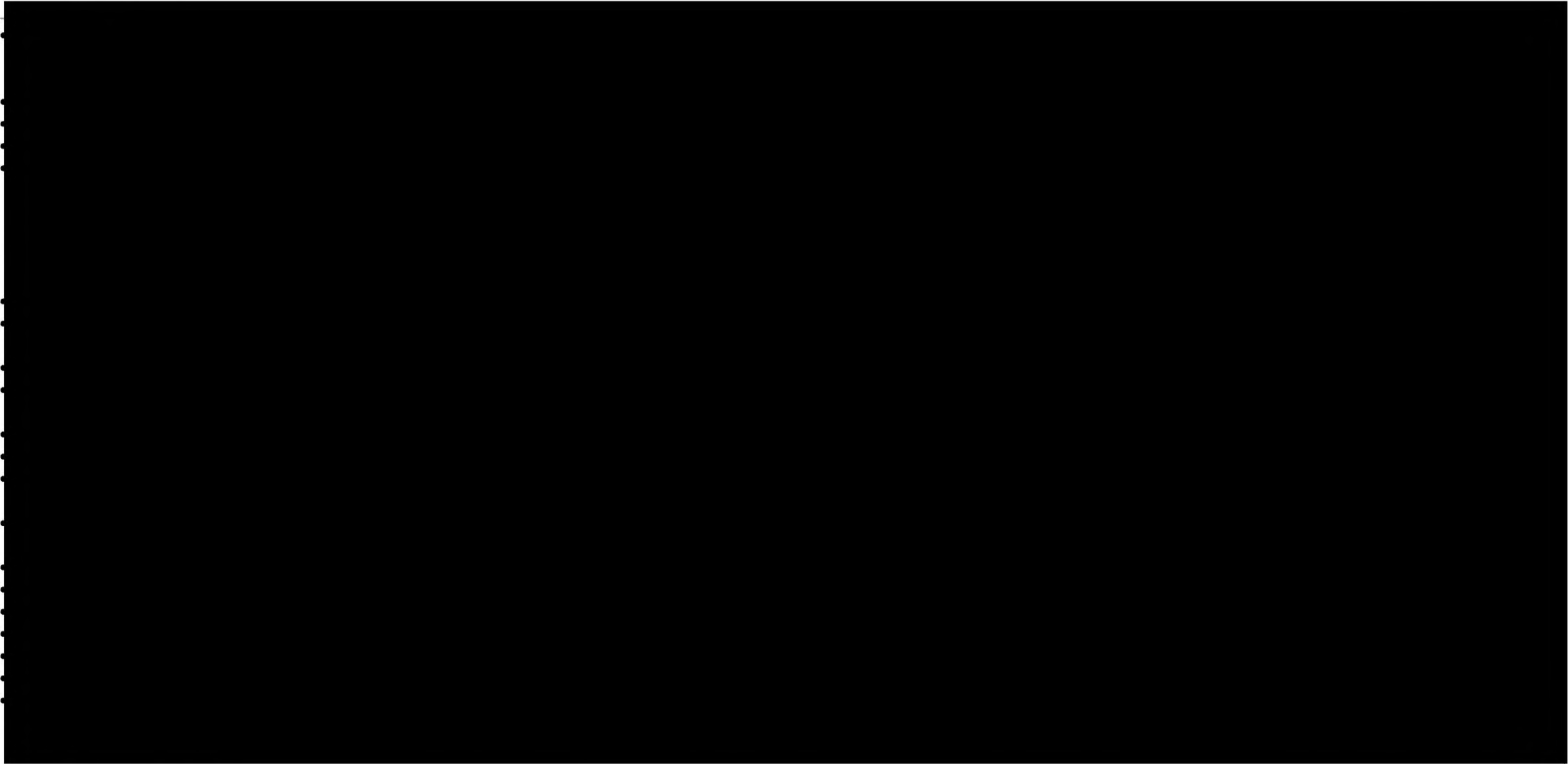

- LSU was notified

Next steps:

- Update LSU

BACKGROUND:

-
-
-

	
Heads Up: NuWTR Fulvic & Black Oxygen Products Recall (2021-026872 & 2021-047885)	<div><div><div><div><div>Update on September 2, 2021</div><div><ul style="list-style-type: none">MAH contacted Central inspector and confirmed they will initiate Type III recalls of two products to the customer level:<ul style="list-style-type: none">Black Oxygen Tablets (NPN 80097385)Fulvic Care (NPN 80106662)Requested the MAH to confirm the following by end of day, Sep 2:<ul style="list-style-type: none">Whether they plan to initiate the recall today to all customersProvide revised recall communicationConfirm how customers with missing emails will be contactedClarify product quantity information</div></div><div><div>Requester agreed to Remove 3rd Party Info</div></div></div></div></div>

ATIA - 21(1)(a)

ATIA - 23

- As of 4:30pm, response from MAH was pending. Call attempts were made to MAH contacts
- [REDACTED]
- [REDACTED]

Next Steps:

- Confirm when MAH initiates the recall.
- [REDACTED]

Heads Up

Update on August 30, 2021

Below you will find an update as of this pm

Next steps:

- Follow up with the wholesaler

Requester agreed to
Remove 3rd Party Info

Update

Update on August 12, 2021

Update:

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Next steps:

-


ATIA - 16(1)(b)
ATIA - 21(1)(a)

HPCE Weekly Thursday Update – September 2, 2021

Valisure report on sunscreen products- Next Steps	<p><u>Update on September 2, 2021</u></p> <p>HPCD & NNHPD call with US FDA September 1 regarding Valisure sunscreen report re. benzene</p> <ul style="list-style-type: none">On September 1, HPCD and NNHPD met with the US FDA to discuss Valisure’s sunscreen report, on detection of benzenes in sunscreen products[REDACTED][REDACTED][REDACTED][REDACTED]J&J has recalled all products in the US that use isobutane as a propellant [REDACTED][REDACTED]If additional products or safety concerns are identified, appropriate action will be taken. <p>Background:</p> <ul style="list-style-type: none">Valisure released a report in May 2021, where they report having detected high levels of a known human carcinogen, benzene in several sunscreen products.78 products (available in the US) had detectable levels of benzene<ul style="list-style-type: none">26 contained benzene in concentrations between 0.1 ppm and 2.0 ppm14 contained over 2 ppm.NNHPD cross referenced the list and identified one licence holder [REDACTED]this resulted in a voluntary type II recall by Johnson & Johnson (July 17th 2021)NNHPD recently reached out to the additional six (6) Canadian companies who were identified on the Valisure report, irrespective of the level of benzene identified in the report.[REDACTED][REDACTED]Based on the information we have received thus far, we do not have reason to believe that the products contain elevated benzene levels.
Update on Investigation - [REDACTED]	<p><u>Update on July 28, 2021</u></p> <p>[REDACTED]</p> <p>Current Status:</p> <ul style="list-style-type: none">[REDACTED][REDACTED][REDACTED][REDACTED][REDACTED][REDACTED][REDACTED][REDACTED][REDACTED][REDACTED] <p>Next steps:</p> <ul style="list-style-type: none">[REDACTED][REDACTED][REDACTED]

Requester agreed to
Remove 3rd Party Info

HPCE Weekly Thursday Update – September 2, 2021

Plain Language Labelling	<p><u>Update on September 2, 2021</u></p> <p>HPCEU met with NNHPD today on the status of the PLL referrals. Please see an update below for your information and the attached recommended approach for dealing with the non-responders (once referred) for your concurrence.</p> <p>Update on PLL and of September 2, 2021:</p> <ul style="list-style-type: none">HPCEU met with NNHPD today (Sept 2). NNHPD provided an update on the status of referrals:<ul style="list-style-type: none">Referrals to date:<ul style="list-style-type: none">[REDACTED] - NNHPD has made contact and referral will be withdrawn (no action required for HPCE)[REDACTED] - NNHPD has made contact and referral will be withdrawn (no action required for HPCE)[REDACTED] - company reached out to NNHPD and has submitted labels. NNHPD reviewing labels and will be providing input on how to comply with requirements (if company revises labels no action will be required from HPCE and referral will be withdrawn)Pending referrals:<ul style="list-style-type: none">NNHPD to refer remaining non-responders (approximately 12) week of Sept 6, 2021 <p>Next Steps:</p> <ul style="list-style-type: none">Attached you will find ROEB-HPCRM an options analysis with a recommendation to utilize a compliance promotion approach for non-responders referred by NNHPD. Please let us know if you concur with approach so we can finalise our action plan. <p>Please let us know if you have any questions and/or concerns.</p> <div><p>Options PLL OTC_20210708_HPC</p></div> <div>Requester agreed to Remove 3rd Party Info</div>							
[REDACTED]	<p><u>Update on August 3, 2021</u></p> <p>The test results were received identifying prescription, analogue to prescription and/or controlled drug. [REDACTED]</p> <p>[REDACTED]</p> <p>TIL Sales Inc. dba Love Boutique – RADAR 2021-040488 (draft IMR: <u>W:\HC\ROEB\HPCD\HPCRM\HEALTH RISK PROTECTION HC6\CASE MGMT\TIL Sales - 2021-040488</u>)</p> <ul style="list-style-type: none">[REDACTED][REDACTED][REDACTED][REDACTED] <p>[REDACTED]</p> <ul style="list-style-type: none">Site visit to Ontario supplier being planned (no date provided yet)							
Ethanol Update	<p><u>September 2, 2021</u></p> <p>The HS RL was last updated Tuesday August 24th with 2 entries (all from HS CMP): https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75267a-eng.php. There may be 2 entries this week as we’re waiting for Embassy Ingredients to confirm they’ve initiated their recall otherwise it will only be 1 entry (DuBois) that is added.</p> <table><tr><th>Product</th><th>Reason for recall</th><th>Company</th><th>NPN or DIN</th><th>Lot Number(s)</th><th>Expiry Date</th><th>Recall Initiated</th></tr></table>	Product	Reason for recall	Company	NPN or DIN	Lot Number(s)	Expiry Date	Recall Initiated
Product	Reason for recall	Company	NPN or DIN	Lot Number(s)	Expiry Date	Recall Initiated		


Embassy Ingredients - Hand Sanitizer	Contains undeclared impurity, acetaldehyde, at elevated levels; not properly labelled (including missing risk statements and information for vulnerable population in French)	Embassy Ingredients	80097955	All	All	To be recalled, pending confirmation.
Hand San Gel	Product not authorized to contain technical-grade ethanol	DuBois Chemicals Canada, Inc.	80105403	20190SV396 20223SV967	July 2022 September 2022	August 27, 2021

Please see attached the IMR that provides an update on the status of the CVs in the HS CMP.

Highlights of HS CMP:

- Through Avalon’s (Batch #2) investigation report, it advised their sanitizer was supplied by another Canadian firm resulting in the creation of a new case to follow-up with that supplier for quality issues that may affect other NPNs by different firms.
- Batch #4: Sample identified in beverage container was confirmed to have been last distributed in June 2020. Therefore no recall is warranted and the request was rescinded.
- 3 Recalls initiated/to be initiated:
 - DuBois – recall for another NPN initiated August 27th as it was manufactured with TGE (without NOL); Adding this week to RL update.
 - Embassy – firm has not initiated their recall as they are want to receive their independent test results first but committed to recall; Add to RL this week (if initiate by tomorrow morning) otherwise next week.
 - Haywick - [REDACTED]

Regulatory notices and KAIs drafted/issued by NNHPD are saved here: [Y:\HC\ROEB\HPCD\HPCRM\HEALTH RISK PROTECTION HC6\CASE MGMT\HS CMP](#)



Hand Sanitizer CMP
IMR_Sept 2 2021 HF

Requester agreed to
Remove 3rd Party Info

Update on September 2, 2021:

Summary from program – based on interactions to date as well as addressing the sample issue.

- Since 2016, [REDACTED] have both been in contact with Health Canada alleging activity conducted by [REDACTED] was contravening federal legislation. They suspected [REDACTED] was 'dose-splitting', tampered product and provided deceptive labelling, all in contravention of federal legislation. Four complaints were submitted and verified by inspectors.
- Further to these allegations, Health Canada completed thorough compliance verification activities in accordance with internal standard operating procedures. This included submission of a provided product sample to Health Canada's laboratory for sterility testing that did not identify issues of concern in 2019.
- Health Canada inspectors determined that there was no non-compliance against the requirements of the *Food and Drug Regulations* (FDR) and referrals were made to the appropriate provincial regulators related to activities identified by the inspectors for any actions, as necessary.
- Recently [REDACTED] requested for a return of their provided sample. They were advised that following testing and assessment by the Department, the sample was destroyed as per standard laboratory practice. [REDACTED] was offered photographs of the sample and its packaging that were taken prior to analysis.
- Over the years, the complainants contacted Health Canada for updates as well as voiced their concerns regarding Health Canada's determinations. They have been advised on multiple occasions (via teleconference and in writing) that their complaint was taken seriously, compliance verification activities were completed thoroughly, and that matters raised fall under the oversight of the various provincial authorities.
- Lastly, they were provided a heads-up regarding amendments to the FDR that would seek to analyze and address any potential gaps in regulatory oversight that exist for the regulation of different levels of government in Canada with public/stakeholder consultations taking place in 2022/2023.

	 <p>Letter to Minister Patty Hajdu dated 5</p>																																														
Nitrosamines	<p><u>Update Week of Aug 30, 2021</u></p> <p>Please see below for the nitrosamine weekly update for this week. Please let me know if you have any questions or concerns.</p> <p>***Any suggestions/comments for these updates are welcome.</p> <p>Please see below for the nitrosamine weekly update for the week of August 23, 2021. Please let us know if you have any questions or concerns.</p> <p>***Any suggestions/comments for these updates are welcome.</p> <table> <tr> <th></th><th>Lead</th><th>Date received/ Timeline</th><th>Issue/Affected product/Company</th><th>Background</th><th>The latest/Update</th><th>Current status and proposed next step</th><th>Comments /Questions</th></tr> <tr> <td>New notifications</td><td>NIL</td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>New results</td><td>NIL</td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>MAH Letter Issuance</td><td>NIL</td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>Stakeholder outreach (responses, Q&A)</td><td>TPD</td><td>2021-08-30</td><td>Stakeholder session</td><td>Virtual Stakeholder Scientific and Technical Session on Nitrosamines: Webinar is intended to provide an opportunity for industry stakeholders to present new technical developments and scientific progress, which could facilitate the risk assessment and control of nitrosamine impurities in human pharmaceuticals. Information presented at this session will inform Health Canada of industry's scientific and technical understanding on key areas as well as identify current gaps and priorities, and may support refining and developing regulatory views going forward.</td><td>CM team met on August 30, 2021 to select proposals. However, due to missing key team members and proposals, meetings was rescheduled to September 7, 2021.</td><td> Timelines: <ul style="list-style-type: none"> call for proposals by August 23, 2021 Accept or decline invitation: August 30, 2021 Documents: <<21-113867-518-Invitee list and email script for the HC October 2021 Stakeholder session on Nitrosamines v7.docx>> </td><td></td></tr> </table>								Lead	Date received/ Timeline	Issue/Affected product/Company	Background	The latest/Update	Current status and proposed next step	Comments /Questions	New notifications	NIL							New results	NIL							MAH Letter Issuance	NIL							Stakeholder outreach (responses, Q&A)	TPD	2021-08-30	Stakeholder session	Virtual Stakeholder Scientific and Technical Session on Nitrosamines: Webinar is intended to provide an opportunity for industry stakeholders to present new technical developments and scientific progress, which could facilitate the risk assessment and control of nitrosamine impurities in human pharmaceuticals. Information presented at this session will inform Health Canada of industry's scientific and technical understanding on key areas as well as identify current gaps and priorities, and may support refining and developing regulatory views going forward.	CM team met on August 30, 2021 to select proposals. However, due to missing key team members and proposals, meetings was rescheduled to September 7, 2021.	Timelines: <ul style="list-style-type: none"> call for proposals by August 23, 2021 Accept or decline invitation: August 30, 2021 Documents: <<21-113867-518-Invitee list and email script for the HC October 2021 Stakeholder session on Nitrosamines v7.docx>>	
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							<<21-113867-518-HC Stakeholder Session - Nitrosamines (2021-10-20) - draft agenda v4_CT.docx>> <<21-113867-518-Email invite attachment for stakeholder session on Nitrosamines Oct 20 2021 v7.docx>> Next steps: <ul style="list-style-type: none">• HPCEU to draft closing remarks for HPCD DG. (Timeline end of september 7, 2021)• TPD to review calls for proposal and select topics (Timeline September 7, 2021)		
	Risk Communi cation	NIL							
	Internatio nal updates	TPD	2021-08-20	NIL	See below Varencline section for more details	The U.S. FDA response to HC's questions regarding Prizer varencline recall and proposal. <div></div>	See below Varenicline section for more details		

Requester agreed to Remove 3rd Party Info

					<p>Timelines to receive these responses have been extended on as follows:</p> <ul style="list-style-type: none"> Annex 1: Risk Assessment Attestation letter – extended to July 30, 2021, Annex 2: Summary of Completed Risk Assessments – extended to Sept. 1, 2021, and Annex 3: Details Regarding Incomplete Risk Assessments (if applicable) – extended to July 30, 2021. 		<p>correct company contacts, that contacts are cross-referenced to ensure that if they represent more than one company – that is reflected etc.).</p> <p>Responses received to date: TBC</p> <p>Status of HPCEU national Action Plan (for follow-up on non responders and incomplete responses) : Action plan will be sent for DO approval this week.</p>		
	APO-varenicline	TPD/HPCE U/HPC Central	2021-08-23	<p>Company: Apotex Inc</p> <p>Products: APO-Varenicline 0.5 mg DIN 02479882 APO-Varenicline 1mg DIN 02419890 APO-Varenicline 0.5mg/1mg combo DIN 02435675</p> <p>Radar #2020-067860</p>	<p>On September 23, 2020, the EMA shared information with international partners that three new nitrosamines were detected in varenicline API. The EMA also reported that an additional nitrosamine impurity, NDEA, was identified for Pfizer’s varenicline product, Champix. HPFB (TPD) confirmed a risk for formation of multiple nitrosamines for all Canadians Market Authorization Holders (MAHs) of varenicline. In line with the standard process, ROEB issued a letter to all MAHs on October 26, 2020 requesting they evaluate the risk for the presence of nitrosamines and to testing for nitrosamines where a risk is identified.</p> <p>Prior to June 2021, Health Canada had established an interim Acceptable Intake (AI) limit of 26.5 ng/day for drug products containing N-nitrosovarenicline, to guide requests for recalls. As of June 2021, international alignment was reached amongst regulatory partners and HC revised the AI limit to 37 ng/day for the N-nitrosovarenicline impurity. Medical necessity determinations were conducted by TPD for varenicline</p>	<p>The latest:</p> <ul style="list-style-type: none"> [REDACTED] A meeting has been scheduled with BPS on Thursday, September 9th (1pm – 2 pm) [REDACTED] 	<p>Current Status:</p> <ul style="list-style-type: none"> Three lots were tested and found to contain n-nitrosovarenicline above the AI. [REDACTED] [REDACTED] [REDACTED] [REDACTED] 	<p>FDA issued PA including results from Apotex above AI.</p>	

Requester agreed to Remove 3rd Party Info

					drug products. [REDACTED]			
					[REDACTED]			
					[REDACTED]			
Requester agreed to Remove 3rd Party Info								
Champix	HPC East/HPC EU	2021-08-06	<p>Radar: 2020-067826</p> <p>Product and Company Description: <u>Company</u> Pfizer Canada ULC 17300 Trans-Canada Highway Kirkland, QC, JH9J 2M5</p> <p><u>API manufacturer:</u></p> <ul style="list-style-type: none">0.5mg: Upjohn Manufacturing Ireland Unlimited Company, Little Island, County Cork, Ireland	<p>Background On September 23, 2020, EMA notified HC that 3 new nitrosamines were detected in varenicline API. In addition to these 3 nitrosamines, another nitrosamine impurity, NDEA, was also identified as a risk for the varenicline brand name product Champix (Pfizer). Following their review of manufacturing processes, HPFB (TPD) confirmed a risk for formation of multiple nitrosamines for all Canadians Market Authorization Holders (MAHs). In line with the standard process, HC sent a letter on October 26, 2020 to all MAHs requesting them to evaluate the risk for the presence of nitrosamines in their varenicline drug product and</p>	Last update (from week of August 9, 2021) [REDACTED]	<p>Current Status:</p> <ul style="list-style-type: none">Pfizer test results [REDACTED] lots currently on the market show levels of N-nitrosovarenicline above HC's AI.<ul style="list-style-type: none">Pfizer recalled 4 lots above their proposed AI, to the retail level as a Type II, [REDACTED][REDACTED]	Pfizer not releasing any lots at this time.	

			<ul style="list-style-type: none">1.0mg: Pfizer Ireland Pharmaceuticals, Ringaskiddy API Plant, Ringaskiddy, County Cork, Ireland <p><u>Products</u> Champix (DIN 02298309, 02291177, 02291185)</p> <ul style="list-style-type: none">Champix is a prescription medication indicated for smoking-cessation treatment in adults, in conjunction with smoking-cessation counselling.	<p>to perform testing for nitrosamines for which a risk has been identified, including N-nitrosovarenicline.</p> <p>Prior to June 2021, Health Canada was using the internally established interim Acceptable Intake (AI) limit of 26.5 ng/day for drug products containing N-nitrosovarenicline, to guide requests for recalls. . As of June 2021, since international alignment was reached amongst regulatory partners and HC initiated using an AI of 37 ng/day for the N-nitrosovarenicline impurity. Medical necessity determinations were conducted by TPD for varenicline drug products.</p>		<ul style="list-style-type: none">The <u>Nitrosamines recall</u> and <u>medication affected</u> webpage were updated to include this recall on July 28, 2021All units of affected lots within Pfizer control have been placed on hold as of May 5, 2021. Pfizer confirmed on August 6, 2021, that not new lots have been released. <p>Next Steps:</p> <ul style="list-style-type: none">ROEB (HPCD) to follow-up with Pfizer<ul style="list-style-type: none">TPD to review proposal and provide input/comments.	
Bumetanide	HPC-East	Bumetanide	<ul style="list-style-type: none">Letter requesting risk assessment and subsequent	Last update (from week of August 9, 2021)	<div>Requester agreed to Remove 3rd Party Info</div> <p>Current Status :</p> <ul style="list-style-type: none">Summary of risk assessment: Based on the findings of the assessment report, the	-Once SAR is received from	

					<div>Based on the findings of the risk assessment, N-nitrosobumetanide and NDEA were identified at risk for formation.</div> <div></div> <div></div>		<div>following two impurities will be subject to confirmatory testing on the drug product: N-nitrosobumetanide and NDEA. Updated risk assessment taking into account additional information regarding extrinsic factors / GMP factors, as noted by BPS, was provided and no further risk were identified.</div> <div></div> <div></div>	<div>MAH, ORM to assess AI.</div>	
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Requester agreed to Remove 3rd Party Info

						<div>including NDMA and N-nitroso-nortriptyline, for all lots currently within distribution and within expiry for all MAHs.</div> <div><ul style="list-style-type: none">Several companies requested an extension (varying from 3 to 5 months) to perform confirmatory testing due to difficulties obtaining standards and validating the method, shortage of staff due to covid-19 pandemic.<ul style="list-style-type: none">HPCE will be granting a 3 months extension has HC re-requesting confirmatory testing 3 months following receipt of RAs.<div></div></div> <div>Next steps:</div> <div><ul style="list-style-type: none">HPCE to follow-up with MAHs regarding confirmatory testing.Following receipt of confirmatory results, HPCE to determine if market actions are required.</div>	
				<div>Affected MAHs</div> <div>Marketed status:</div> <div></div>		<div>Requester agreed to Remove 3rd Party Info</div>	
Key Items this week:							



HPCE Weekly Thursday Update – September 2, 2021

CM meeting planned on September 1, 2021. No topics for discussions.

- HPCEU will request to have discussion around varenicline (response received from FDA; next steps with Pfizer)

Here is the link to our nitrosamines [CV tracking sheet](#).

[Y:\HC\ROEB\HPCD\HPCRM\HEALTH RISK PROTECTION HC6\CASE MGMT\Nitrosamines](#)

Tasks	Comments
NHP-GMP Inspection Pilot	<p><u>Update September 23, 2021:</u></p> <p>Please find attached the updated project dashboard and inspection status. The project roadmap is higher level and did not require a revision. We will now be providing these updates every second Thursday to help with senior management bilat notes.</p> <p>Project Dashboard Highlights:</p> <ul style="list-style-type: none">• [REDACTED]• [REDACTED]• [REDACTED] <p>Inspection Update Highlights:</p> <ul style="list-style-type: none">• [REDACTED]• Manufacturer inspections start next week. <div><div> NHP GMP Project Dashboard 23Sep20</div><div> Inspection Summary</div></div> <div>Requester agreed to Remove 3rd Party Info</div>
[REDACTED]	<p><u>Update on September 23, 2021</u></p> <p>[REDACTED] As such, NNHPD will be issuing a communication. If no response is received, a referral may be made to ROEB. NNHPD is planning to send the communication out on Monday September 27, 2021 with a response requested within 5 business days.</p> <p>If you have any questions please let me know.</p>
Heads-Up (Site Visit) - CONVENIENCE 4U - Sexual Performance Drugs (RADAR 2021-060107)	<p><u>Update on September 23, 2021</u></p> <p>This is to let you know of an upcoming site visit planned for Sept 27th or 28th (depending on travel time), requiring air travel. Details are as follows:</p> <p>Details</p> <ul style="list-style-type: none">• A complaint was received on Sept 20th, alleging the sale of ED drugs (Rush Hour 72, [REDACTED]) at CONVENIENCE 4U, a retail store located in Halifax• There are no previous cases for this retail location• These products have been subject to previous seizures and PAs as they were found to contain Sildenafil or equivalent active ingredients that represent a type 1 risk. <p>Next Steps, as deemed necessary:</p> <ul style="list-style-type: none">• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]

HPCE Weekly Thursday Update – September 23, 2021

Site Visit on Sept 24th: [REDACTED]	<p><u>Update on September 22, 2021</u></p> <p>This is to let you know that a site visit is planned for this Friday as follows:</p> <ul style="list-style-type: none">• [REDACTED]• [REDACTED]• The visit will include review of complaint records/log, labels and advertising material. [REDACTED]
Update on Ivermectin Signage in MB (September 23, 2021)	<p><u>Update on September 23, 2021</u> **MHPD DGO Requesting C&E Verification**</p> <p>As discussed at look-ahead, please find an update below on the ivermectin signage issues being dealt with by MHPD.</p> <div>Requester agreed to Remove 3rd Party Info</div> <p>Current Status:</p> <ul style="list-style-type: none">• 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.<ul style="list-style-type: none">◦ The letter sent by MHPD to Magnetsigns referenced the [REDACTED] locations (Winkler, [REDACTED] identified in the complaints they received, this includes the location referenced from the College of Pharmacists in MB (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) <p>MHPD has requested that ROEB drives to the location of the signage (Winkler, Manitoba) to further confirm that it has indeed been removed.</p> <p>HPCE Recommendation:</p> <p>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 visual confirmation that MHPD is requesting. Please let me know if you concur with this approach.</p>
Azido impurity losartan MAHs letters	<p><u>Update on September 23, 2021</u></p> <p>Please see enclosed the <u>template letter</u> for losartan MAHs. Letter was reviewed by TPD and comments incorporated.</p> <p>In order to determine the extent of Canadian impact of presence of the mutagenic losartan azido impurity in losartan products, the following is proposed:</p> <p>Engagement of Market Authorisation Holders (MAHs)</p> <ul style="list-style-type: none">• Contact the other MAHs of marketed losartan products [REDACTED] to make them aware of the issue and request information on marketed products within expiry, risk assessment, and product testing as necessary.• In addition [REDACTED] (AuroPharma a [REDACTED] as the presence of the azido impurity was detected above the TTC in all lots of losartan active pharmaceutical ingredients (APIs) from this site tested by Sandoz.<ul style="list-style-type: none">• [REDACTED]• MAHs having only approved/dormant DINs will be asked to confirm that they will provide risk assessment and testing prior to commencing sale if they have no lots currently on the market within expiry <p>List of losartan MAHs: MAHs who already notified HC and recalled all lots:</p> <ul style="list-style-type: none">• Sandoz Canada (all lots already recalled) [REDACTED]• SANIS HEALTH INC [REDACTED] all lots already recalled), [REDACTED]

- Page: 1,275 of/de 1,302
-
- A2021000997

	<p>This file for [REDACTED] was brought to DGO’s attention back in July due to an MP letter to HC (Dated July 13, 2021). There are some new developments so I’m sharing an update. On Sept. 17, 2021, HPC a/ Regional Manager, C</p> <p>[REDACTED]</p> <ul style="list-style-type: none">[REDACTED][REDACTED][REDACTED] <p>Next Steps:</p> <ul style="list-style-type: none">[REDACTED][REDACTED][REDACTED]
Site Visit to [REDACTED] on September 17, 2021	<p><u>Update on September 16, 2021</u></p> <p>Bringing this site visit expected to take place tomorrow to your attention as an FYI:</p> <ul style="list-style-type: none">An unannounced site visit is expected to take place on Sept 17th to a company [REDACTED][REDACTED] <p>Background:</p> <ul style="list-style-type: none">[REDACTED][REDACTED][REDACTED]
Heads up [REDACTED]	<p><u>Update on September 9, 2021</u></p> <p>As discussed at risk meeting</p> <p>Update on the product [REDACTED]</p> <p>[REDACTED]</p> <p>Background:</p> <ul style="list-style-type: none">[REDACTED][REDACTED][REDACTED][REDACTED][REDACTED][REDACTED]


Requester agreed to Remove 3rd Party Info




HPCE Weekly Thursday Update – September 23, 2021

	<p>Actions to date:</p> <ul style="list-style-type: none">• [REDACTED]• [REDACTED] <p>Next Steps:</p> <ul style="list-style-type: none">• [REDACTED]
[REDACTED]	<p><u>Update on September 9, 2021</u></p> <p>[REDACTED]</p> <div>Requester agreed to Remove 3rd Party Info</div> <p>Actions to date</p> <ul style="list-style-type: none">• CV initiated [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED] <p>Next Steps:</p> <ul style="list-style-type: none">• [REDACTED]
Recall - Type III - NuWTR - Fulvic & Black Oxygen Products (2021-026872 & 2021-047885)	<p><u>Update on September 23, 2021</u></p> <p>PA has now been posted:</p> <p>Web: https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76457a-eng.php</p>


	<p>https://canadiensensante.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76457a-fra.php</p> <p>Wire: http://www.newswire.ca/en/releases/archive/September2021/23/c1208.html http://www.newswire.ca/fr/releases/archive/September2021/23/c3543.html</p>
Heads up - [REDACTED]	<p><u>Update on September 14, 2021</u></p> <p>Issue: [REDACTED]</p> <p>Details:</p> <ul style="list-style-type: none">[REDACTED][REDACTED][REDACTED][REDACTED] <p>Proposed next steps:</p> <ul style="list-style-type: none">[REDACTED]GMP to assess compliance once the formal request has been receivedFollow-up with DELU and GMP to confirm receipt of application and determine their next stepsHPCRM will exercise enforcement discretions due to the needs of the patients until DELU/GMP identify any other issues <div>Requester agreed to Remove 3rd Party Info</div>
Hand Sanitizer Briefing Note, Attestation Form/Email, ROD for DEL Transition	<p><u>Update on September 9, 2021</u></p> <p>Please find attached the latest versions of the Hand Sanitizer DG Briefing Note (prepared by HPIL), Attestation Form, Attestation Email and HPCE ROD for DO approval.</p> <p>Issue: As of September 2, 2021, all companies conducting licensable activities under the interim order exemption for a designated hand sanitizer without holding a Drug Establishment Licence (DEL) must have applied for a DEL to continue their activities. Companies that have not submitted a completed DEL application on or before September 1, 2021 will be required to cease activities as of September 2, 2021.</p> <p>Current Status: HPIL to send attestations forms after September 20 (date to be confirmed), to regulated parties that did not submit DEL applications on or prior to September 1, 2021 requesting them to attest they have ceased all licensable activities. HPCEU is recommending that no pro-active compliance verification activities be conducted for companies who have attested they have ceased licensable activities. Compliance verification will therefore only be conducted following receipt of a complaint.</p> <p>Next Steps:</p> <ul style="list-style-type: none">Finalize BN, attestation form, attestation email and RODHPIL to send attestation forms after September 20 (date to be confirmed)Non-responders and companies that indicate they have not ceased licensable activities will be referred to HPCE, for CV action

HPCE Weekly Thursday Update – September 23, 2021

NHP-GMP Budget Proposal Costing	<p><u>Update on September 23, 2021</u></p> <p>HPCD (Border, CV, SOU (to be added) and NHP GMP Team) and Laboratory Directorate are finalising the proposed costing options for the NHP-GMP Budget proposal. Current working draft is attached and will be ready to present by late September.</p> <div><p>NHP Options template CV+ Border</p></div> <div>Requester agreed to Remove 3rd Party Info</div>
International Outreach- Dr. Jason Klop Fecal Microbial Transplant File CBC Article	<p><u>Update on September 9, 2021</u></p> <p>HPCEU spoke to West, [REDACTED]</p> <p>Background:</p> <ul style="list-style-type: none">• Media article posted Aug 31 that may generate attention: <u>Naturopath banned from selling pills, enemas made from feces after complaint they were made in 'household lab'</u>• As of August 19, 2021 the College of Naturapathic Physicians of BC has banned the manufacture (of pills or enemas), advertising and sale of the fecal microbiota transplants (FMT) while investigating a complaint• Health Canada is mentioned in the article - 'Health Canada has already investigated an earlier complaint about Klop, and <u>banned him from accepting Canadian patients</u> [Apr 2020] at his Mexican retreats.'• HPCD is looking into the information reported in the article to determine whether any follow-up action is required. Particularly this line: "...The decision says the unidentified former employee first reached out in April with concerns, later providing shipping labels and invoices showing that Klop had exported his pills and enemas to Denmark, Edmonton and across the U.S. "
Haywick Industries (HS CMP)	<p><u>Update on September 23, 2021</u></p> <p>PA to be posted by September 24, 2021 (if not tonight) and HS RL update to take place next week.</p>
Plain Language Labelling	<p><u>Update on September 2, 2021</u></p> <p>HPCEU met with NNHPD today on the status of the PLL referrals. Please see an update below for your information and the attached recommended approach for dealing with the non-responders (once referred) for your concurrence.</p> <p>Update on PLL and of September 2, 2021:</p> <ul style="list-style-type: none">• HPCEU met with NNHPD today (Sept 2). NNHPD provided an update on the status of referrals:<ul style="list-style-type: none">• Referrals to date:<ul style="list-style-type: none">• [REDACTED] - NNHPD has made contact and referral will be withdrawn (no action required for HPCE)• [REDACTED] - NNHPD has made contact and referral will be withdrawn (no action required for HPCE)• [REDACTED] company reached out to NNHPD and has submitted labels. NNHPD reviewing labels and will be providing input on how to comply with requirements (if company revises labels no action will be required from HPCE and referral will be withdrawn)• Pending referrals:<ul style="list-style-type: none">• NNHPD to refer remaining non-responders (approximately 12) week of Sept 6, 2021 <p>Next Steps:</p> <ul style="list-style-type: none">• Attached you will find ROEB-HPCRM an options analysis with a recommendation to utilize a compliance promotion approach for non-responders referred by NNHPD. Please let us know if you concur with approach so we can finalise our action plan.

	<div><p>Options PLL OTC_20210708_HPC</p><p>Please let us know if you have any questions and/or concerns.</p></div>
Ethanol Update	<p><u>September 23, 2021</u></p> <p>The HS RL was last updated on Tuesday September 14th with 5 entries (including 2 from HS CMP): https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75267a-eng.php . There will be no HS RL update this week. We would like to defer 1 firm's recalls to next week as we focus on revising the current RL template to be inclusive of various scenarios: recall initiated by firm, recall requested by HC (to reflect those who have not complied) and not available at retail (but were requested to recall).</p> <p>I updated the latest IMR found in the IMR folder on the Y drive. Flagging the following updates:</p> <ol style="list-style-type: none">1) Haywick's standalone PA to be published, consideration of an import alert and NNHPD's intent to contact COVID-19 SL holders who have the same foreign building as Haywick listed on their licence.2) [REDACTED] s intent to discontinue all HS activity and recall of 5 NPNs (deferred posting to next week).3) [REDACTED] <div><p>Hand Sanitizer CMP IMR_Sept 23 2021 H</p></div> <div>Requester agreed to Remove 3rd Party Info</div>
[REDACTED]	<p><u>Update on September 9, 2021:</u></p> <p>Summary from program – based on interactions to date as well as addressing the sample issue.</p> <ul style="list-style-type: none">• Since 2016 [REDACTED] have both been in contact with Health Canada alleging activity conducted [REDACTED] was contravening federal legislation. They suspected [REDACTED] was 'dose-splitting', tampered product and provided deceptive labelling, all in contravention of federal legislation. Four complaints were submitted and verified by inspectors.• Further to these allegations, Health Canada completed thorough compliance verification activities in accordance with internal standard operating procedures. This included submission of a provided product sample to Health Canada's laboratory for sterility testing that did not identify issues of concern in 2019.• Health Canada inspectors determined that there was no non-compliance against the requirements of the <i>Food and Drug Regulations</i> (FDR) and referrals were made to the appropriate provincial regulators related to activities identified by the inspectors for any actions, as necessary.• Recently [REDACTED] requested for a return of their provided sample. They were advised that following testing and assessment by the Department, the sample was destroyed as per standard laboratory practice. [REDACTED] was offered photographs of the sample and its packaging that were taken prior to analysis.• Over the years, the complainants contacted Health Canada for updates as well as voiced their concerns regarding Health Canada's determinations. They have been advised on multiple occasions (via teleconference and in writing) that their complaint was taken seriously, compliance verification activities were completed thoroughly, and that matters raised fall under the oversight of the various provincial authorities.• Lastly, they were provided a heads-up regarding amendments to the FDR that would seek to analyze and address any potential gaps in regulatory oversight that exist for the regulation of different levels of government in Canada with public/stakeholder consultations taking place in 2022/2023. <p>Recent Letter to Minister:</p> <div><p>Letter to Minister Patty Hajdu dated S</p></div>

Draft Response:


21-011546-367_DG
response Draft_202'

Next Steps:

HPCE considering revisions to current letter and seeking legal consult. Letter will most likely not be sent out until after caretaker period ends.

Nitrosamines

Update September 23, 2021

Please see below for the nitrosamine weekly update for the week of September 13, 2021. All documents can be found on the onenote nitrosamine page.

	Lead	Date received/Timeline	Issue/Affected product/Company	Background	The latest/Update	Current status and proposed next step	Comments/C
New notifications	NIL						
New results	NIL						
MAH Letter Issuance	NIL						
Stakeholder outreach (responses, Q&A)	TPD	2021-09-16	Stakeholder session	Virtual Stakeholder Scientific and Technical Session on Nitrosamines: Webinar is intended to provide an opportunity for industry stakeholders to present new technical developments and scientific progress, which could facilitate the risk assessment and control of nitrosamine impurities in human pharmaceuticals. Information presented at this session will inform Health Canada of industry's scientific and technical understanding on key areas as well as identify current gaps and priorities, and may support refining and developing regulatory views going forward.	NIL	<div>Next steps:</div> <ul style="list-style-type: none">HPCEU to draft closing remarks for HPCD DG. (Timeline end of week of september 27, 2021)TPD to send revised documents to stakeholders (waiting till after election)	
Stakeholder outreach (responses, Q&A)	TPD	2021-09-13	Letter received from [REDACTED]	<<09.10.21 [REDACTED] re Generic Quality Safety and Efficacy.pdf>> [REDACTED]	HC was copied [REDACTED] [REDACTED]	NIL	

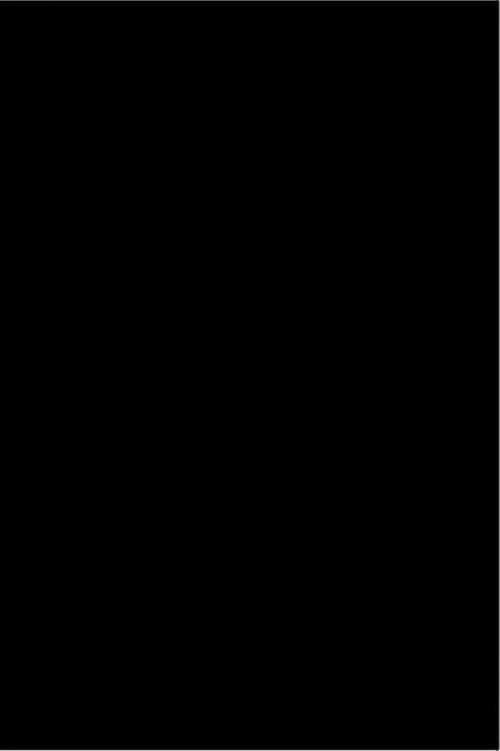
Requester agreed to Remove 3rd Party Info

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					received by HPFB and all incomplete responses and non-responders will be forwarded to ROEB for compliance verification action. Timelines to receive these responses have been extended on as follows: <ul style="list-style-type: none">• Annex 1: Risk Assessment Attestation letter – extended to July 30, 2021,• Annex 2: Summary of Completed Risk Assessments – extended to Sept. 1, 2021, and• Annex 3: Details Regarding Incomplete Risk Assessments (if applicable) – extended to July 30, 2021.		of non responders. More analysis on the non-responders will be required from pre-market (e.g. ensuring that we have the correct company contacts, that contacts are cross-referenced to ensure that if they represent more than one company – that is reflected etc.). Responses received to date: 601 responses were received to date for risk assessment follow-up (total of 729 MAHs). Numbers to be confirmed by TPD. Status of HPCEU national Action Plan (for follow-up on non responders and incomplete responses) : Action plan will be sent for DO approval this week.	
	APO-varenicline	TPD/HPCEU/HPC Central	2021-08-23	Company: Apotex Inc Products: APO-Varenicline 0.5 mg DIN 02479882 APO-Varenicline 1mg DIN 02419890 APO-Varenicline 0.5mg/1mg combo DIN 02435675 Radar #2020-067860	On September 23, 2020, the EMA shared information with international partners that three new nitrosamines were detected in varenicline API. The EMA also reported that an additional nitrosamine impurity, NDEA, was identified for Pfizer's varenicline product, Champix. HPFB (TPD) confirmed a risk for formation of multiple nitrosamines for all Canadians Market Authorization Holders (MAHs) of varenicline. In line with the standard process, ROEB issued a letter to all MAHs on October 26, 2020 requesting they evaluate the risk for the presence of nitrosamines and to testing for nitrosamines where a risk is identified. Prior to June 2021, Health Canada had established an interim Acceptable Intake (AI) limit of 26.5 ng/day for drug products containing N-nitrosovarenicline, to guide requests for recalls. As of June 2021, international alignment was reached amongst regulatory partners and HC revised the AI limit to 37 ng/day for the N-nitrosovarenicline impurity. Medical necessity determinations were conducted by TPD for varenicline drug products. Only		Current Status: <ul style="list-style-type: none">• Three lots were tested and found to contain n-nitrosovarenicline above the AI.• • • • • 	FDA issued P including res Apotex above

Requester agreed to Remove 3rd Party Info



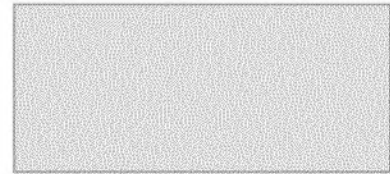
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				<div></div> <p><u>Products</u> Champix (DIN 02298309, 02291177, 02291185)</p> <ul style="list-style-type: none">• Champix is a prescription medication indicated for smoking-cessation treatment in adults, in conjunction with smoking-cessation counselling.• <div></div>	<p>Acceptable Intake (AI) limit of 26.5 ng/day for drug products containing N-nitrosovarenicline, to guide requests for recalls. . As of June 2021, since international alignment was reached amongst regulatory partners and HC initiated using an AI of 37 ng/day for the N-nitrosovarenicline impurity <div></div></p> <div></div>	<p>As a reminder, Pfizer recalled 4 lots above their proposed AI, to the retail level as a Type II, <div></div></p> <p>HPC East not planning any additional action at this time.</p>	<p>August 6, 2021, that not new lots have been released.</p> <ul style="list-style-type: none">• <div></div>• <div></div> <p>Next Steps:</p> <ul style="list-style-type: none">• ROEB (HPCD) to:<ul style="list-style-type: none">• Follow-up with Pfizer to obtain root cause investigation report.• <div></div>
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Requester agreed to Remove 3rd Party Info

- Key Items this week:**
- CM meeting planned on September 22, 2021.
 - DG meeting is also planned on September 22, 2021. Topics to be discussed (to be finalized): Oct 2021 stakeholder session, varenicline, preparation/ updates for NITWG, RA follow ups, and response to IGBA letter.

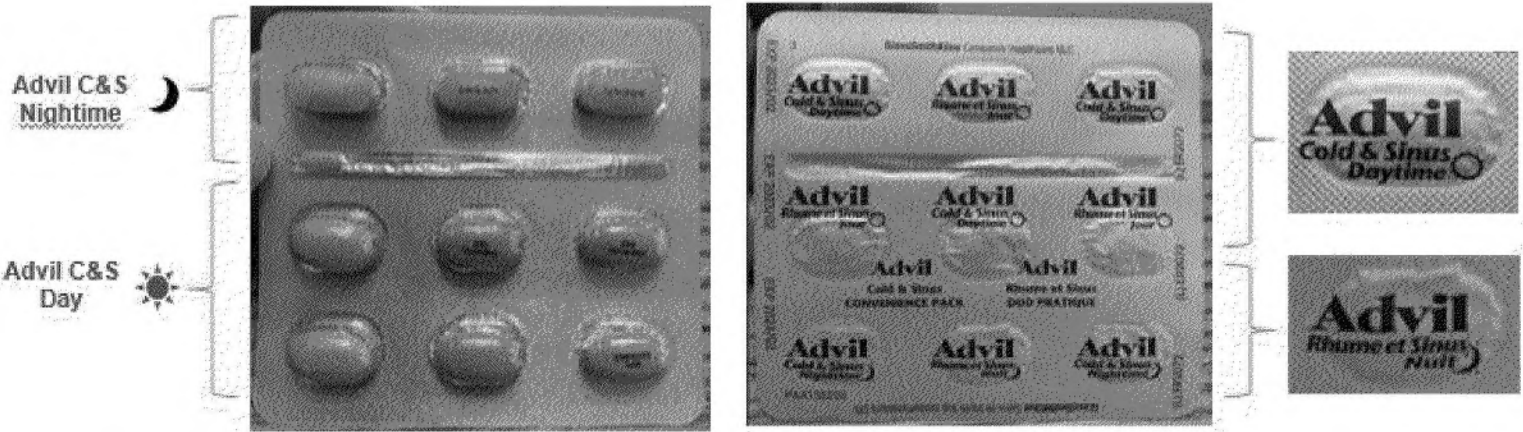
Here is the link to our nitrosamines [CV tracking sheet](#).



Y:\HC\ROEB\HPCD\HPCRM\HEALTH RISK PROTECTION HC6\CASE MGMT\Nitrosamines

Taskis	Comments
NHP-GMP Inspection Pilot	<p><u>Update September 23, 2021:</u></p> <p>Please find attached the updated project dashboard and inspection status. The project roadmap is higher level and did not require a revision. We will now be providing these updates every second Thursday to help with senior management bilat notes.</p> <p>Project Dashboard Highlights:</p> <ul style="list-style-type: none">• [REDACTED]• [REDACTED]• Proposed NCs for [REDACTED] and to be confirmed early next week <p>Inspection Update Highlights:</p> <ul style="list-style-type: none">• Inspections for [REDACTED] are closed.• Manufacturer inspections start next week. <div> NHP GMP Project Dashboard 23Sep2021 Inspection Summary :  Dashboard</div> <div>Requester agreed to Remove 3rd Party Info</div>
OCP Meeting	<p><u>Update on September 29, 2021</u></p> <p>HPCEU/MDCLU to setup meeting with [REDACTED] to discuss following request:</p> <p>From [REDACTED]</p> <p>[REDACTED]</p> <p>We would like to set up a meeting at your earliest convenience to discuss [REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED] had indicated at our meeting that he was going to follow up based on information that we had provided regarding one DPP.</p>
MHPD New Pilot Project - NHP ads making cancer-related claims	<p><u>Update on September 29, 2021</u></p> <p>Background:</p> <ul style="list-style-type: none">• MHPD STARS has started a pilot project [REDACTED] to proactively monitor NHP ads making cancer-related claims as a result of the OAG audit.• The pilot is for 6 months, after which STARS will alter the scope to another schedule A claim.• If the advertised products are authorized these will be actioned by STARS.• If the advertised products are unauthorized or if STARS is unable to achieve compliance with the regulated party of the authorized product they will be referred to ROEB. This is being discussed. <p>Current Status:</p> <ul style="list-style-type: none">• STARS and HPCEU met on June 10 to discuss the scope of the pilot, search parameters being used in the AI and the referral process.• To date STARS has received 2 reports [REDACTED]

	<ul style="list-style-type: none"> ○ At this time they have reviewed one report, which identified over 1600 cases. After an assessment by STARS, 102 cases have been deemed actionable (90 for MHPD as the products were authorized and 12 for ROEB as the products were unauthorized). • The estimated number of referrals to ROEB is unknown as it will depend on what is identified in each report but it could be up to 10+/week/report (tbc). • STARS indicated that if upon their review of the website they identify any other unauthorized health product outside of the scope of this pilot it will also be referred to ROEB. <p>Next Steps:</p> <ul style="list-style-type: none"> • HPCEU to finalise options analysis for HPCRM DO for the scope of the referrals. To be sent to HPCRM DO during week of October 4, 2021.
Type I Recall - Apotex - Mirvala 28 (DIN 02410257)	<p><u>Update on September 29, 2021</u></p> <p>Central was notified by Apotex Inc on the afternoon of Sep 29 that it is proposing a Type I consumer level recall for 1 lot of Mirvala 28 (DIN 02410257; Desogestrel and Ethinyl Estradiol Tablets, USP). Due to the nature and the timing of the recall, the attachments Apotex sent have been attached to this email for reference. (see Product Image file for defect)</p> <p>Background:</p> <ul style="list-style-type: none"> • One placebo pill (green colour) in the place of a birth control pill (white colour) in the blister card • Apotex proposed: <ul style="list-style-type: none"> ○ Initiate Type I recall to the consumer level for 1 lot (LF21272B EXP 08/2022) on Sep 30 ○ Post Public Communication (Press Release) on Apotex's website on Sep 30 ○ Post Public Communication (Press Release) via Newswire in Canada on Sep 30 • HRA, distribution info, and draft recall letters were provided by Apotex <p>Next Steps:</p> <ul style="list-style-type: none"> • Inspector to contact Apotex for additional information • Review draft recall communications from Apotex • Send a heads up email to SOGC on September 29. • PA to be posted September 30. <div style="border: 2px solid blue; padding: 5px; text-align: center; margin-top: 10px;"> <p>Requester agreed to Remove 3rd Party Info</p> </div>
GSK - Advil Cold & Sinus Convenience Pack (Daytime and Nighttime) - Labelling Error – Proposed Recall	<p>Central received notification from GlaxoSmithKline (GSK) that they are proposing to initiate a recall [REDACTED] to the retail level for the product Advil Cold and Sinus Convenience Pack (two packaging sizes, 18 count and 36 count). The pack contains two products (see attached artwork of the outer cartons):</p> <ul style="list-style-type: none"> - ADVIL COLD AND SINUS DAYTIME, DIN 02267616 - ADVIL COLD AND SINUS NIGHTTIME, DIN 02267632 <p>The Issue:</p> <ul style="list-style-type: none"> - The backing of the blister card was inverted 180 degrees. Therefore, for the DAYTIME tablet, the backing of the blister card is labelled as NIGHTTIME and vice versa (See photo below).



- NIGHTTIME tablets contain 2mg of antihistamine which can cause drowsiness
- The two types of tablets are of different colours
- GSK will provide an HRA by Friday, Oct 1
- GSK will post a notice on its website on the labelling error
- GSK has put remaining affected product on hold (58,000 units)

Requester agreed to
Remove 3rd Party Info

Next steps:

- Central to follow-up with GSK on HRA and its recall plan
- Follow-up on recall and its effectiveness

Update September 28, 2021

[Redacted content]

preparation table API Mgmt Discussion on

*HPCRM to verify columns 3 and 4 that apply to us in the attached word document and provide confirmation no later than October 6th 2021 to Dalia.

Requester agreed to
Remove 3rd Party Info

Potential type I recall by AuroPharma due to presence of azido impurity above TTC

Update on September 29, 2021

Heads Up - AuroPharma to confirm intentions with regards to type I recall and confirm timing of recall initiation (expected by 3pm today). Further details below.

Issue :

- **AuroPharma** notified HPC Central on September 28, 2021, of the confirmed presence of the second Azido impurity associated with losartan (5-[4' -(5-(Azidomethyl)-2-butyl-4-chloro-1 H-imidazol-1-yl)methyl]-[1,1 '-biphenyl]2-yl]-1H-tetrazole) significantly above the TTC level in **7 lots** currently on the market within expiry [REDACTED] Auropharma has placed all lots of losartan on hold pending results of the AMES test [REDACTED]
 - HPC central requested a type 1 recall at retail level of these 7 lots on September 29, 2021, as HC received and reviewed results of an AMES test from another MAH [REDACTED] which shows the impurity is mutagenic [REDACTED]
- **Impact on shortage** [REDACTED]

Affected Products and lots:

Description	DINs	Lot no	Expiry Date
AURO-LOSARTAN 100 (100's)	02403358	AEJ1020001A	2023-DE-19
AURO-LOSARTAN 100 (100's)	02403358	AEJ1020002A	2023-DE-20
AURO-LOSARTAN 100 (100's)	02403358	AEJ1020003A	2023-DE-21
AURO-LOSARTAN 25 mg (100's)	02403323	AEJ2520001A	2023-DE-19
AURO-LOSARTAN 50 mg (100's)	02403331	AEJ5020001A	2023-DE-16
AURO-LOSARTAN 50 mg (100's)	02403331	AEJ5020002A	2023-DE-17
AURO-LOSARTAN 50 mg (100's)	02403331	AEJ5020003A	2023-DE-18

API manufacturer:

Next Steps:

- AuroPharma to confirm intentions with regards to type I recall and confirm timing of recall initiation (expected by 3pm today)
- Once recall is confirmed:
- HPCEU to work on stakeholder message (draft to be sent by COB today)
- HPCEU to work with CPAB on PA update (target timeline for issuance; after recall initiation by AuroPharma)
- HPCEU to update IMR for this issue (target; October 1, 2021).

Please note that letters to all losartan MAHs requesting risk assessment and testing as necessary for this second azido impurity will be sent by COB today.

One Stop Love Shop

September 29, 2021

Issue Summary (RADAR 2021-029798):

Unmarked product blisters were sold in a retail sex store located in Chilliwack and Abbotsford BC (One Stop Love Shop) in blister packs of (10) and (2) capsules with no outer packaging – no brand name, Lot #, expiration date, or directions for use. The products were sold in individual blister packs from a display carton labelled as “Herberex”, with no NPN

Herberex has a valid NPN 80029339, belonging to Nutraloid Labs in the US.

Product blisters were seized and all those tested were found to contain Nortadalafil, a tadalafil analogue (Prescription ingredient).

	<div></div> <p>Next steps: Discuss case with Central to determine next steps</p> <div></div>
Unannounced Site Visit at	<u>Update on September 28, 2021</u> <div></div>
	<u>Update on September 23, 2021</u> <ul style="list-style-type: none"><div></div><div></div>If no response is received, a referral may be made to ROEB. NNHPD is planning to send the communication out on Monday September 27, 2021 with a response requested within 5 business days.
Heads-Up (Site Visit) - CONVENIENCE 4U - Sexual Performance Drugs (RADAR 2021-060107)	<u>Update on September 29, 2021</u> <p>Highlight – Halifax site visit to CONVENIENCE 4U update in red below. products were seized with voluntary forfeiture. No supplier information obtained. Border alert to be requested. We will confirm ETA for the update to the PA shortly.</p> <p>Travel date: Monday Sept 27. Site visit official date: Monday Sept 27 or Tuesday Sept 28 depending on travel time.</p> <p>More details below</p> <div>Requester agreed to Remove 3rd Party Info</div> <p>Radar: 2021-060107 Company: CONVENIENCE 4U (retail store) Location: 604 Bedford Hwy 1, Halifax, NS B3M 2L8 Canada, (902) 406-7070 Product: Health products that are promoted for sexual enhancement : Rush Hour 72</p> <p>Background:</p> <ul style="list-style-type: none">FRM-0317 complaint indicates that the store is selling health products listed on public advisory, near the cash area.Health Canada issued previous advisory for similar products due to presence of undeclared prescription drug ingredients that were seized at retail location :<ul style="list-style-type: none">“Rush Hour 72” <u>Product with similar packaging</u> (previously seized) was tested and found to contain <u>sildenafil</u> and <u>tadalafil</u>

[REDACTED]

- Location appears to be a retail store in a small commercial plaza with its own outward-facing entrance at around 12 km of downtown Halifax.
- RADAR search with “Convenience 4U” in Halifax yielded no results.

Actions to date:

- A pathfinder report was requested to find out if the unauthorized product were possibly imported (TBD)
- September 27, 2021:
 - Inspector made an anonymous purchase of an unauthorized product from the retailer [REDACTED]
 - The products of the complain [REDACTED] Rush Hour 72 [REDACTED] are in full view for sale not far from the checkout.
 - An invoice has been issued but without details of the sale of the product.
- September 28, 2021:
 - Unannounced visit to the retailer
 - A seizure took place for [REDACTED] unauthorized products (see table below). All areas of the retail stores were verified for more products
 - Voluntary forfeiture has been obtained
 - The name and contact details of the supplier were not obtained.

[REDACTED]

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Rush Hour 72 – 1 cap	142436	May 16, 2025	67
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Next Steps:

- Verify with Border if this store have documented importation refusal
- Request a border alert if deemed necessary.
- Follow up with the company with a compliance letter or any other compliance and enforcement actions deemed necessary.
- Update PA






Convenience 4 U_
IMR_September 29 2021

Update on Ivermectin
Signage in MB (September
23, 2021)

Update on September 29, 2021

As discussed at look-ahead, please find an update below on the ivermectin signage issues being dealt with by MHPD.

Page: 1,294 of/de 1,302
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	<ul style="list-style-type: none">• The HS rolling list will be updated to include the recalled product and the PA will be updated to reflect the initiated recall with a link to its recall notice (week of October 4, 2021)• Follow-up for more information and monitor the effectiveness of the recall
HS RL Update	<p><u>September 29, 2021</u></p> <p>HS RL template to be updated to reflect various scenarios of the actions taken by companies and HC. RMD and HPCEU have worked with CPAB for draft that will be shared with DO for approval on Oct 1 with the 7 new entries this week.</p> <div><p>ROEB_RL_HandSanitizersP2_2021-09-27_1:</p></div> <div>Requester agreed to Remove 3rd Party Info</div>
	<p><u>Update on September 29, 2021:</u></p> <p>Summary from program – based on interactions to date as well as addressing the sample issue.</p> <ul style="list-style-type: none">• Since 2016 [REDACTED] have both been in contact with Health Canada alleging activity conducted by [REDACTED] was contravening federal legislation. They suspected [REDACTED] was 'dose-splitting', tampered product and provided deceptive labelling, all in contravention of federal legislation. Four complaints were submitted and verified by inspectors.• Further to these allegations, Health Canada completed thorough compliance verification activities in accordance with internal standard operating procedures. This included submission of a provided product sample to Health Canada's laboratory for sterility testing that did not identify issues of concern in 2019.• Health Canada inspectors determined that there was no non-compliance against the requirements of the <i>Food and Drug Regulations</i> (FDR) and referrals were made to the appropriate provincial regulators related to activities identified by the inspectors for any actions, as necessary.• Recently [REDACTED] requested for a return of their provided sample. They were advised that following testing and assessment by the Department, the sample was destroyed as per standard laboratory practice [REDACTED] was offered photographs of the sample and its packaging that were taken prior to analysis.• Over the years, the complainants contacted Health Canada for updates as well as voiced their concerns regarding Health Canada's determinations. They have been advised on multiple occasions (via teleconference and in writing) that their complaint was taken seriously, compliance verification activities were completed thoroughly, and that matters raised fall under the oversight of the various provincial authorities.• Lastly, they were provided a heads-up regarding amendments to the FDR that would seek to analyze and address any potential gaps in regulatory oversight that exist for the regulation of different levels of government in Canada with public/stakeholder consultations taking place in 2022/2023. <p>Recent Letter to Minister:</p> <div><p>Letter to Minister Patty Hajdu dated Sep</p></div> <p>Draft Response:</p> <div><p>21-011546-367_DG response Draft_2021-</p></div> <p>Next Steps: HPCEU draft response (with LSU comments incorporated) approved by DO on September 28, 2021</p>

Nitrosamines

Update September 27, 2021

Please see below for the nitrosamine weekly update for the week of September 13 , 2021. All documents can be found on the onenote nitrosamine page.

	Lead	Date received/Timeline	Issue/Affected product/Company	Background	The latest/Update	Current status and proposed next step	Comments/Questions
New notifications	NIL						
New results	NIL						
MAH Letter Issuance	NIL						
Stakeholder outreach (responses, Q&A)	TPD	2021-09-21	Stakeholder session	Virtual Stakeholder Scientific and Technical Session on Nitrosamines: Webinar is intended to provide an opportunity for industry stakeholders to present new technical developments and scientific progress, which could facilitate the risk assessment and control of nitrosamine impurities in human pharmaceuticals. Information presented at this session will inform Health Canada of industry's scientific and technical understanding on key areas as well as identify current gaps and priorities, and may support refining and developing regulatory views going forward.	Invites to stakeholders, including agenda, were updated accordingly and were issued last week (week of September 20, 2021). International partners were also informed.	Latest updated documents: <<2021 Nitrosamine Stakeholder Session_Agenda_EN-FR.pdf>> <<Waiver Form_EN.pdf>> <<2021 Nitrosamine Stakeholder Session_Invitation_EN-FR.pdf>> Next steps: <ul style="list-style-type: none">HPCEU to draft closing remarks for HPCD DG. (Timeline end of week of september 27, 2021)	
Stakeholder outreach (responses, Q&A)	TPD	2021-09-24	Letter received from [REDACTED]	[REDACTED] [REDACTED]	Draft response was circulated for comments. [REDACTED] [REDACTED]	Next steps: <ul style="list-style-type: none">[REDACTED][REDACTED]	

Requester agreed to Remove 3rd Party Info

					<div>•</div> <div>•</div> <div>NICC – LNTWC</div> <div></div>		
						<div>Requester agreed to Remove 3rd Party Info</div>	
	Stakeholder outreach (responses, Q&A)	TPD	2021-09-20	Letter received from <div></div>	<div></div> <div>lack of consistency within international regulators and Als vary across jurisdiction.</div> <div></div>	TPD (BPS) drafted response and sent to the working group for review and comments.	Next steps: HPCEU to send comments back to TPD by COB 2021-09-27 HC to bring concerns <div></div>
	Risk Communication	NIL					
	International updates	NIL					
	Other issues						

	Risk assessment follow-up	TPD/HPCEU	N/A	NIL	<p>A letter dated of April 14, 2021, to follow up on Step 1 of our call for review in order to gauge completion levels and to gain insight into any risks identified was issued to all affected MAHs (roughly 1200 MAHs). MAHs were asked to complete an attestation letter to confirm risk assessment have been completed for all marketed, approved and dormant products (Annex 1). If risk assessments have not been completed, then the MAHs were asked to provide details and rationale for non completion (Annex 3). If risk assessments have been completed then a summary of completed risk assessments (Annex 2) was asked to be provided. These responses will be received by HPFB and all incomplete responses and non-responders will be forwarded to ROEB for compliance verification action. Timelines to receive these responses have been extended on as follows:</p> <ul style="list-style-type: none"> • Annex 1: Risk Assessment 	No update	<p>Responses received to date: 601 responses were received to date for risk assessment follow-up (total of 729 MAHs). Numbers to be confirmed by TPD.</p> <p>Status of HPCEU national Action Plan (for follow-up on non responders and incomplete responses) : Action plan will be sent for DO approval shortly.</p> <p>Next steps:</p> <ul style="list-style-type: none"> • TPD to provide an update on October 1, 2021. Meeting to discuss next steps is scheduled. • TPD to refer to HPCE an updated list of non responders and MAHs who have not completed they risk assessments for C&E actions with including information on: <ul style="list-style-type: none"> a) MAHs who have marketed products b) MAHs who only have dormant DINs (i.e., are not in the marketed products list c) MAHs who only have approved but not marketed DINs (i.e., are not in the marketed products list) • Additional actions may be taken prior to referring to cases to regions depending on list of non responders. More analysis on the non-responders will be required from pre-market (e.g. ensuring that we have the correct company contacts, that contacts are cross-referenced to ensure that if they represent more than one company – that is reflected etc.). 	
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				<p>Attestation letter – extended to July 30, 2021,</p> <ul style="list-style-type: none"> Annex 2: Summary of Completed Risk Assessments – extended to Sept. 1, 2021, and Annex 3: Details Regarding Incomplete Risk Assessments (if applicable) – extended to July 30, 2021. 			
					<div>Requester agreed to Remove 3rd Party Info</div>		
Champix	HPC East/HPCEU	2021-09-22	<p>Radar: 2020-067826</p> <p>Product and Company Description: <u>Company</u> Pfizer Canada ULC 17300 Trans-Canada Highway Kirkland, QC, JH9J 2M5</p> <p><u>API manufacturer:</u></p> <ul style="list-style-type: none"> 0.5mg: Upjohn Manufacturing Ireland Unlimited Company, Little Island, County Cork, Ireland 1.0mg: Pfizer Ireland Pharmaceuticals, Ringaskiddy API Plant, Ringaskiddy, County Cork, Ireland <p><u>Products</u> Champix (DIN 02298309, 02291177, 02291185)</p>	<p>Background On September 23, 2020, EMA notified HC that 3 new nitrosamines were detected in varenicline API. In addition to these 3 nitrosamines, another nitrosamine impurity, NDEA, was also identified as a risk for the varenicline brand name product Champix (Pfizer). Following their review of manufacturing processes, HPFB (TPD) confirmed a risk for formation of multiple nitrosamines for all Canadians Market Authorization Holders (MAHs). In line with the standard process, HC sent a letter on October 26, 2020 to all MAHs requesting them to evaluate the risk for the presence of nitrosamines in their varenicline drug product and to perform testing for nitrosamines for which a risk has been identified,</p>	<ul style="list-style-type: none"> [REDACTED] 	<p>Current Status:</p> <ul style="list-style-type: none"> Pfizer test results for all [REDACTED] lots currently on the market show levels of N-nitrosovarenicline above HC's AI. Pfizer recalled 4 lots above their proposed AI, to the retail level as a Type I [REDACTED] All units of affected lots within Pfizer control have been placed on hold as of May 5, 2021. Pfizer confirmed on August 6, 2021, that not new lots have been released. [REDACTED] [REDACTED] Pfizer also confirmed they will not be releasing 	Pfizer not releasing any lots at this time.

			<ul style="list-style-type: none">• Champix is a prescription medication indicated for smoking-cessation treatment in adults, in conjunction with smoking-cessation counselling.• Impacted Canadian lots:<div></div>	<p>including N-nitrosoarenicline.</p> <p>Prior to June 2021, Health Canada was using the internally established interim Acceptable Intake (AI) limit of 26.5 ng/day for drug products containing N-nitrosoarenicline, to guide requests for recalls. . As of June 2021, since international alignment was reached amongst regulatory partners and HC initiated using an AI of 37 ng/day for the N-nitrosoarenicline impurity. Medical necessity determinations were conducted by TPD for varenicline drug products.</p> <div></div>	<div></div>	<p>new lots of Champix until agreement with Health Canada is reached on an interim plan.</p> <div></div>
				<p>Pfizer proposes an AI of 733 ng/day for the N-nitrosoarenicline impurity based on less than lifetime treatment duration.</p>		<ul style="list-style-type: none">• Pfizer has recalled all their batches of Chantix on the US market due to

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							presence of unacceptable levels of N-nitrosovarenicline. <ul style="list-style-type: none">• Next Steps:• ROEB (HPCD) to:<div></div>
	<div><div>Key Items this week:</div><div><ul style="list-style-type: none">• NITWG meeting on September 28, 2021. The following topics will be discussed:<div>Updates on establishing Acceptable Intakes (AIs), Application of a general nitrosamine-specific TTC of 18 ng/day, Control of multiple nitrosamine impurities, Discussion on PhRMA’s Global Workshop on Nitrosamines, Limits for nitrosamine impurities in oncology drugs, Clarifications/proposals from industry relevant to Step 2 confirmatory testing</div>• NISG meeting on September 29, 2021. The following topics will be discussed (annotated agenda will be provide on September 28)<div>Updates on existing APIs (varenicline, bumetanide, ciprofloxacin) Risk assessment follow-up</div>• </div></div>						
	<div><div>Here is the link to our nitrosamines CV tracking sheet. Y:\HC\ROEB\HPCD\HPCRM\HEALTH RISK PROTECTION HC6\CASE MGMT\Nitrosamines</div><div>Requester agreed to Remove 3rd Party Info</div></div>						

Simard, Chris (HC/SC)

From: Kluchnik, Ian (HC/SC)
Sent: 2021-09-28 10:08 AM
To: Massey, Ranjeet (HC/SC)
Cc: Rajwani, Salima (HC/SC); Simard, Chris (HC/SC); Bak, Celina (HC/SC); Zayoun, Toufic (HC/SC)
Subject: Winnipeg Free Press: Health agency fights dewormer drug claims

Follow Up Flag: Follow up
Flag Status: Flagged

An article in the paper here about Ivermectin use and advertising in Southern Manitoba. A quick mention of Health Canada; don't anticipate any follow up or impact.

Winnipeg Free Press: Health agency fights dewormer drug claims [Winnipeg Free Press](#)

Ian Kluchnik

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