From: Genier, Anne (HC/SC)
Sent: 2021-09-10 1:43 PM
To: Dodson, Heather (HC/SC)
Subject: RE: For ADM ROEB / HPFB / CPAB approval: Media Query: Toronto Star [redacted] Use of Ivermectin to treat COVID-19 + incident report

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Thank you Heather! I apologize for not sending to the positional mailbox – I couldn't locate it as I had the pre-migration email! I will amend our contact lists.

Anne Génier
613-327-1967

From: Dodson, Heather (HC/SC) <heather.dodson@hc-sc.gc.ca>
Sent: 2021-09-10 12:47 PM
To: CPAB MEDIA RELATIONS / RELATIONS AVEC LES MEDIAS DGCAP (HC/SC) <cpab.media.relations-relations.avec.les.media.sdgcap@hc-sc.gc.ca>; ROEB ADMO Correspondence / Correspondance BSMA DGORAL (HC/SC) <roeb.admo.corr-bsma.dgoral@hc-sc.gc.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>; Allison, Catherine (HC/SC) <catherine.allison@hc-sc.gc.ca>; Morrissette, Eric (HC/SC) <eric.morrissette@hc-sc.gc.ca>; Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; LeBrun, Matt (HC/SC) <matt.lebrun@hc-sc.gc.ca>
Subject: RE: For ADM ROEB / HPFB / CPAB approval: Media Query: Toronto Star [redacted] Use of Ivermectin to treat COVID-19 + incident report

Hello Anne,

Stefania has approved the response below – no changes.

Also, please ensure you copy "ROEB ADMO Correspondence" on all media requests coming our way for approval, as per the usual process.

Thanks,
Heather (covering for Jenny today)

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca> **On Behalf Of** CPAB MEDIA RELATIONS / RELATIONS AVEC LES MEDIAS DGCAP (HC/SC)
Sent: 2021-09-10 11:00 AM
To: Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; McLaughlin, Jenny (HC/SC)

<jenny.mclaughlin@hc-sc.gc.ca>; Allison, Catherine (HC/SC) <catherine.allison@hc-sc.gc.ca>; Morrissette, Eric (HC/SC) <eric.morrissette@hc-sc.gc.ca>; Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>
Subject: For ADM ROEB / HPFB / CPAB approval: Media Query: Toronto Star [redacted] Use of Ivermectin to treat COVID-19 + incident report

Good day,

For ROEB, HPFB and CPAB ADM approval, 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))

The info was provided by MHPD and vetted and approved by ROEB.

Your approval by 1:00 pm would be greatly appreciated.

Thank you.

Anne

Media/Reporter: Toronto Star [redacted]

Deadline to reporter: September 8 / 5 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?**

A1: Ivermectin is an antiparasitic agent approved for use in humans and animals. There are concerns about consumers purchasing veterinary Ivermectin to prevent or treat COVID-19. On August 31, 2021, Health Canada published a Public Advisory (https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php) informing the public that Ivermectin is not authorized to prevent or treat COVID-19 and using it for such purposes can cause serious health problems. This advisory noted that the Department has received concerning reports of the use of veterinary ivermectin to prevent or treat COVID-19. This is in reference to reports of patients in the U.S. as stated in the advisory.

At this time, Health Canada has not directly received complaints or reports of adverse events associated with the use of ivermectin-containing products in humans for COVID-19

purposes.

Tasked to:
Approved by:
Linsey Hollett, ROEB- HPCD DG (approved)
Kelly Robinson, HPFB-MHPD DG (approved)
Eric Morrissette, Chief Media Relations (pending)
Marilyn Nahum, A/Director Strat Comms (pending)
Jon Ward, Strat Comms DG (pending)
Julia Cropley, DG MCD (FYI)
Cathy Allison for Pam Aung-Thin, CPAB ADM (pending)
Stefania Trombetti, ADM ROEB (pending)
HBFB ADM (pending)
DMO (pending)

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, E/CE: media@hc-sc.gc.ca

From: Trombetti, Stefania (HC/SC)
Sent: 2021-09-10 12:36 PM
To: Dodson, Heather (HC/SC)
Cc: LeBrun, Matt (HC/SC)
Subject: RE: For ADM ROEB / HPFB / CPAB approval: Media Query: Toronto Star [redacted] Use of Ivermectin to treat COVID-19 + incident report

---

No concerns on my end either. Grateful if you could let CPAB know that I've approved and ask them to include the ROEB ADMO Correspondence email address on all media requests coming our way for approval, as per the usual process.

Thx

S

From: Dodson, Heather (HC/SC) <heather.dodson@hc-sc.gc.ca>
Sent: 2021-09-10 12:29 PM
To: Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Cc: LeBrun, Matt (HC/SC) <matt.lebrun@hc-sc.gc.ca>
Subject: RE: For ADM ROEB / HPFB / CPAB approval: Media Query: Toronto Star [redacted] Use of Ivermectin to treat COVID-19 + incident report
Importance: High

Hi Stefania,

I have reviewed and do not have any concerns with the response – it reflects the comments provided by Jenny (to include reference to 'complaints' as that can be perceived as a 'report' by some people).

Thanks,
Heather

From: Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Sent: 2021-09-10 12:16 PM
To: Dodson, Heather (HC/SC) <heather.dodson@hc-sc.gc.ca>
Cc: LeBrun, Matt (HC/SC) <matt.lebrun@hc-sc.gc.ca>
Subject: FW: For ADM ROEB / HPFB / CPAB approval: Media Query: Toronto Star [redacted] Use of Ivermectin to treat COVID-19 + incident report

Hi Heather,

Can you take a quick look and advise. I see that this did not go to the ROEB email, so you may not have seen it yet.

Thx

S

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca> **On Behalf Of** CPAB MEDIA RELATIONS / RELATIONS AVEC LES MEDIAS DGCAP (HC/SC)
Sent: 2021-09-10 11:00 AM
To: Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>; Allison, Catherine (HC/SC) <catherine.allison@hc-sc.gc.ca>; Morrissette, Eric (HC/SC) <eric.morrissette@hc-sc.gc.ca>; Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>
Subject: For ADM ROEB / HPFB / CPAB approval: Media Query: Toronto Star [redacted] Use of Ivermectin to treat COVID-19 + incident report

Good day,

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The info was provided by MHPD and vetted and approved by ROEB.

Your approval by 1:00 pm would be greatly appreciated.

Thank you.

Anne

Media/Reporter: Toronto Star [redacted]

Deadline to reporter: September 8 / 5 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?

A1: Ivermectin is an antiparasitic agent approved for use in humans and animals. There are concerns about consumers purchasing veterinary Ivermectin to prevent or treat

COVID-19. On August 31, 2021, Health Canada published a Public Advisory (https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/76365a-eng.php) informing the public that Ivermectin is not authorized to prevent or treat COVID-19 and using it for such purposes can cause serious health problems. This advisory noted that the Department has received concerning reports of the use of veterinary ivermectin to prevent or treat COVID-19. This is in reference to reports of patients in the U.S. as stated in the advisory.

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

Tasked to:
Approved by:
Linsey Hollett, ROEB- HPCD DG (approved)
Kelly Robinson, HPFB-MHPD DG (approved)
Eric Morrissette, Chief Media Relations (pending)
Marilyn Nahum, A/Director Strat Comms (pending)
Jon Ward, Strat Comms DG (pending)
Julia Cropley, DG MCD (FYI)
Cathy Allison for Pam Aung-Thin, CPAB ADM (pending)
Stefania Trombetti, ADM ROEB (pending)
HBFB ADM (pending)
DMO (pending)

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, E/CE: media@hc-sc.gc.ca

McLaughlin, Jenny (HC/SC)

From: McLaughlin, Jenny (HC/SC)
Sent: 2021-08-30 3:53 PM
To: Baxter, Sarah (HC/SC)
Cc: Olsen, Clarke (HC/SC)
Subject: Update - Ivermectin advertisement in Manitoba - COVID-19

Hi Sarah,

An update to the previous heads up provided last week is highlighted below. Please let me know if you have any questions. This is ok to share with MO, should the DMs wish to share further.

Thanks,
Jenny

Requester agreed to Remove 3rd Party Info

Heads up – Unauthorized advertising of Ivermectin to treat C

- ROEB has been made aware by HPFB that Ivermectin (an authorized anti-parasitic drug used in 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 warned about not using this drug for the treatment of COVID-19 and the issue has received media coverage (e.g., CNN , Global News).
- [redacted]
- ROEB is working with HPFB on next steps, which will include a regulatory letter to the advertiser to direct that all non-compliant signage be removed. Additional action will be taken should the advertiser not comply.
- A public advisory regarding Ivermectin and unauthorized promotion as a treatment/prevention for COVID-19 is planned to be issued on August 31.

From: St-Jean, Romy Ochmann (HC/SC) <romy.ochmann.st-jean@hc-sc.gc.ca>
Sent: 2021-08-26 11:33 AM
To: Clarke, Andrea (HC/SC) <andrea.clarke@hc-sc.gc.ca>; McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Ferrer, Marvin (HC/SC) <marvin.ferrer@hc-sc.gc.ca>
Subject: RE: Heads up - Ivermectin advertisement in Manitoba - COVID-19

Thanks Andrea, it's been shared (Lissa cc'd).

From: Clarke, Andrea (HC/SC) <andrea.clarke@hc-sc.gc.ca>
Sent: 2021-08-26 11:29 AM
To: McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>; St-Jean, Romy Ochmann (HC/SC) <romy.ochmann.st-jean@hc-sc.gc.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Ferrer, Marvin (HC/SC) <marvin.ferrer@hc-sc.gc.ca>
Subject: RE: Heads up - Ivermectin advertisement in Manitoba - COVID-19

Hi Romy,

DM approved to share up to the MO for info.

Thanks,
Andrea

From: McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>
Sent: 2021-08-25 12:34 PM
To: Clarke, Andrea (HC/SC) <andrea.clarke@hc-sc.gc.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>
Subject: Heads up - Ivermectin advertisement in Manitoba - COVID-19

Hi Andrea,

Please see heads up below. Will keep you updated on any developments. Ok to share this with MO for awareness if DMO deems appropriate for sharing.

Heads up – Unauthorized advertising of Ivermectin to treat COVID-19

- ROEB has been made aware by HPFB that Ivermectin (an authorized anti-parasitic drug used in 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 warned about not using this drug for the treatment of COVID-19 and the issue has received media coverage (e.g., CNN , Global News).
- [redacted]
- ROEB is following up to determine who is responsible for the advertisement and to direct that it be removed. A public advisory is being considered.

Requester agreed to
Remove 3rd Party Info

Thanks,
Jenny

McLaughlin, Jenny (HC/SC)

From: McLaughlin, Jenny (HC/SC)
Sent: 2021-08-31 4:46 PM
To: Superle, Tamy (HC/SC); Ministerial Services / Services Ministériels (HC/SC); ADMO CPAB / BSMA DGCAP (HC/SC); Aung-Thin, Pamela (HC/SC); Smith, Melissa (HC/SC); Olsen, Clarke (HC/SC); Mastine, Daniel (HC/SC); Zimmermann, Margaret (HC/SC); Roufik, Samira (HC/SC); Trombetti, Stefania (HC/SC)
Cc: HC.F Comms_Coordination F.SC; HC.F CPAB ADMO Advisors F.SC; Cropley, Julia (HC/SC); HC.F SCD DGO / BDG DCS F.SC; Payette, Louise (HC/SC); HC.F CPHO Coordination / Coordination ACSP F.SC; Lafkas, Cathy (HC/SC); Nahum, Marilyne (HC/SC); HC.F ROEB ADMO / BSMA DGORAL F.SC; Bellefeuille, Aldege (HC/SC)
Subject: RE: For URGENT ADM Approval: PA | Ivermectin
Attachments: ROEB_PA_Ivermectin and COVID-19_2021-08_31_1540 SS (003)_JM.docx

Stefania has approved this version, with one additional edit noted under "What to do".

Thanks,
Jenny

From: Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>
Sent: 2021-08-31 4:15 PM
To: Ministerial Services / Services Ministériels (HC/SC) <ministerialservices-servicesministeriels@hc-sc.gc.ca>; ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>; Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Mastine, Daniel (HC/SC) <daniel.mastine@hc-sc.gc.ca>; Zimmermann, Margaret (HC/SC) <margaret.zimmermann@hc-sc.gc.ca>; Roufik, Samira (HC/SC) <samira.roufik@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Cc: HC.F Comms_Coordination F.SC <comms_coordination@hc-sc.gc.ca>; HC.F CPAB ADMO Advisors F.SC <cpab_admo_advisors@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; HC.F SCD DGO / BDG DCS F.SC <hc.scddgobdgdcs.sc@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; HC.F CPHO Coordination / Coordination ACSP F.SC <hc.cphocoordination-coordinationacsp.sc@hc-sc.gc.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Subject: RE: For URGENT ADM Approval: PA | Ivermectin

Approved version attached. Thanks,

Tamy

From: Ministerial Services / Services Ministériels (HC/SC) <ministerialservices-servicesministeriels@hc-sc.gc.ca>
Sent: 2021-08-31 3:53 PM
To: Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>; ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>; Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Mastine, Daniel (HC/SC) <daniel.mastine@hc-sc.gc.ca>; Zimmermann, Margaret (HC/SC) <margaret.zimmermann@hc-sc.gc.ca>; Roufik, Samira (HC/SC) <samira.roufik@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Cc: HC.F Comms_Coordination F.SC <comms_coordination@hc-sc.gc.ca>; HC.F CPAB ADMO Advisors F.SC

<cpab_admo_advisors@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; HC.F SCD DGO / BDG DCS F.SC <hc.scddgobdgdcs.sc@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; HC.F CPHO Coordination / Coordination ACSP F.SC <hc.cphocoordination-coordinationacsp.sc@hc-sc.gc.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Subject: RE: For URGENT ADM Approval: PA | Ivermectin

Good afternoon,

Please find attached a revised advisory in tracked and clean, for approval.

Merci,
Alexandre Richer-Brulé
(he / him | il / lui)

Communications Officer | Agent de communications
Tel: 343-572-1833

From: Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>
Sent: 2021-08-31 2:49 PM
To: Ministerial Services / Services Ministériels (HC/SC) <ministerialservices-servicesministeriels@hc-sc.gc.ca>; ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>; Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Mastine, Daniel (HC/SC) <daniel.mastine@hc-sc.gc.ca>; Zimmermann, Margaret (HC/SC) <margaret.zimmermann@hc-sc.gc.ca>; Roufik, Samira (HC/SC) <samira.roufik@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Cc: HC.F Comms_Coordination F.SC <comms_coordination@hc-sc.gc.ca>; HC.F CPAB ADMO Advisors F.SC <cpab_admo_advisors@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; HC.F SCD DGO / BDG DCS F.SC <hc.scddgobdgdcs.sc@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; HC.F CPHO Coordination / Coordination ACSP F.SC <hc.cphocoordination-coordinationacsp.sc@hc-sc.gc.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Subject: RE: For URGENT ADM Approval: PA | Ivermectin

Hi all,

Please find attached additional comments from Supriya. She noted that with all the edits it's a little disconnected in places. Thanks,

Tamy

From: Ministerial Services / Services Ministériels (HC/SC) <ministerialservices-servicesministeriels@hc-sc.gc.ca>
Sent: 2021-08-31 2:04 PM
To: ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; Ministerial Services / Services Ministériels (HC/SC) <ministerialservices-servicesministeriels@hc-sc.gc.ca>; Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>; McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>; Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Mastine, Daniel (HC/SC) <daniel.mastine@hc-sc.gc.ca>; Zimmermann, Margaret (HC/SC) <margaret.zimmermann@hc-sc.gc.ca>; Roufik, Samira (HC/SC) <samira.roufik@hc-sc.gc.ca>; Trombetti, Stefania

(HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Cc: HC.F Comms_Coordination F.SC <comms_coordination@hc-sc.gc.ca>; HC.F CPAB ADMO Advisors F.SC <cpab_admo_advisors@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; HC.F SCD DGO / BDG DCS F.SC <hc.scddgobdgdcs.sc@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; HC.F CPHO Coordination / Coordination ACSP F.SC <hc.cphocoordination-coordinationacsp.sc@hc-sc.gc.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Subject: RE: For URGENT ADM Approval: PA | Ivermectin

Thanks JP! HPFB ADMO – any concerns with this version?

Heather Leclerc
(she | elle)

Chief, Ministerial Services, Health Canada and the Public Health Agency of Canada
heather.leclerc@hc-sc.gc.ca | 613-791-4649

Chef, Services ministériels, Santé Canada et l'Agence de la santé publique du Canada
heather.leclerc@hc-sc.gc.ca | 613-791-4649

From: Bousquet, Jean-philippe (HC/SC) <jean-philippe.bousquet@hc-sc.gc.ca> **On Behalf Of** ADMO CPAB / BSMA DGCAP (HC/SC)
Sent: 2021-08-31 1:41 PM
To: Ministerial Services / Services Ministériels (HC/SC) <ministerialservices-servicesministeriels@hc-sc.gc.ca>; Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>; McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>; Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Mastine, Daniel (HC/SC) <daniel.mastine@hc-sc.gc.ca>; Zimmermann, Margaret (HC/SC) <margaret.zimmermann@hc-sc.gc.ca>; Roufik, Samira (HC/SC) <samira.roufik@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Cc: ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; HC.F Comms_Coordination F.SC <comms_coordination@hc-sc.gc.ca>; HC.F CPAB ADMO Advisors F.SC <cpab_admo_advisors@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; HC.F SCD DGO / BDG DCS F.SC <hc.scddgobdgdcs.sc@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; HC.F CPHO Coordination / Coordination ACSP F.SC <hc.cphocoordination-coordinationacsp.sc@hc-sc.gc.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Subject: RE: For URGENT ADM Approval: PA | Ivermectin

Bonjour,

Please find Pam revised approved version.

Apologies for the delay.

Thanks,
JP

Jean-Philippe Bousquet
(il / him)
BSMA de la DGCAP / CPAB ADMO
Jean-Philippe.Bousquet@hc-sc.gc.ca / 613-884-3017

From: Ministerial Services / Services Ministériels (HC/SC) <ministerialservices-servicesministeriels@hc-sc.gc.ca>
Sent: 2021-08-31 11:08 AM
To: Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>; McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>; Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Mastine, Daniel (HC/SC) <daniel.mastine@hc-sc.gc.ca>; Zimmermann, Margaret (HC/SC) <margaret.zimmermann@hc-sc.gc.ca>; Roufik, Samira (HC/SC) <samira.roufik@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Cc: ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; HC.F Comms_Coordination F.SC <comms_coordination@hc-sc.gc.ca>; HC.F CPAB ADMO Advisors F.SC <cpab_admo_advisors@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; HC.F SCD DGO / BDG DCS F.SC <hc.scddgobdgdcs.sc@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; HC.F CPHO Coordination / Coordination ACSP F.SC <hc.cphocoordination-coordinationacsp.sc@hc-sc.gc.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Subject: RE: For URGENT ADM Approval: PA | Ivermectin

Good morning,

Thank you for your feedback, please find attached a revised advisory in tracked and clean.

Tamy, could you please confirm that Supriya approves with these changes?

Once confirmed, we will move to DMO ☺

Merci,
Alexandre Richer-Brulé
(he / him | il / lui)

Communications Officer | Agent de communications
Tel: 343-572-1833

From: Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>
Sent: 2021-08-31 10:03 AM
To: McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>; Ministerial Services / Services Ministériels (HC/SC) <ministerialservices-servicesministeriels@hc-sc.gc.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>; Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Mastine, Daniel (HC/SC) <daniel.mastine@hc-sc.gc.ca>; Zimmermann, Margaret (HC/SC) <margaret.zimmermann@hc-sc.gc.ca>; Roufik, Samira (HC/SC) <samira.roufik@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Cc: ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; HC.F Comms_Coordination F.SC <comms_coordination@hc-sc.gc.ca>; HC.F CPAB ADMO Advisors F.SC <cpab_admo_advisors@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; HC.F SCD DGO / BDG DCS F.SC <hc.scddgobdgdcs.sc@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; HC.F CPHO Coordination / Coordination ACSP F.SC <hc.cphocoordination-coordinationacsp.sc@hc-sc.gc.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Subject: RE: For URGENT ADM Approval: PA | Ivermectin

Hi all,

Please see Supriya's comments in the attached doc. Thanks,

Tamy

From: McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>
Sent: 2021-08-31 9:38 AM
To: Ministerial Services / Services Ministériels (HC/SC) <ministerialservices-servicesministeriels@hc-sc.gc.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>; Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Mastine, Daniel (HC/SC) <daniel.mastine@hc-sc.gc.ca>; Zimmermann, Margaret (HC/SC) <margaret.zimmermann@hc-sc.gc.ca>; Roufik, Samira (HC/SC) <samira.roufik@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Cc: ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; HC.F Comms_Coordination F.SC <comms_coordination@hc-sc.gc.ca>; HC.F CPAB ADMO Advisors F.SC <cpab_admo_advisors@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; HC.F SCD DGO / BDG DCS F.SC <hc.scddgobdgdcs.sc@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; HC.F CPHO Coordination / Coordination ACSP F.SC <hc.cphocoordination-coordinationacsp.sc@hc-sc.gc.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Subject: RE: For URGENT ADM Approval: PA | Ivermectin

Good morning,

Stefania has approved the attached version with comments.

Thanks,
Jenny

From: Ministerial Services / Services Ministériels (HC/SC) <ministerialservices-servicesministeriels@hc-sc.gc.ca>
Sent: 2021-08-31 9:04 AM
To: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>; Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; Mastine, Daniel (HC/SC) <daniel.mastine@hc-sc.gc.ca>; Zimmermann, Margaret (HC/SC) <margaret.zimmermann@hc-sc.gc.ca>; Roufik, Samira (HC/SC) <samira.roufik@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Cc: ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; HC.F Comms_Coordination F.SC <comms_coordination@hc-sc.gc.ca>; HC.F CPAB ADMO Advisors F.SC <cpab_admo_advisors@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; HC.F SCD DGO / BDG DCS F.SC <hc.scddgobdgdcs.sc@hc-sc.gc.ca>; Payette, Louise (HC/SC) <louise.payette@hc-sc.gc.ca>; HC.F CPHO Coordination / Coordination ACSP F.SC <hc.cphocoordination-coordinationacsp.sc@hc-sc.gc.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Subject: For URGENT ADM Approval: PA | Ivermectin

Good morning Stefania, Pam, and HPFB ADMO,

Please find attached an advisory for your approval by 11am, if possible.

Apologies for the rush, we are aiming to post today.

Merci!
Alexandre

Context: 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.

Approved by:
Linsey Hollett, DG, ROEB (August 30, 2021)
Bruce Randall, DG, TPD (August 30, 2021)
Marilena Bassi, DG, VDD (August 30, 2021)
Simon Carvalho, Legal Advisor, LSU (August 30, 2021)
Marilyne Nahum, Comm Exec, HPFB-ROEB (August 30, 2021)
Cathy Lafkas, Director, SCD-CPAB (August 30, 2021)
Jon Ward, DG, SCD-CPAB (August 31, 2021)
Stefania Trombetti, ADM, ROEB (pending)
Pamela Aung-Thin, ADM, CPAB (pending)
Supriya Sharma, Chief Medical Advisor, HPFB (pending)
DMO (pending)
PCO (FYI-pending)

Alexandre Richer-Brulé
(he / him | il / lui)

Communications Officer | Ministerial Communications Directorate (Ministerial Services)
Health Canada and the Public Health Agency of Canada
alexandre.richer-brule@hc-sc.gc.ca | 343-572-1833
Team email : Comms_Coordination@hc-sc.gc.ca

Agent de communications | Direction des communications ministériels (Services ministériels)
Santé Canada et l'Agence de la santé publique du Canada
alexandre.richer-brule@hc-sc.gc.ca | 343-572-1833
Courriel de l'équipe : Comms_Coordination@hc-sc.gc.ca

Please note *emails to comms_coordination@hc-sc.gc.ca are monitored from 8 am – 9 pm during the week and from 9 am – 5 pm on weekends and holidays. The Ministerial Services inbox is only checked periodically. Please continue to cc comms_coordination@hc-sc.gc.ca on all approvals and requests.*
Veuillez noter *que la boîte de réception comms_coordination@hc-sc.gc.ca est surveillée de 8 h à 21 h du lundi au vendredi, et de 9 h à 17 h les fins de semaine et les jours fériés. La boîte de réception des Services ministériels n'est vérifiée que périodiquement. Pour toute demande et approbation, veuillez continuer de mettre comms_coordination@hc-sc.gc.ca en cc.*

Advisory

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

Tweet: #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 #COVID-19 and may cause serious health problems. [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, ~~and~~ discard it immediately. Consult a healthcare professional if you have used this product and have health concerns.

Issue

~~In response to~~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 ~~to~~ by them.

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

McLaughlin, Jenny (HC/SC)

From: McLaughlin, Jenny (HC/SC)
Sent: 2021-09-23 5:11 PM
To: CPAB MEDIA RELATIONS / RELATIONS AVEC LES MEDIAS DGCAP (HC/SC); ADMO CPAB / BSMA DGCAP (HC/SC); Trombetti, Stefania (HC/SC)
Cc: HC.F ROEB ADMO / BSMA DGORAL F.SC; Johnson, Mark (HC/SC); Morrissette, Eric (HC/SC); Perrier-Belanger, Stephanie (HC/SC); Beattie, Alexander (HC/SC); Cropley, Julia (HC/SC); Genier, Anne (HC/SC); Olsen, Clarke (HC/SC)
Subject: RE: For ADMs CPAB/ HPFB / ROEB approval: Media Query: Winnipeg Free Press [redacted]) Regulations of agricultural ivermectin

Hi Anne,

The version below is approved by Stefania:

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

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

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

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

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

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* 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 meet~~ing~~ regulatory requirements, visit https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/illegal-marketing/complaint.html.

As part of its ongoing commitment to openness and transparency, Health Canada posts a summary of health product advertising complaints as well as health product advertising incidents related to COVID-19 addressed by the Department.

Thanks,
Jenny

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca> **On Behalf Of** CPAB MEDIA RELATIONS / RELATIONS AVEC LES MEDIAS DGCAP (HC/SC)
Sent: 2021-09-23 4:13 PM
To: ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Cc: HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Johnson, Mark (HC/SC) <mark.johnson@hc-sc.gc.ca>; Morrissette, Eric (HC/SC) <eric.morrissette@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>
Subject: RE: For ADMs CPAB/ HPFB / ROEB approval: Media Query: Winnipeg Free Press [redacted] Regulations of agricultural ivermectin

Hi Jenny,

Please find the revised response at the bottom of this email. Note that an earlier version of the response was approved by Dr. Sharma and Manon Bombardier over at HPFB.

Merci,

Anne

From: McLaughlin, Jenny (HC/SC) <jenny.mclaughlin@hc-sc.gc.ca>
Sent: 2021-09-23 11:49 AM
To: CPAB MEDIA RELATIONS / RELATIONS AVEC LES MEDIAS DGCAP (HC/SC) <cpab.media.relations-relations.avec.les.media.sdgcap@hc-sc.gc.ca>; ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>
Cc: HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Johnson, Mark (HC/SC) <mark.johnson@hc-sc.gc.ca>; Morrissette, Eric (HC/SC) <eric.morrissette@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>
Subject: RE: For ADMs CPAB/ HPFB / ROEB approval: Media Query: Winnipeg Free Press [redacted] Regulations of agricultural ivermectin

Hello,

Please see comments below. Can you please ask the programs to address and send back for approval?

Thanks,
Jenny

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

One of ~~The role of~~ Health Canada's roles, as the federal regulator, is the approval of veterinary drug products. [should also say something here about HC's role re: compliance and enforcement to ensure that regulated products are not being advertised or sold for indications that are not authorized] The Department helps ensure that all veterinary drugs fully satisfy requirements under the *Food and Drug Regulations* before they can be marketed in Canada. Restrictions associated with the sale of a product intended for use in livestock would be of provincial or territorial jurisdiction [please confirm accuracy. Isn't any drug subject to FDR and FDA requirements related to advertising and sale? I think we should provide more info here to clarify that HC doesn't have jurisdiction over how a product is ultimately used but we do regulate the sale and advertising of drugs and take action when a product is being advertised or sold outside the terms of its market authorization]. Depending on the province or territory where the drugs are sold, there may be restrictions on who is permitted to purchase products intended for use in livestock~~.~~

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

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

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

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its Regulations, it takes steps to verify that non-compliance has occurred. Incidents of non-compliance are prioritised and action is taken based on the risk they may pose to the general public. It 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 meet~~ing~~ regulatory requirements, visit https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/illegal-marketing/complaint.html.

As part of its ongoing commitment to openness and transparency, Health Canada posts a summary of health product advertising complaints addressed by the Department. [Can we also include the link to the summary of advertising complaints specific to COVID-19?]

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca> **On Behalf Of** CPAB MEDIA RELATIONS / RELATIONS AVEC LES MEDIAS DGCAP (HC/SC)
Sent: 2021-09-23 11:14 AM
To: ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>
Cc: HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Johnson, Mark (HC/SC) <mark.johnson@hc-sc.gc.ca>; Morrissette, Eric (HC/SC) <eric.morrissette@hc-sc.gc.ca>; Perrier-Belanger, Stephanie (HC/SC) <stephanie.perrier-belanger@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>; Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>
Subject: For ADMs CPAB/ HPFB / ROEB approval: Media Query: Winnipeg Free Press [redacted] Regulations of agricultural ivermectin

Good day,

For ADMs CPAB, HPFB, and ROEB approval, we have received a media query on agricultural ivermectin. The response below was provided by HPDC, VDD and MHPD and approved by the 3 respective DGs.

Your approval by 2 pm would be greatly appreciated.

Merci!

Anne

Media/Reporter: Winnipeg Free Press [redacted]

Deadline to reporter: September 22 / 5 pm

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

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

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

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

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

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

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

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

As part of its ongoing commitment to openness and transparency, Health Canada posts a summary of health product advertising complaints as well as Health product advertising incidents related to COVID-19 addressed by the Department.

Tasked to: HPCD, MHPD, VDD
Approved by:
Marilena Bassi, DG, VDD (approved)
Kelly Robinson, DG MHPD (approved Q2)
Linsey Hollet, DG HPCD (approved)
Eric Morrissette , Chief Media Relations (approved)
Marilyne Nahum for Cathy Lafkas, Director Strat Comms (approved)
Jon Ward, Strat Comms DG (approved)
Julia Cropley, DG MCD (FYI)
Pam Aung-Thin, CPAB ADM (pending)
Manon Bombardier and Dr. Supriya Sharma, HPFB ADM (approved)
Stefania Trombetti, ROEB ADM (pending)
DMO (pending)

McLaughlin, Jenny (HC/SC)

From: McLaughlin, Jenny (HC/SC)
Sent: 2021-09-27 2:32 PM
To: CPAB MEDIA RELATIONS / RELATIONS AVEC LES MEDIAS DGCAP (HC/SC); ADMO CPAB / BSMA DGCAP (HC/SC); Derry, Mélanie (HC/SC); Trombetti, Stefania (HC/SC)
Cc: Olsen, Clarke (HC/SC); HC.F ROEB ADMO / BSMA DGORAL F.SC; Cropley, Julia (HC/SC); Johnson, Mark (HC/SC); Morrissette, Eric (HC/SC); Genier, Anne (HC/SC); Beattie, Alexander (HC/SC)
Subject: RE: For ADMS ROEB, HPFB and CPAB approval: Media Query: Follow-up: Winnipeg Free Press [redacted] Regulations of agricultural ivermectin

Hello,

Stefania has approved the response below with the edits noted in red.

Thanks,
Jenny

Q1. Do you have more information on the false advertising in Manitoba?
Q2. How many billboards were there and where were they located?

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

Q3. Were they claiming ivermectin cures COVID-19?

Billboards were advertising Ivermectin for the treatment of COVID-19.

Q4. Was the company fined?

Health Canada issued a letter ~~requesting~~ directing ~~that~~ the sponsor of these ads to remove them immediately. The sponsor has confirmed that these ads are no longer being displayed and committed to refrain from engaging in this non-compliant action in the future.

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

It is illegal in Canada to sell or advertise a drug in a false, misleading or deceptive manner and would be a contravention of the *Food and Drugs Act* (FDA). The primary objective of Health Canada's compliance and enforcement approach is to manage risks to Canadians using the most appropriate level of intervention. A number of options are available to Health Canada to address non-compliance, including the issuance of compliance letters, on-site visits, product recalls and public communications. ~~Drugs are regulated under the FDA and its associated Regulations.~~ Health Canada may also refer charges under the FDA to the Public Prosecution Service of Canada for potential prosecution. The courts have the sole discretion to impose penalties. Additional information regarding Health Canada's compliance and enforcement approach for health products can be found in its policy, available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html

The Department encourages anyone who has information regarding the potential illegal sale or advertising of ivermectin or any other health product to report it using the online complaint form.

From: Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca> **On Behalf Of** CPAB MEDIA RELATIONS / RELATIONS AVEC LES MEDIAS DGCAP (HC/SC)
Sent: 2021-09-27 1:32 PM
To: ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>; HC.F ROEB ADMO / BSMA DGORAL F.SC <hc.roebadmo-bsmadgoral.sc@hc-sc.gc.ca>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>; Johnson, Mark (HC/SC) <mark.johnson@hc-sc.gc.ca>; Morrissette, Eric (HC/SC) <eric.morrissette@hc-sc.gc.ca>; Genier, Anne (HC/SC) <anne.genier@hc-sc.gc.ca>; Beattie, Alexander (HC/SC) <Alexander.Beattie@hc-sc.gc.ca>
Subject: For ADMS ROEB, HPFB and CPAB approval: Media Query: Follow-up: Winnipeg Free Press [redacted] Regulations of agricultural ivermectin

Good day,

For ADMs ROEB, HPFB and CPAB approval, we have received a follow-up query from the reporter that was inquiring on the ivermectin billboards in Manitoba last week.

Input was provided by MHPD (Q1-4) and HPCD (Q5) and approved by their respective DGs.

I have also included our original response for awareness below.

Your approval by 4:00 pm would be greatly appreciated.

Merci,

Anne

Media/Reporter: Winnipeg Free Press [redacted]

Deadline to reporter: September 27

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Background: X

Questions and answers:

Q1. **Do you have more information on the false advertising in Manitoba?**
Q2. **How many billboards were there and where were they located?**

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

Q3. **Were they claiming ivermectin cures COVID-19?**

Billboards were advertising Ivermectin for the treatment of COVID-19.

Q4. Was the company fined?

Health Canada issued a letter requesting that the sponsor of these ads to remove them immediately. The sponsor has confirmed that these ads are no longer being displayed and committed to refrain from engaging in this non-compliant action in the future.

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

It is illegal in Canada to sell or advertise a drug in a false, misleading or deceptive manner and would be a contravention of the *Food and Drugs Act* (FDA).

Drugs are regulated under the FDA and its associated Regulations. Health Canada may refer charges under the FDA to the Public Prosecution Service of Canada for potential prosecution. The courts have the sole discretion to impose penalties.

Response previously provided:

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

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

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

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

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

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

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

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

Tasked to: HPCD, MHPD
Approved by:
Kelly Robinson, DG MHPD (approved Q1-4)
Linsey Hollet, DG HPCD (approved Q5)
Eric Morrissette and Mark Johnson , Chief Media Relations (approved)
Cathy Lafkas, Director Strat Comms (approved)
Jon Ward, Strat Comms DG (FYI)
Julia Cropley, DG MCD (FYI)
Cathy Allison, CPAB Associate ADM (pending)
Manon Bombardier and Dr. Supriya Sharma, HPFB ADM (pending)
Stefania Trombetti, ROEB ADM (pending)
DMO (pending)

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, E/CE: media@hc-sc.gc.ca

RORB BEC Look-Ahead Meeting
Monday, May 10, 2021

VACCINES

- Kim to provide most recent update on Emergent.

SHORTAGES

Requester agreed to Remove 3rd Party Info

(1) Magnesium Sulfate for Injection – Tier 3 shortage

- A mineral replacement drug with a variety of uses, including in the treatment of low levels of magnesium. PTs have also indicated it is necessary in cardiac surgery.
- [redacted] is reporting a shortage [redacted] A multi-week stock out in June/July is possible.
- PTs indicate a stock-out would have a significant impact on the health systems and expressed their concerns at a May 6th multi-stakeholder call
- A proposal has been received [redacted]
- All proposals will be reviewed as priority given the critical nature of the drug

(2) Ivermectin (anti-parasitic) (Covid-related) - *NEW

- Ivermectin is used to treat Strongyloides, a parasitic infection.
- Strongyloides are a parasitic infection for which up to 1 in 9 people from certain geographic regions (South-East Asia, South and Central America, sub-Saharan Africa and the Philippines) are infected. Most infections are asymptomatic; most people do not know they are infected
- [redacted]
- [redacted]
- [redacted] Global supply of the drug is limited.
- DSU has recently learned that COVID-19 has caused an increase for on-label use of this product.

- COVID-19 patients are often administered immunosuppressive drugs which can cause an asymptomatic Strongyloides infection to turn into a hyper-infection, which can be fatal.
- [redacted] is considering the use of Ivermectin in a prophylactic manner for treatment of all patients from potentially infected regions. Supply information is required in order to allow such a decision to be made.
- DSU has requested additional supply information [redacted]
- [redacted]
- Next steps to be determined [redacted]

Requester agreed to Remove 3rd Party Info

(3) EpiPen 0.3 mg Supply (EpiPen Jr, not impacted)

- [redacted]
- DSU has confirmed supply of Alternatives [redacted]

(4) Kadian – Opioid crisis may impact demand for drugs

- Kadian is a sustained release morphine tablet, used extensively in opioid use treatment.
- A considerable increase in demand is resulting in shortages but also creating supply constraints for other extended release morphine tablets.
- A multi-stakeholder call was conducted on May 3rd
- Kadian's 24 hour sustained release morphine capsules, is the shortage of predominant concern.
- [redacted] shortages of three formats with estimated end dates of June, September and October. Stakeholders reported that opioid-use disorder treatment programs are set to expand, significantly increasing demand for Kadian, and putting the estimated shortage end dates in doubt.

- HPCD met with OCS and TPD on May 6th to discuss alternatives to help resolve shortages of these types of drugs. Next steps to be determined.

RISK FILE

[redacted]

- [redacted]

Requester agreed to
Remove 3rd Party Info

Health Canada - RADAR Report – Health Products

This report may contain Protected B information

Date Created: 2021-10-15 14:40 **Created by: Yogesh Sharma**

Case

Programme	Case #	Case Type	SubType
Health Products	2021-050677	Vet Drug	Internal-CV
Priority	**Activity**	**Status**	**Outcome**
B	Complete	Complete	Compliance Achieved
Primary Officer	**Subject Type**	**Subject Name**	
Thivya Jeyakanthan	Product	Valuheart Gold (60mcg ivermectin)	
Date Received	**Date Updated**	**Date Closed**	
2021-07-28	2021-08-05	2021-08-16	

Case Number Crosswalk

Case Number Type	Value

Related Cases

Case No.	Case Type	SubType	Subject Name	Lead Case
2021-049236 I	Vet Drug	Complaint-Trade	Advantage Multi (Advocate)	
2021-050674 I	Vet Drug	Internal-CV	Advantage Blue for dogs	
2021-050675 I	Vet Drug	Internal-CV	Stronghold (15mg selamectin)	
2021-050676 I	Vet Drug	Internal-CV	Revolution (30mg selamectin)	
2021-050677 I	Vet Drug	Internal-CV	Valuheart Gold (60mcg ivermectin)	
2021-050678 I	Vet Drug	Internal-CV	Valuheart Gold (120mcg ivermectin)	
2021-050679 I	Vet Drug	Internal-CV	Valuheart Gold (240mcg ivermectin)	

Case Notes

Effective Date	Modified Date	Author
2021-08-05	2021-08-05	[redacted]
Synchronised to - Synchronisée avec : 2021-049236. See lead case for complete history. - Voir le cas principal pour l'histoire complète.		

Effective Date	Modified Date	Author
2021-08-05	2021-08-05	[redacted]
Case cloned from - Cas cloné à partir de: 2021-049236		

Effective Date	Modified Date	Author
2021-08-16	2021-08-16	Thivya Jeyakanthan(JEYAKANTHAN)
Desynchronised from - Desynchronisée de : 2021-049236		

Case Categories

Case Category Details

Governance

Governance Details

Subject: Product

Product

Product Brand and Name:	**Valuheart Gold (60mcg ivermectin)**
Regulatory Type:	Veterinary Drug
Product License Number:	
Regulatory ID:	
Regulatory Status:	No Market Authorization
Notifier's Reference:	
Model Number:	
Serial Number:	
Date Codes:	
Barcode:	
Batch Number:	
Certification / Standards:	
Container Size:	
Country of Origin:	
Description:	
Reference Table Product ID:	

Product Specifications

Received Date	Specification File	Ingredients	Specification

List of Ingredients (Note: for Valid Specification only, otherwise this table is empty; maximum one Specification can be valid)

Ingredient Name	Lower Limit (%)	Upper Limit (%)	Status	May Contain

Product Notes

Effective Date	Modified Date	Author

Product Categories

Product Category Details

Product Alias

Name

PoP

PoP Type	Start Date	End Date

End Subject: Product

Contacts

Primary Contact	**Yes**
Context : Retailer [redacted]	

Primary Contact	**No**
Context : [redacted]	

Resources

Resource	Function	Activity	Status	Modified Date
Archive	Archive	Inactive	In Queue	2021-08-16
Thivya Jeyakanthan	Manager/Supervisor	Complete	Complete	2021-08-13
[redacted]	Lead Inspector-Central 2	Complete	Complete	2021-08-13
Olivier Landry AS CTU	Administrative staff	Complete	Complete	2021-07-29
Central Triage Unit	Triage	Complete	Complete	2021-08-04
Yogesh Sharma	Triage	Complete	Complete	2021-08-04

Documents

Internal/External	Effective Date	Submission Number	Type	Title	Authority

Case Disposition

Activity	Function	Action
100 Regulatory Compliance	HC6 Health Risk Protection	Queue for Deletion
Authority	**Retention Period**	**Retention Trigger Date**
	10	

Health Canada - RADAR Report – Health Products

This report may contain Protected B information

Date Created: 2021-10-15 15:01 **Created by: Yogesh Sharma**

Case

Programme	Case #	Case Type	SubType
Health Products	2021-053760	Human Drug	Internal-Border
Priority	**Activity**	**Status**	**Outcome**
A	Compliance Verification	In Queue	
Primary Officer	**Subject Type**	**Subject Name**	
[redacted]	Product	Iverheal 12 (Ivermectin 12 mg)	
Date Received	**Date Updated**	**Date Closed**	
2021-08-18	2021-08-23		

Case Number Crosswalk

Case Number Type	Value
Trigger Number	2021-053760

Related Cases

Case No.	Case Type	SubType	Subject Name	Lead Case

Case Notes

Effective Date	Modified Date	Author
2021-08-19	2021-08-19	Valerie Laflamme(VLAFLAMME)

Details (CTU assessment and information gathering): Based on the information provided in this referral, this case is being triaged to the region in order to follow-up on the potential advertisement/sale of unauthorized prescription drug products as well as possibly importing without a site license. Compliance History (Hint): A search in RADAR for '[redacted]' produced no results. Product Information (Hint): Useful resource(s) - DPD / PDL / LNHPD / NHPID / VHP / HC Online COVID list Multiple prescription drug products Company Information: Useful resource(s) - DnB/HC databases [eCES, NHP SL list, NHPSAS][redacted] Sensitivities: Nil Priority: A - as per triage tool, potential importation without DEL, advertisement/sale of unauthorized prescription drugs. Assigned Region: HPC-East

Effective Date	Modified Date	Author
2021-08-19	2021-08-19	Valerie Laflamme(VLAFLAMME)

Complaint/Referral/Case creation request received by CTU via: Referral Email (External - Outside HC) Receive Date: 2021-08-18 / Time: 14:36 (Eastern) Product Type: Prescription Drugs (A) Regulatory Status: Not Market Authorized Complaint/Referral mentions online advertising and/or sale: No Website address provided in complaint/referral: Click or tap here to enter text. Suspected Non-Compliance(s) (Hint): SL/EL Issue - Importation (A) Advertisement and/or Sale of Unauthorized Product(s) Information to assist CV (hover over NC): Product Quality Issue, Labelling/Packaging Issue, Advertising Issue, SL/EL Issue, Unauthorized Product HPCD Active Investigation (List): No National Action Plan (Tracker): No Complaint/Referral description (paste pertinent text from complaint into this section): Bonjour, Voici une importation de drogue sur ordonnance par un médecin. L'importateur a contacté notre service à la clientèle suite à notre recommandation de refus et a mentionné qu'il est médecin et qu'il distribue le produit non homologué (médicaments sur ordonnance) sans DIN à ses patients au Canada. L'importateur a également mentionné qu'il avait réussi à importer ce type de produits (médicaments sur ordonnance) et à les distribuer à plusieurs reprises aux patients dans le passé. L'importateur ne possède pas non plus de DEL. Pour votre suivi. Cordialement, [redacted] Agent de conformité et d'application de la loi, Centre Frontalier Est Santé Canada / Gouvernement du Canada NOUVEAU [redacted] Tél [redacted] Regulatory Compliance and Enforcement Officer, Border Centre East Health Canada / Government of Canada NEW : [redacted] Tel [redacted]

Effective Date	Modified Date	Author
2021-08-23	2021-08-23	[redacted]

1) ASSIGNATION du dossier à l'inspecteur [redacted] par la superviseur intérimaire Lyne Michaud (Jean Laurin).

Effective Date	Modified Date	Author
2021-09-09	2021-09-13	[redacted]

3) RECHERCHES PRÉLIMINAIRES – L'ivermectine (pour usage vétérinaire ou humain), un agent antiparasitaire (comprimé, pâte, solution orale [soluté buvable], solution injectable, prémélange médicamenteux ou préparation topique). La vente d'ivermectine (un médicament sur ordonnance) est permise au Canada pour le traitement chez les humains d'infestations par vers, un type d'infection parasitaire, en particulier l'anguillulose et l'onchocercose intestinales. Recherche BDPP avec « Ivermectin » donne plusieurs produits commercialisés pour usage vétérinaire et 2 pour humain. Recherche PDL avec « Ivermectin » la classe dans « Avermectine ou ses dérivés » pour usage humain et vétérinaire (chevaux, chiens et chats). Recherche Avis et Rappels : Avis public pour l'Ivermectine n'étant pas homologué pour la prévention ni pour le traitement de la COVID-19 et indique qu'il peut entraîner de graves problèmes de santé (RA-76365). Dans cet avis, il y a un lien pour un article sur internet publié par la US-FDA intitulé « Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 ». Recherche avancée RADAR avec produit : « Ivermectin » donne 7 résultats et 20 résultats dans l'outil Recherche Rapide. Le cas RADAR 2021-050679 implique également un médecin qui aurait importé des produits de santé non autorisés. Une recherche internet avec « [redacted] » aucun résultat à part le registre des médecins du N.B [redacted] y est listé sur la Liste des prescripteurs des régimes de médicament du N. B. licence # [redacted] Une recherche sur internet avec « Iverheal 12 mg » donne un divers sites internet faisant la promotion de ce produit par [redacted] mais il le fabriquant ou le distributeur n'est pas connu à ce stade. L'adresse de l'exportateur [redacted]) ne semble pas associée à une entreprise sur internet. Selon la SOP-0269 - risque type I. Recherche Google maps avec adresse du [redacted] donne une maison d'habitation.

Case Categories

Case Category Details
Effective Date: 2021-08-19
Category: Performance>Triage>Triage Completed

Case Category Details
Effective Date: 2021-08-19
Category: Performance>Triage>Triage Started

Case Category Details
Effective Date: 2021-08-19
Category: Suspected Non-Compliance>Initial Priority>A

Case Category Details
Effective Date: 2021-08-19 Category: Suspected Non-Compliance>Market Authorization>No Market Authorization

Case Category Details
Effective Date: 2021-08-19 Category: Suspected Non-Compliance>SL/EL Issue>Importation

Case Category Details
Effective Date: 2021-08-19 Category: Triage Activities>Notification Method>Email

Case Category Details
Effective Date: 2021-08-23 Category: Performance>CV>Assigned to Inspector

Case Category Details
Effective Date: 2021-08-23 Category: Compliance Verification>Information from Other Internal Unit>Requested

Case Category Details	
Effective Date: 2021-08-25 Category: Compliance Verification>Information from Other Internal Unit>Received	
2021-08-25	2) DEMANDE D'INFORMATION SUPPLÉMENTAIRE – JM communique avec l'inspecteur [redacted] de l'Unité d'Intégrité Frontalière (BIU) pour obtenir plus d'information sur les coordonnées de [redacted], car une recherche internet ne permet pas de trouver un numéro de téléphone y compris sur le site de www.newbrunswickdoctordirectory.ca [redacted] et une description des produits de la plainte, car il n'y a aucune indication à ce sujet. Les informations suivantes sont obtenues pour concernant le refus aux douanes (Customs Identification Number [redacted] • Le produit est Iverheal 12 (Ivermectin 12 mg) – 20 comprimés • Exportateur [redacted] Téléphone de [redacted] Aucune photo du colis et des produits n'est disponible. Le cas est initié.

Governance

Governance Details

Subject: Product

Product

Product Brand and Name:	**Iverheal 12 (Ivermectin 12 mg)**
Regulatory Type:	Human Drug-Prescription
Product License Number:	
Regulatory ID:	
Regulatory Status:	No Market Authorization
Notifier's Reference:	
Model Number:	
Serial Number:	
Date Codes:	
Barcode:	
Batch Number:	
Certification / Standards:	
Container Size:	20 tablets
Country of Origin:	
Description:	
Reference Table Product ID:	

Product Specifications

Received Date	Specification File	Ingredients	Specification

List of Ingredients (Note: for Valid Specification only, otherwise this table is empty; maximum one Specification can be valid)

Ingredient Name	Lower Limit (%)	Upper Limit (%)	Status	May Contain

Product Notes

Effective Date	Modified Date	Author

Product Categories

Product Category Details
Effective Date: 2021-09-09 Category: Dose Form>Tablet

Product Category Details
Effective Date: 2021-09-09 Category: Intended Use Population>General adult population

Product Category Details
Effective Date: 2021-09-09 Category: Product Result>Seizure

Product Category Details
Effective Date: 2021-09-09 Category: Route of Administration>Oral

Product Category Details
Effective Date: 2021-09-09 Category: Verified Product Non-Compliance>Market Authorization>No Market Authorization

Product Category Details
Effective Date: 2021-09-09 Category: Verified Product Non-Compliance>SL/EL Issue>Distribution

Product Category Details
Effective Date: 2021-09-09 Category: Verified Product Non-Compliance>SL/EL Issue>Importation

Product Alias

Name

PoP

PoP Type	Start Date	End Date

End Subject: Product

Contacts

Primary Contact	**Yes**
Context : Importer 	

Resources

Resource	Function	Activity	Status	Modified Date
Valerie Laflamme	Triage	Complete	Complete	2021-08-19
Central Triage Unit	Triage	Triage	Complete	2021-08-19
[redacted]	Lead Inspector-East	Compliance Verification	In Queue	2021-08-23

Documents

Internal/External	Effective Date	Submission Number	Type	Title	Authority
Ext.	2021-08-19		Referral	CTU - [redacted]	Valerie Laflamme
Ext.	2021-08-19		Report	[redacted] - CTU Referral.docx	Valerie Laflamme

Case Disposition

Activity	Function	Action
100 Regulatory Compliance	HC6 Health Risk Protection	Queue for Deletion
Authority	**Retention Period**	**Retention Trigger Date**
	10	

Health Canada - RADAR Report – Health Products

This report may contain Protected B information

Date Created: 2021-10-15 15:16 **Created by: Yogesh Sharma**

Case

Programme	**Case #**	**Case Type**	**SubType**
Health Products	2021-060592	Vet Drug	Complaint-Consumer
Priority	**Activity**	**Status**	**Outcome**
Not Assigned	Complete	Complete	Outside Mandate
Primary Officer	**Subject Type**	**Subject Name**	
Yogesh Sharma	Product	Ivermectin	
Date Received	**Date Updated**	**Date Closed**	
2021-09-20	2021-09-21	2021-09-21	

Case Number Crosswalk

Case Number Type	**Value**
Trigger Number	2021-060592

Related Cases

Case No.	**Case Type**	**SubType**	**Subject Name**	**Lead Case**

Case Notes

Effective Date	Modified Date	Author
2021-09-21	2021-09-21	Yogesh Sharma(YSHARMA)
FRM-0317 submitted to CTU dated September 20, 2021. Details: The complainant alleged that the new media article from thedcpatriot.com indicated that India has announced they have eradicated Covid from an entire state of 246 million people using Ivermectin. Why is Health Canada still saying their is no use or treatment for ivermectin with Covid? How do you guys justify these disgusting mandates with leaky vaccines when there is an actual treatment available? How can I possibly trust any recommendations from Health Canada when they are so obviously off on this issue? https://thedcpatriot.com/india-announces-its-biggest-state-uttar-pradesh-241-million-people-is-covid-19-free-after-using-imectin As there are no product quality concerns reported the complainant and incoming request is an inquiry related to Ivermectin use and COVID, the complaint was forwarded to HPCE for further consideration. See internal documents.		

Case Categories

Case Category Details
Effective Date: 2021-09-20 Category: Compliance Verification>Sample>Unknown

Case Category Details
Effective Date: 2021-09-20 Category: Suspected Non-Compliance>Level of Harm>No adverse reaction, injury or death

Case Category Details
Effective Date: 2021-09-20 Category: Triage Activities>Notification Method>Form 317

Case Category Details
Effective Date: 2021-09-21 Category: Performance>Triage>Triage Completed

Case Category Details
Effective Date: 2021-09-21 Category: Performance>Triage>Triage Started

Case Category Details
Effective Date: 2021-09-21 Category: Referral (Outside Mandate)>Health Canada>Other

Case Category Details
Effective Date: 2021-09-21 Category: Tag/Identifier>COVID-19

Governance

Governance Details

Subject: Product

Product

Product Brand and Name:	**Ivermectin**
Regulatory Type:	Veterinary Drug
Product License Number:	
Regulatory ID:	
Regulatory Status:	Market Authorized
Notifier's Reference:	
Model Number:	
Serial Number:	
Date Codes:	
Barcode:	
Batch Number:	
Certification / Standards:	
Container Size:	
Country of Origin:	
Description:	
Reference Table Product ID:	

Product Specifications

Received Date	Specification File	Ingredients	Specification

List of Ingredients (Note: for Valid Specification only, otherwise this table is empty; maximum one Specification can be valid)

Ingredient Name	Lower Limit (%)	Upper Limit (%)	Status	May Contain

Product Notes

Effective Date	Modified Date	Author

Product Categories

Product Category Details

Product Alias

Name

PoP

PoP Type	Start Date	End Date

End Subject: Product

Contacts

Primary Contact	**No**
Context : Complainant - Consumer Canada	

Resources

Resource	Function	Activity	Status	Modified Date
Yogesh Sharma	Triage	Complete	Complete	2021-09-21
Central Triage Unit	Triage	Complete	Complete	2021-09-21
Archive	Archive	Inactive	In Queue	2021-09-21

Documents

Internal/External	Effective Date	Submission Number	Type	Title	Authority
Ext.	2021-09-20	2021-09-20-000237	Health Products - Complaint (FRM-0317)	Submission/Soumission	NOT AVAILABLE / N'EST PAS DISPONIBLE
Int.	2021-09-21		Referral	Inquiry Ivermectin and COVID (anonymous complaint).msg	Yogesh Sharma

Case Disposition

Activity	Function	Action
100 Regulatory Compliance	HC6 Health Risk Protection	Queue for Deletion
Authority	**Retention Period**	**Retention Trigger Date**
	10	2031-09-21

From: Renart-McGowan, Isabel (HC/SC)
To: Sharma, Supriya (HC/SC)
Cc: Olsen, Clarke (HC/SC)
Subject: RE: For review/ADM approval: 21-007306-134 - MIN CORR - Potential effectiveness of ivermectin for the treatment of COVID-19 patients
Date: 2021-06-29 3:32:00 PM

Noted. I will send back with that request.

From: Sharma, Supriya (HC/SC) <supriya.sharma@canada.ca>
Sent: 2021-06-29 3:27 PM
To: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@canada.ca>
Subject: Re: For review/ADM approval: 21-007306-134 - MIN CORR - Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Hi Isabel

For this one, I think it would be best to reference this meta-analysis on Ivermectin released yesterday. https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab591/6310839

It certainly is the most comprehensive assessment of all the studies on Ivermectin, and indicates that there isn't data to support its use in COVID-19

Supriya

> On Jun 29, 2021, at 3:17 PM, Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca> wrote:
>
> Hi Supriya,
>
> Here's another one. This is a response on the ivermectin issue. I think it is well laid out, outlining our powers (and lack thereof) in a logical way around drug approvals and CTs. Over to you for your review.
>
> Thanks,
> Isabel
> <21-007306-134 - HPFB Input.docx>
> <21-007306-134.pdf>

From: Mineau, Philippe (HC/SC)
To: Soo, Evelyn (HC/SC); Stewart, John Patrick (HC/SC)
Cc: Randall, Bruce (HC/SC)
Subject: RE: HPEC Sept 13
Date: 2021-09-13 11:38:45 AM

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
- Budenoside (Pulmicort)
- Doxycycline
- Fluvoxamine

Requester agreed to Remove 3rd Party Info

[redacted]

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>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>
Cc: Manick, Alexis (HC/SC) <alexis.manick@hc-sc.gc.ca>; Burke, Suzanne (HC/SC) <suzanne.burke@hc-sc.gc.ca>
Subject: HPEC Sept 13
Importance: High

Good morning,
Lisa is back tomorrow so this is your last set of HPEG notes from me for now! Have a great day ☺
Kailey

HPEG:

Dr Tam:

- People are ordering another strange covid treatment product (didn't catch the name) – saw on GPHN this morning – will monitor and flag if we need to communicate on this.
    - Comms – dust off lines on COVID treatment in case w need them

From: Randall, Bruce (HC/SC)
To: Mineau, Philippe (HC/SC)
Subject: RE: For action - FW: Ivermectin - change in status to over the counter?
Date: 2021-05-27 5:09:15 PM

~~Minor revisions~~

-

~~You suggest that ivermectin's potential benefit in preventing COVID-19 related deaths *likely* outweighs the risks of using this medication; however,~~ there remains substantial uncertainty regarding the risk profile when ivermectin is used at the doses seen in studies assessing ivermectin's effects on patients with COVID-19.

Thanks

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-05-27 2:38 PM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Subject: FW: For action - FW: Ivermectin - change in status to over the counter?

Hey Bruce,
For approval, a response on ivermectin, but this time it's about removing the prescription status on ivermectin (incoming is below, instead of attached)
Let me know what you think,
Thanks!
P

From [redacted]
Sent: 2021-04-21 11:02 PM
To: Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>
Subject: Ivermectin - change in status to over the counter?

Hello,

There seems to be evidence that the medication ivermectin is effective against SARS-CoV-2.

Since ivermectinis an authorized product, but currently prescription status, is the Department of Health considering making this available on a non-prescription basis, such that consumers can access it and use it early on in the disease progression, especially as hospitals are reaching critical levels.

I would appreciate if you could please further investigate this possibility, since at this point, off label use with a benefit of preventing Covid deaths would likely outweigh the risks associated with using the medication.

My understanding is that there is also evidence in the literature that cetirizine an famotidine also help prevent the cytokine storm from taking place. These are at least available over the counter, however public education could be useful in this instance to prevent hospitalizations.

Thank you very much for taking these suggestions into serious consideration.

[redacted]

From: Randall, Bruce (HC/SC)
To: Keeping, Elizabeth (HC/SC); Mineau, Philippe (HC/SC)
Cc: Legault-Thivierge, Geoffroy (HC/SC)
Subject: RE: PHM Q's - Iver and HCQ
Date: 2021-09-23 10:25:00 AM

Hi Beth,

Ivermectin is antiparasitic, HCQ is an antimalarial and to treat certain autoimmune conditions

Bruce

From: Keeping, Elizabeth (HC/SC) <elizabeth.keeping@hc-sc.gc.ca>
Sent: 2021-09-23 10:16 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Randall, Bruce (HC/SC) <bruce.randall@hc-sc.gc.ca>
Cc: Legault-Thivierge, Geoffroy (HC/SC) <geoffroy.legault-thivierge@hc-sc.gc.ca>
Subject: FW: PHM Q's - Iver and HCQ

Hey Philippe and Bruce:

For the ivermectin/HCQ one, would we say something like this?:

Health Canada authorizes, but does not conduct clinical trials in Canada. Ivermectin and hydroxychloroquine are both authorized in Canada as antiparasitic drugs. They have not been authorized for the treatment of COVID-19.

Thanks,
B

From: Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>
Sent: 2021-09-23 10:00 AM
To: Kealey, Ashton (HC/SC) <ashton.kealey@hc-sc.gc.ca>; COVIDvaccineComms / VaccinContrelaCOVIDcommunications (HC/SC) <covidvaccinecomms-vaccincontrelacovidcomms@hc-sc.gc.ca>; Inglese, Gianna (HC/SC) <gianna.inglese@hc-sc.gc.ca>; Ouellette, Fannie (HC/SC) <fannie.ouellette@hc-sc.gc.ca>
Cc: Lorenz, Jessica (HC/SC) <jessica.lorenz@hc-sc.gc.ca>; Martin, David S. (HC/SC) <david.s.martin@hc-sc.gc.ca>; Francis-Lamb, Laura (HC/SC) <laura.francis-lamb@hc-sc.gc.ca>; Keeping, Elizabeth (HC/SC) <elizabeth.keeping@hc-sc.gc.ca>; Legault-Thivierge, Geoffroy (HC/SC) <geoffroy.legault-thivierge@hc-sc.gc.ca>
Subject: RE: PHM Q's

We can take on the one you have tagged us for, though on the monoclonal treatments we may need input from Fannie's team. We can speak to what has been authorized by HC but they can speak to what has been made available to PTs.

Looping in Laura, David, Beth and Geoffroy from my team to address the various topics addressed in the question.

Thanks

From: Kealey, Ashton (HC/SC) <ashton.kealey@hc-sc.gc.ca>
Sent: 2021-09-23 9:56 AM
To: COVIDvaccineComms / VaccinContreLaCOVIDcommunications (HC/SC) <covidvaccinecomms-vaccincontrelacovidcomms@hc-sc.gc.ca>; Inglese, Gianna (HC/SC) <gianna.inglese@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; Ouellette, Fannie (HC/SC) <fannie.ouellette@hc-sc.gc.ca>
Cc: Lorenz, Jessica (HC/SC) <jessica.lorenz@hc-sc.gc.ca>
Subject: FW: PHM Q's

Hi Everyone,

Please find a question below for each of your respective teams. Would it be possible to hear back with a proposed response, or to hear what you think the best course of action is for these questions?

Thank you,

Ashton Kealey
Communications Officer, Public Affairs Branch
Agent de Communications, Direction des affaires publiques
343-543-2975

From: Damini, Megan (HC/SC) <megan.damini@hc-sc.gc.ca>
Sent: 2021-09-17 4:27 PM
To: Hipson, Erika (HC/SC) <erika.hipson@hc-sc.gc.ca>; Kealey, Ashton (HC/SC) <ashton.kealey@hc-sc.gc.ca>
Cc: O'Rourke, Maggie (HC/SC) <maggie.orourke@hc-sc.gc.ca>
Subject: RE: PHM Q's

Hi Ashton,

Erika is offline now, but here are her proposed responses:

Thanks!
Megan

Our team wouldn't be responsible for the following questions. Here are our recommendations for who you could reach out to:

- Why aren't public schools allowed? (In reference to rapid testing) Rapid Testing is Gianna Inglese's team
- Demand answers for: I suggest referring this to HPFB. [redacted]
  1. Why no monoclonal treatment available (much cheaper than hosp stays)
  2. Why haven't you trialed ivermectin or hcq?
  3. What is true number of adverse reactions?
  4. Publish raw data on PCR tests with CT values (what % >28) Gianna Inglese
     [redacted]
- What is the Delta Variant and how does the spike protein in it differ? This falls under [redacted]

Megan Damini
Adviser, Communications Advisor, PCRO
Conseillère principale en communications par intérim, BCCP
megan.damini@hc-sc.gc.ca / Tel : 343-553-4429

From: Hipson, Erika (HC/SC) <erika.hipson@hc-sc.gc.ca>
Sent: 2021-09-17 3:37 PM
To: Damini, Megan (HC/SC) <megan.damini@hc-sc.gc.ca>; Kealey, Ashton (HC/SC) <ashton.kealey@hc-sc.gc.ca>
Cc: O'Rourke, Maggie (HC/SC) <maggie.orourke@hc-sc.gc.ca>
Subject: RE: PHM Q's

Thanks Megan! I'll start looking into all of these and see which ones we can respond to. Ashton, when are you hoping to have responses back for these?

Thanks,
Erika

From: Damini, Megan (HC/SC) <megan.damini@hc-sc.gc.ca>
Sent: 2021-09-17 3:33 PM
To: Kealey, Ashton (HC/SC) <ashton.kealey@hc-sc.gc.ca>
Cc: Hipson, Erika (HC/SC) <erika.hipson@hc-sc.gc.ca>; O'Rourke, Maggie (HC/SC) <maggie.orourke@hc-sc.gc.ca>
Subject: RE: PHM Q's

Hi Ashton,

Looping in my colleague Erika to assist in Maggie's absence.

Thanks!
Megan

Megan Damini
Adviser, Communications Advisor, PCRO
Conseillère principale en communications par intérim, BCCP
megan.damini@hc-sc.gc.ca / Tel : 343-553-4429

From: Kealey, Ashton (HC/SC) <ashton.kealey@hc-sc.gc.ca>
Sent: 2021-09-17 3:20 PM
To: O'Rourke, Maggie (HC/SC) <maggie.orourke@hc-sc.gc.ca>
Cc: Damini, Megan (HC/SC) <megan.damini@hc-sc.gc.ca>
Subject: PHM Q's

Hi Maggie,

Here are some PHM Q's from the past 2 days. Would it be possible to provide response, or point me to the correct team to contact?

Thank you so much

		Twitter EN			@GovCanHealth are you currently recommending that fully vaxxed people remove masks indoors, given the potential for spillover events, waning immunity among elderly, and the Δ surge? Genuinely asking bc I am not sure this guidance works given people's social bubbles are quite large	Public Health Measure	https://twitter.com/[redacted]/status/1438461985711431681
11:43 AM · Sep 16, 2021		Twitter EN			Can you advise.. what safety measures are in place for early treatment? Seeing that we dont want to see hospitals overwhelmed?	Public Health Measure	https://twitter.com/[redacted]/status/1438529093017501253
Sept 16, 3:42PM	FB Public - ENG	Ok so if I have had both vaccines why do I have to wear a mask		PHM			https://www.facebook.com/HealthyCanadians/photos/a.10150334948756719/10159073313273710/?comment_id=10159073671298719&__tn__=R*F
7:30 AM · Sep 17, 2021	Twitter EN	Why aren't public schools allowed			Public Health Measure		https://twitter.com/[redacted]/status/1438827981882198016
10:44 PM · Sep 16, 2021	Twitter EN	Demand answers for:			Public Health Measure		https://twitter.com/QuestionAuthor16/status/1438386212436860226

			1. Why no monoclonal treatment available (much cheaper than hosp stays) 2. Why haven't you trialed Ivermectin or hcq? 3. What is true number of adverse reactions? 4. Publish raw data on PCR tests with CT values (what % >28)	
Sept 16, 11:57AM	Hi there I do have a question...is there a place at the current time to be tested to see if you have already have covid 19?	PHM	[redacted]	
Sept 16, 6:32PM	What is the Delta Variant and how does the spike protein in it differ?	PHM		https://www.facebook.com/HealthyCdns/photos/a.10150534848756719/1015067409[illegible]? comment_id=10159874136051718&__cft__[0]=AZX[illegible] [illegible]

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@hc-sc.gc.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@hc-sc.gc.ca/ Tél: 343-543-2975

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. STROMECOTL has been marketed in Canada since 2018.

- Health Canada is closely monitoring all potential therapeutic treatments and vaccines in development in Canada and abroad, including products such as ivermectin that are being use outside of their authorized indication (off-label use), as potential treatments for COVID-19.
- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Heath 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.

- At this time, no ivermectin manufacturer has made an application for this drug to be approved for the treatment or prevention of COVID-19. Therefore, the effectiveness of ivermectin as a therapeutic option for COVID-19 has not been evaluated by Health Canada.

- For drugs that have potential to be helpful in treating COVID-19, Health Canada encourages drug manufacturers to conduct clinical trials. This would provide an opportunity for the healthcare community to collect information on the effectiveness of the treatment and its associated risks. Evidence from adequately powered well-designed studies is needed to determine whether ivermectin might be helpful in preventing or treating COVID-19.

- A list of all clinical trials approved for the prevention or treatment of COVID-19 can be found on Health Canada's website: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-clinical-trials/list-authorized-trials.html

- In Canada, clinical trials for COVID-19 are facilitated under an Interim Order, which was signed by the Minister of Health on May 23, 2020: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/notice-interim-order.html

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

- To date, Health Canada has not received any clinical trial application for studying the safety and efficacy of ivermectin for the prevention or treatment of COVID-19. However, Health Canada is aware that such clinical trials may be planned or underway internationally.

- Following the clinical trial stage, companies can choose between two different authorization pathways for COVID-19-related drugs and vaccines: existing regulatory pathways outlined in the *Food and Drug Regulations* or the Interim Order pathway for COVID-19-related drugs and vaccines, which was signed by the Minister of Health and came into effect on September 16, 2020: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs/note.html

- This interim order facilitates timely access for Canadians to drugs and vaccines that have demonstrated the ability to diagnose, prevent, treat or cure COVID-19. It introduces temporary regulations to expedite the authorization for importing, selling and advertising COVID-19-related drugs without compromising patient safety.

- Health Canada's position on ivermectin is aligned with that of other regulators. Ivermectin has not been approved by the FDA or the EMA for the prevention or treatment of COVID-19.

MECS# 21-103194-488

MINISTER'S OFFICE REQUEST

REQUEST:

Minister's Office received a request from MP Schiefke's Office, on behalf of a constituent, regarding the use of Ivermectin for patients with Covid-19.

***RESPONSE* (CAN BE SHARED WITH THE MP's OFFICE)**

- Health Canada is closely tracking all potential therapeutic treatments, vaccines, diagnostic tests, medical devices, and disinfectants currently available and in development in Canada and abroad. Every day, we are adding to our knowledge of COVID-19, keeping pace with the rapid growth of new scientific evidence as it emerges.

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECTOL has been marketed in Canada since 2018.

- 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.

- 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. Heath 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 (this is referred to as "off-label use"), based on other sources of information such as medical literature. Off-label use falls under the practice of medicine and is regulated at the provincial and territorial level.

- For drugs that have potential to be helpful in treating COVID-19, Health Canada encourages drug manufacturers to conduct clinical trials. This would provide an opportunity for the healthcare community to collect information on the effectiveness of the treatment and its associated risks. Evidence from well-designed studies is needed to determine whether ivermectin 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. 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.

- 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.

MECS# 21-108169 - 651

MINISTER'S OFFICE REQUEST

REQUEST:

Minister's Office received a request from MP Schiefke's Office, on behalf of a constituent, regarding the use of Ivermectin for patients with Covid-19.

***RESPONSE* (CAN BE SHARED WITH THE MP's OFFICE)**

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECOTL has been marketed in Canada since 2018.

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

- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Heath 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

- 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.

DM BILAT UPDATES
September 3, 2021

REGULATORY PACKAGES

- **CGI – Supplemented Foods –** On June 26, 2021, the regulatory proposal was published in *Canada Gazette*, Part I for a 60-day consultation (ending August 25, 2021). Following written requests from two key trade organizations [redacted], the consultation was extended to 90 days ending September 24, 2021. Stakeholders were notified via *Canada Gazette*, Technical Barriers to Trade (TBT) notification, Health Canada consultation page, and CSIMS. To date, there have been 23 stakeholder responses/ inquiries from the public, academia, health professionals, industry and international regulatory authorities, and three requests for the CBA report. As approved via the notification process for public activities during the caretaker period, meetings are taking place with [redacted] next week and the following week, respectively, to clarify technical details of our proposal.

  Officials are also working closely with CFIA to support preparations for compliance and enforcement activities related to the new Supplemented Foods regulations. A working level interdepartmental committee has been established to facilitate implementation including guidance for inspectors.

  - Next Steps: [redacted]

- **CGI - Improved Natural Health Products (NHP) Labelling –** On June 26, 2021, the regulatory proposal was published in *Canada Gazette*, Part I for a 70-day consultation (ending September 4, 2021). Following a written request from a key stakeholder [redacted], the consultation was extended to 90 days ending September 24, 2021. Stakeholders were notified via *Canada Gazette*, Technical Barriers to Trade (TBT) notification, Health Canada consultation page, and CSIMS. Three information sessions were held with a broad range of stakeholders following publication of the regulatory proposal, including one session dedicated to consumer and patient safety organizations. As approved via the notification process for public activities during the caretaker period, further stakeholder questions will be addressed through written responses and meetings will be held as needed. Any discussions will be limited to clarifying technical details of the proposal.

  Next Steps:
  - [redacted]
  - [redacted]

- [redacted]**Improving Access to Generics (GiC) + Consequential Amendment to Fees Order (Fees Order) + related amendments to the Patented Medicines (Notice of Compliance) Regulations (led by**

ISED) – [redacted] Regulations. On July 28, HPFB's ADM met with [redacted] to discuss regulatory modernization within the generics space [redacted] also met with ISED in late July. On August 11, HPFB's Chief Regulatory Officer, TPD and ISED, [redacted] TPD and ISED held a follow-up debrief meeting on August 19. [redacted]

FOOD AND NUTRITION

- **PHACtually speaking seminar (Nutrition studies in residential schools)** – HPFB is working with PHAC's Indigenous Relations Team on a PHACtually speaking seminar for October 2021. [redacted] will be invited to make a presentation. He will speak to the nutrition studies that took place in residential schools without appropriate ethical controls. An elder will provide a sharing circle after the session.
    - Next steps:
        - HPFB will invite Indigenous academics, who were involved in the development of the 2019 Canada's food guide, to participate and provide their perspectives on how Indigenous considerations were included in the food guide.
        - HPFB employees will be encouraged to participate.

- **Marketing to Kids (M2K)** – On August 23, the DM and AsDM were briefed on an analysis of the new industry code to restrict advertising to children and proposed next steps which are now reflected in the MTP deck on the Healthy Eating Strategy.
    - Next steps: Pending concurrence on the proposed approach, engage stakeholders in late Fall/Winter 2021 to recognize progress, encourage robust implementation of the code, and signal our intention to scale up monitoring and report on effectiveness.

- **Vitamin D marketing authorization (MA) –** [redacted] The MA will enable manufacturers to voluntarily increase the vitamin D content in cow's milk, goat's milk and margarine by creating an exemption from certain prohibitions in the FDA and FDR. It is important that the increases to vitamin D levels in milks and margarines be aligned with the 2016 nutrition labelling regulations as manufacturers must soon apply a new, higher, vitamin D Daily Value in the Nutrition Facts table. The transition period for the nutrition labelling changes is set to end on December 14, 2021. [redacted] On June 1, the Food Directorate met with [redacted]

[redacted] to inform them of the proposal, which was well received. On July 22, Health Canada posted a formal notice of intent (NOI) and sent a letter to stakeholders via the Department's Consultation and Stakeholder Information Management System to inform them of plans to publish an MA.

  - Next steps: A Memo to seek the Minister's sign-off to publish the MA in *Canada Gazette,* Part II will be sent for DM approval on October 18. The anticipated publication date is November 24, 2021.

- **Plant Breeding Guidance** – Health Canada is updating its guidance to address the latest innovations in plant breeding and improve the transparency, clarity and predictability of the Canadian novel foods regulations. The 60-day consultation closed on May 24, 2021. Approximately 4,700 comments were received. The revised guidance, a supporting science document on the use of gene editing in plant breeding, and a 'What We Heard report' are being developed. Industry stakeholders have indicated that they will issue a public statement at the same time of the release of the final guidance. They are committing to participating in the proposed transparency initiative and as such, notify HC of new food products derived from gene editing proposed for sale in Canada, for publication on our website. Media lines and Qs & As are also being updated.

  - Next steps:
    - [redacted]
    - An update on this project will be provided at the DH-CFS meeting on September 14.
    - Planned stakeholder engagements and a presentation at the P/T Regulatory Agility Subcommittee are being rescheduled for October to respect the caretaker convention.
    - Publication of the guidance, the science document and the 'What We Heard report' is planned for November 18.

- **Codex Committee on Food Labelling** – Canada will be hosting the 46th Session of the Codex Committee on Food Labelling virtually from September 27 to October 7. Opening remarks for the AsDM to provide via a pre-recorded video have been provided to your office. The video will be played at the opening of the plenary session of the Codex Committee on Food Labelling on September 27. The Food Directorate is working with CPAB who will coordinate with DMO to arrange the recording.

- **Committee on Food Safety (CFS)** – The DH CFS meeting will occur on September 14. Documents for that meeting will be sent to DMO by September 10 for inclusion in the invite. The focus of the meeting will be updates from AAFC's Agile Regulations Table, Antimicrobial Resistance, as well as a discussion on the CFS Governance Review recommendations.

DRUGS AND VACCINES

- **Industry guidance for COVID-19 treatment submissions** – HPFB has developed guidance for industry on the minimum evidence requirements for market authorization of COVID-19 treatments under the *Food and Drug Regulations* (FDR). To date, guidance to industry on how to meet evidence requirements for the rolling review of new treatments has only been shared through pre-submission meetings, whereas guidance has been published for vaccines.

- Next Steps: Finalize the Health Canada guidance document and work with CPAB to publish online following the end of the Caretaker period, as you requested through our notification process for public activities
- Continue discussions with Access partners and the EMA on the potential joint statements, with the goal of publishing the statement at the same time as the Health Canada guidance document, following the end of the Caretaker period.

- **Agile Regulations for Licensing Drugs, Phase 1** - HPFB has resumed its work on the regulatory modernization files. In Phase 1 we are proposing to make targeted amendments that focus on immediate needs and will build upon well established policies and practices as well as the recent regulatory agilities successfully implemented through the COVID-19 interim orders.

[redacted] On July 31st, a Notice of Intent (NOI) was published in CGI for a 90-day comment period ending October 28, 2021. Emails were sent to industry stakeholders that included the NOI link and CBA survey. A separate email was also sent to non-industry stakeholders (e.g. health professional and patient groups), and CSIMS was used to reach a broader audience.

Next Steps [redacted]

- **Advanced Therapeutic Products (ATP)** – HPFB is re-focussing its efforts towards implementing the new ATP pathway. HPFB has identified the first two candidates for the pathway: 1) adaptive machine learning-enabled medical devices, and 2) fecal microbiota therapy (FMT). External Reference Groups (ERG) are being established to provide technical guidance on the regulatory requirements for each candidate. The FMT ERG was launched on July 26, 2021, and consists of eight physicians, representatives from CADTH and INESS, and standing members from HPFB and ROEB. As you approved via the notification process for public events during the caretaker period, the first ERG meeting for adaptive machine learning-enabled medical devices is scheduled for September 16, 2021. This ERG consists of 25 experts from organizations [redacted] as well as a number of industry representatives and standing members from HPFB and ROEB.

  - Next Steps: HPFB and ROEB will brief you on ATP progress to date and next steps before launching public consultations in late fall 2021/winter 2022.
  - We anticipate that tailored regulatory pathways for these candidates will be launched in 2022, following internal and external consultations to inform the development of technical requirements.

- **Clinical Trial Modernization** – On May 20, International Clinical Trials Day, Health Canada launched a 45-day consultation on the modernization of the clinical trials regulatory framework for drugs,

natural health products, and medical devices (which closed on July 4, 2021). Modernization of the regulatory framework will focus on providing proportional risk-based oversight, new regulatory agilities over the lifecycle of the trial, greater transparency through registration and public disclosure of results, and a modernized compliance and enforcement regime. Analysis of stakeholder feedback is being finalized, with comments received via webinars/presentations (12), stakeholder engagement sessions (2), responses to the online questionnaire (85), and email (35).

As part of the clinical trial modernization initiative, Health Canada will also introduce regulations to permit clinical trials for foods for a special dietary purpose (FSDP). The regulations will be closely aligned with health products clinical trials. A targeted 45-day consultation was launched on April 28 and a technical webinar held on May 18. The consultation closed on June 12, 2021 and 5 stakeholders submitted comments.

- Next steps: Closed-door, informal consultation with international regulatory counterparts have been ongoing over the summer and will continue into fall 2021. Finalization of the HPFB Clinical Trial Modernization policy document is expected by October 2021, to support development of a *Canada Gazette* I regulatory package for fall 2022.

Antimicrobial Resistance (AMR) [redacted]

- Next steps include:

- Advancing the Pan-Canadian Action plan, including re-engaging with provinces and territories to determine the path forward and explore options for addressing key themes, priorities and actions outlined in the Action Plan;
- On-going work on strategies to support innovation and improve access to novel therapeutic products, including an October 2021 Best Brains Exchange (with CIHR and PHAC), and a potential report from the Council of Canadian Academies on the role of economic incentives in increasing access;
- The Innovative Solutions Canada (ISC) Challenge for Point-of-care diagnostics to combat AMR is ongoing with two projects continuing to Phase 2. [redacted]
- HPFB leading AMR knowledge exchange through the International Coalition of Medicines Regulatory Authorities (ICMRA) over the fall and is exploring opportunities for future collaboration under the Canada-EU Regulatory Cooperation Forum;
- Continued interdepartmental efforts to reduce the need for using antimicrobials in animals, and explore opportunities to consider AMR in medium-term planning, and develop a medium-term AMR work plan.

- **The Scientific Advisory Committee on Health Products for Women (SAC-HPW) -** met on June 23rd to discuss how SGBA+ is currently applied during drug submission, review and labelling. An overview of the considerations that go into drug reviews and approvals, with an emphasis on how disaggregated data are analysed to produce recommendations specific to sex, age, and ethnic groups was provided. HPFB's n SGBA+ Action Plan was introduced to solicit feedback on its scope and priorities. The majority of the committee's June recommendations may be addressed through implementation of the SGBA+ Action Plan. Members noted that they are feeling heard, and appreciated seeing their recommendations translated into concrete deliverables.

The draft guidance of Clinical Evidence Requirements for Medical Devices was sent to the committee's core members to seek their initial input prior to posting the guidance for public consultations. This document provides guidance to manufacturers of Class III and IV medical devices on when clinical data/evidence is required, methods to assemble acceptable clinical data, and how to compare devices appropriately and clarifies how SGBA+ considerations can be applied throughout the lifecycle of medical devices. Feedback from the SAC-HPW members was positive and they provided some recommendations related to SGBA+ considerations.

- Next steps: The next committee meeting will be October 27, 2021.
- The guidance on Clinical Evidence Requirements for Medical Devices will be published at the end of the caretaker period.

- **Veterinary health products (VHPs) pilot –** VHPs are low-risk products used to maintain or promote the health and wellness of animals. As a pilot project, HC and the CFIA will be allowing livestock feeds to include VHPs for the first time. VDD has recently notified manufacturers of 12 VHPs that they are included in the pilot project. The CFIA has updated its related "VHP in Feed Compendium", and food producers can now use the 12 pilot VHPs in livestock feed.
  - Next steps:

  -VDD and CFIA will conduct an internal "lessons learned" exercise on the development of the pilot, and monitor the use of the approved VHPs in feed to understand the uptake of products and inform future policy work.

  -In late fall, HPFB will also work with the Animal Nutrition Association of Canada, industry and other stakeholders to gather feedback on the pilot.

Ivermectin -- There have been concerning reports of the use of veterinary ivermectin to prevent or treat COVID-19. In addition, Ivermectin is being advertised as a treatment/prevention for COVID-19 on a billboard in Manitoba. On August 31, HC issued a Public Advisory (PA) to advise Canadians that Ivermectin has not been authorized to treat/prevent COVID-19. A targeted email was sent to key vet health professional organizations/partners to make them aware and solicit their assistance in maximizing the outreach. CFIA was also informed and asked to distribute the PA to their stakeholders.

HPFB-MHPD is monitoring this issue, including working with Canadian Poison Control Centres to inform additional measures as required. An outreach plan to maximize HC's message has been developed and is being implemented with CPAB, ROEB and CFIA.

NATURAL AND NON-PRESCRIPTION HEALTH PRODUCTS

Return to standard timelines for disinfectants – As there is now sufficient supply of these products to meet the needs of Canadians, NNHPD will return to normal performance standards for disinfectant drugs on October 1, 2021. Submissions received prior to this date will continue to be prioritized as per the expedited timelines and as operationally feasible. Normal performance standards will apply to any new submissions received on or after October 1, 2021. This update was communicated in a notice to key stakeholder associations on August 12, and in the update of relevant webpages.

MEDICAL DEVICES

Artificial Intelligence/Machine Learning (AI/ML) - HPFB is drafting a joint statement with the US FDA and UK MHRA on essential principles of Good Machine Learning Practices. This Notice is intended to increase awareness of key concepts, drive engagement, and identify areas for further advancement in this field. After the caretaker period has ended, it will be posted on each regulator's website.

CANNABIS

Science Advisory Committee on Health Products Containing Cannabis (SAC-HPCC) – The Committee is scheduled to meet on September 2, 2021 and will focus on considerations related to the efficacy of CBD. The Australian Therapeutic Goods Administration will participate in the meeting and present on recent work on CBD. An external writer has been hired to support the Committee and the Secretariat in drafting the reports. The writer will observe upcoming meetings to ensure the reports reflect Committee deliberations.

The next Sub-Committee on Animal Health was previously scheduled for September 30th, but is now being rescheduled to accommodate the federal holiday for the National Day for Truth and Reconciliation. The meeting will focus on considerations for food-producing animals, and the Canadian Food Inspection Agency will provide a presentation.

- Next steps:
    - Updates to the Committee's webpage to reflect the latest records of proceeding, including for recent meetings regarding the Committee membership and COI policies will be made following the end of the caretaker period. DMO and MO will be notified in advance of posting. Media lines have been developed proactively.
    - Draft final report on CBD – November 2021 (TBC)
    - Publication of final CBD report – February 2022 (TBC)

INTERNATIONAL

- **Access Consortium Statement on Next Generation of COVID-19 Vaccines** – Access partners have agreed on the need for a Statement on the minimal requirements for authorization of next generation COVID-19 vaccines (immunobridging), aligned with the US FDA, EMA and the WHO. A draft Statement has been endorsed by Access partners at the working level.

    - Next Steps: Seek approval of the Statement by Access heads of agency. HPFB will seek your approval prior to publishing the Statement. Publication is targeted for the week of September 13.

- **Virtual Consultation on guidelines in development: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)** – As you approved via the notification process for public events during the caretaker period, this biannual event led by Health Canada and the U.S. FDA will take place on October 8, 2021. The technical meeting provides stakeholders with an update on the ICH guidelines under development and solicits stakeholder comments in preparation for the ICH General Assembly Meeting (November 9, 15 and 16, 2021).

MEDIUM TERM PLANNING

- **HPFB Policy Advice Decks –** HPFB is advancing 4 decks to be used for the purposes of early briefings to the incoming Minister:
    - Regulatory Innovation for Health Products: The latest, ADM-approved deck was shared as part of the DM's weekend binder on August 27. This deck was not condensed based on the revised length guidelines given the range of activities covered (the deck can be considered several mini decks in one). As of September 1, HPFB is awaiting feedback from the DM on this product.
    - Regulatory Innovation for Food / Food Safety: The deck will be submitted to SPB/DMO by the requested September 2nd deadline. This deck will not meet revised length guidelines given the range of activities covered.
    - Healthy Eating Strategy: Following DM review of a draft during the weekend of August 28-29, a condensed deck will be shared with SPB/DMO by the requested September 2nd deadline.
    - Low-Risk Health Products: The deck will be shared with SPB/DMO by the requested September 2nd deadline.

- **HPFB Overview Deck –** As of September 1, the deck is being revised based on DM feedback to include more focus on an overview of the Branch as well as on what and how we regulate. Deck will be delivered during week of September 7, per SPB request.

- **Policy Advice Decks from Other Branches –** HPFB has been engaged on a number of other products, notably, One Health, AMR, cannabis, CMP & CEPA renewal, alcohol, overall regulatory modernization, digital health, PMPRB reform, climate change, pharmacare, and rare diseases.

HPFB CORPORATE ACTIVITIES & HUMAN RESOURCES

Nil

FINANCE

- **COVID-19 Funding –** On August 26, CFOB submitted HPFB and ROEB's joint funding request to you for regulatory activities directly related to COVID-19 for fiscal year 2022-23.

INFORMATION TECHNOLOGY

- NIL

DOCKET #: 21-005071 - 222

Subject: Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Date of Correspondence: April 26, 2021

The Therapeutic Products Directorate suggests the following for Branch Input to the above-mentioned correspondence.

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECOTL has been marketed in Canada since 2018.

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

- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Heath 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

- 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: Mineau, Philippe (HC/SC)
To: Soo, Evelyn (HC/SC)
Cc: Peate, Jaspyn (HC/SC)
Subject: FW: For Review: Health Portfolio Hot Issues | POUR ACTION: Enjeux importants du portefeuille de la santé
Date: 2021-08-30 1:37:48 PM

Hey Evelyn,

This is sort of interesting, it's the list of issues to support the new incoming Minister's first 3 to 5 days in office.

There are no TPD items in here, and I don't think we'd have anything to add, the only thing that comes to mind is related to this ivermectin business, something like "misleading and false information related to unapproved COVID-19 therapies"... But not sure it really warrants a note to the Minister?

P

From: Alwani, Kiran (HC/SC) <kiran.alwani@hc-sc.gc.ca>
Sent: 2021-08-30 1:07 PM
To: Beregszaszy, Rita (HC/SC) <rita.beregszaszy@hc-sc.gc.ca>; Gillham-Eisen, Liz Anne (HC/SC) <liz.anne.gillham-eisen@hc-sc.gc.ca>; David, Saira (HC/SC) <saira.david@hc-sc.gc.ca>; Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>; Dion, Catherine (HC/SC) <catherine.dion@hc-sc.gc.ca>; Anoop, Poovadan (HC/SC) <poovadan.anoop@hc-sc.gc.ca>; Vu, Thanh (HC/SC) <thanh.vu@hc-sc.gc.ca>; Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Poulin, Manon L (HC/SC) <manon.l.poulin@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; HC.F MDD Issues / DIM Enjeux F.SC <hc.mddissues-dimenjeux.sc@hc-sc.gc.ca>; McGrath, Eva (HC/SC) <eva.mcgrath@hc-sc.gc.ca>; NNHPD DGO Corr / BDG DPSNSO (HC/SC) <nnhpd.dgo.corr-bdg.dpsnso@hc-sc.gc.ca>; Fougere, Derek (HC/SC) <derek.fougere@hc-sc.gc.ca>; McGuire, Meghan (HC/SC) <meghan.mcguire@hc-sc.gc.ca>; Food_DGO_Issues / Aliment_BDG_Enjeux (HC/SC) <food_dgo_issuesaliment_bdg_enjeux.sc@hc-sc.gc.ca>; Campsall, Danielle (HC/SC) <danielle.campsall@hc-sc.gc.ca>; Bell, Emily (HC/SC) <emily.bell@hc-sc.gc.ca>; Davis, Meggan (HC/SC) <meggan.davis@hc-sc.gc.ca>; Sunquist, Sean (HC/SC) <sean.sunquist@hc-sc.gc.ca>; Hebert, Sybil (HC/SC) <sybil.hebert@hc-sc.gc.ca>; Dion, Catherine (HC/SC) <catherine.dion@hc-sc.gc.ca>; Bruce, Andrea (HC/SC) <andrea.bruce@hc-sc.gc.ca>; Yousufzhai, Maham (HC/SC) <maham.yousufzhai@hc-sc.gc.ca>
Cc: Kirjan, Christine (HC/SC) <christine.kirjan@hc-sc.gc.ca>; Zaman, Muhammad (HC/SC) <muhammad.zaman@hc-sc.gc.ca>
Subject: For Review: Health Portfolio Hot Issues | POUR ACTION: Enjeux importants du portefeuille de la santé

Hello everyone,

CPAB is working to prepare high-level speaking points on Health Portfolio hot issues to support the incoming Minister's first three to five days in office. These notes will be provided to the new Minister

in the Pocketbook that will be presented to them by the Deputy at swearing-in. As the first step, they have prepared the attached list of issues to be included. Please review and share your DG-approved input with me **by 10 am on Wednesday, September 1**.

Thanks so much,
Kiran

From: Julien, Julie (HC/SC) <julie.julien@hc-sc.gc.ca> **On Behalf Of** Aung-Thin, Pamela (HC/SC)
Sent: 2021-08-30 11:55 AM
To: De Sousa, Edward (HC/SC) <edward.desousa@hc-sc.gc.ca>; Weber, KendalL (HC/SC) <kendal.weber@hc-sc.gc.ca>; Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>; Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>; Sabourin, Pierre (HC/SC) <pierre.sabourin@hc-sc.gc.ca>; Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>; Chan, Isabella (HC/SC) <isabella.chan@hc-sc.gc.ca>; Bogden, Jacqueline (HC/SC) <jacqueline.bogden@hc-sc.gc.ca>; Nix, Shannon (HC/SC) <shannon.nix@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Brander, Peter (HC/SC) <peter.brander@hc-sc.gc.ca>; Nasrallah, Michel (HC/SC) <michel.nasrallah@hc-sc.gc.ca>; Jeffrey, Heather (HC/SC) <heather.jeffrey@hc-sc.gc.ca>; Srivastava, Raman (HC/SC) <raman.srivastava@hc-sc.gc.ca>; MacDonald, Cameron (HC/SC) <cameron.macdonald@hc-sc.gc.ca>; Hum, Ryan (HC/SC) <ryan.hum@hc-sc.gc.ca>; Johnstone, Christopher (HC/SC) <christopher.johnstone@hc-sc.gc.ca>; Aubertin-Giguere, Sebastien (HC/SC) <sebastien.aubertin-giguere@hc-sc.gc.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@phac-aspc.gc.ca>; Poliquin, Guillaume (PHAC/ASPC) <guillaume.poliquin@phac-aspc.gc.ca>; Kropp, Rhonda (PHAC/ASPC) <rhonda.kropp@phac-aspc.gc.ca>; Levesque, Kaili (PHAC/ASPC) <kaili.levesque@hc-sc.gc.ca>; Gagnon, Luc (PHAC/ASPC) <luc.gagnon@phac-aspc.gc.ca>; Diogo, Brigitte (PHAC/ASPC) <brigitte.diogo@phac-aspc.gc.ca>; Lutfallah, Jennifer (PHAC/ASPC) <jennifer.lutfallah@phac-aspc.gc.ca>; Evans, Cindy (PHAC/ASPC) <cindy.evans@phac-aspc.gc.ca>; St-Aubin, Candice (PHAC/ASPC) <candice.st-aubin@phac-aspc.gc.ca>; Romano, Anna (PHAC/ASPC) <anna.romano@phac-aspc.gc.ca>; Krumins, Martin (PHAC/ASPC) <martin.krumins@phac-aspc.gc.ca>; Borys, Shelley (PHAC/ASPC) <shelley.borys@phac-aspc.gc.ca>; Pearson, Michael (PHAC/ASPC) <michael.pearson@phac-aspc.gc.ca>; Beresford-Green, Debbie (HC/SC) <debbie.beresford-green@hc-sc.gc.ca>
Cc: ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; Kenney, Katie (HC/SC) <katie.kenney@hc-sc.gc.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>
Subject: FOR ACTION: Health Portfolio Hot Issues | POUR ACTION: Enjeux importants du portefeuille de la santé

Colleagues,
As we advance all aspects of transition planning, CPAB has kicked off its effort to provide the incoming Minister with high-level speaking points on Health Portfolio hot issues to support the first three to five days in office. These notes will be provided to

the new Minister in the Pocketbook that will be presented to him/her by the Deputy at swearing-in.
As a first step, we are working on a short list of hot issues that is consistent with the First 100 Days material and cross-checked with ongoing media scans and media interest. We will continue to refine this list in the weeks ahead to eventually land on the top 10 hot issues and associated messages that will be included in the Pocketbook.
We will be preparing speaking points for all issues on this list, and in the 1-2 weeks between the election and swearing-in, will update the lines [redacted]

As a first step, **I'm asking that you please take a look at the list of issues attached and let me know by COB Wednesday, September 1 if there is anything missing from your point of view.** Responses can be sent to Katie Kenney at katie.kenney@hc-sc.gc.ca, with a copy to my office (admocpab-bsmadgcap@hc-sc.gc.ca).
This updated list will then be shared by the end of next week with the DM for review, along with some initial key messages as a sample of the Pocketbook content.
I will keep you updated as we proceed and of course, you will have the opportunity to review and approve the speaking points for your respective files once we land our final list of issues.
Many thanks for your assistance and collaboration.

Pam

Collègues,

Alors que nous travaillons sur tous les aspects de la planification de la transition, la DGCAP a débuté le travail afin de fournir au prochain ministre des points de discussion génériques sur les enjeux importants du portefeuille de la santé pour soutenir les trois à cinq premiers jours de son mandat. Ces notes seront remises au nouveau ministre dans un livre de poche qui lui sera présenté par le Député lors de la cérémonie d'assermentation.

Tout d'abord, nous avons dressé une courte liste d'enjeux importants qui sont en ligne non seulement avec le matériel développé pour les 100 premiers jours, mais qui a été également vérifiée à la lumière des analyses des médias et de l'intérêt général des médias. Nous continuerons d'ajuster cette liste dans les semaines à venir pour éventuellement choisir les 10 principaux enjeux et messages associés qui seront inclus dans le livre de poche.

Nous préparerons des points de discussion pour tous les enjeux de cette liste et, dans les 1-2 semaines entre les élections et la cérémonie d'assermentation, nous allons mettre à jour les lignes [redacted]

Dans un premier temps, **je vous demande de bien vouloir examiner la liste des enjeux ci-jointe et faites-moi savoir avant la fin de la journée du mercredi 1er septembre s'il manque quelque chose de votre point de vue. Les réponses peuvent être envoyées à Katie Kenney à katie.kenney@hc-sc.gc.ca, avec une copie à mon bureau (admocpab-bsmadgcap@hc-sc.gc.ca).**

Cette liste mise à jour sera ensuite partagée d'ici la fin de la semaine prochaine avec le SM pour révision, ainsi que certains messages clés préliminaires à titre d'exemple du contenu du livre de poche.

Je vous tiendrai informé des développements et bien entendu, vous aurez la possibilité de réviser et d'approuver les points de discussion pour vos dossiers respectifs une fois que nous aurons une liste finale des enjeux.

Un grand merci d'avance pour votre aide et collaboration.

Pam

Pam Aung Thin
Assistant Deputy Minister/Sous-Ministre Adjointe (acting/par interim)
Communications and Public Affairs / communications et affaires publiques
Health Canada/Santé Canada
Mobile: 613-878-3379
Pamela.aung-thin@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. STROMECOTL has been marketed in Canada since 2018.

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

- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Heath Canada has no jurisdiction over how health care professionals prescribe drugs once they are approved.

- Healthcare practitioners may prescribe drugs, including ivermectin, outside of their authorized indications (off-label use), based on other sources of information such as medical literature. Off-label use falls under the practice of medicine and is regulated at the provincial and territorial level.

- However, at this time, no ivermectin manufacturer has made an application for this drug to be approved for the treatment or prevention of COVID-19. Therefore, the effectiveness of ivermectin as a therapeutic option for COVID-19 has not been evaluated by Health Canada.

- For drugs that have potential to be helpful in treating COVID-19, Health Canada encourages drug manufacturers to conduct clinical trials. This would provide an opportunity for the healthcare community to collect information on the effectiveness of the treatment and its associated risks. Evidence from well-designed studies is needed to determine whether ivermectin might be helpful in preventing or treating COVID-19.

- A list of all clinical trials approved for the prevention or treatment of COVID-19 can be found on Health Canada's website: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-clinical-trials/list-authorized-

trials.html

- In Canada, clinical trials for COVID-19 are facilitated under an Interim Order, which was signed by the Minister of Health on May 23, 2020: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/notice-interim-order.html

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

- To date, Health Canada has not received any clinical trial application for studying the safety and efficacy of ivermectin for the prevention or treatment of COVID-19. However, Health Canada is aware that such clinical trials may be planned or underway internationally.

- Following the clinical trial stage, companies can choose between two different authorization pathways for COVID-19-related drugs and vaccines: existing regulatory pathways outlined in the *Food and Drug Regulations* or the Interim Order pathway for COVID-19-related drugs and vaccines, which was signed by the Minister of Health and came into effect on September 16, 2020: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs/note.html

- This interim order facilitates timely access for Canadians to drugs and vaccines that have demonstrated the ability to diagnose, prevent, treat or cure COVID-19. It introduces temporary regulations to expedite the authorization for importing, selling and advertising COVID-19-related drugs without compromising patient safety.

- Health Canada's position on ivermectin is aligned with that of other regulators. Ivermectin has not been approved by the U.S. Food and Drug Administration or the European Medicines Agency for the prevention or treatment of COVID-19.

From: Soo, Evelyn (HC/SC)
To: Mineau, Philippe (HC/SC)
Cc: Peate, Jaspyn (HC/SC)
Subject: RE: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19
Date: 2021-08-30 12:47:15 PM

From: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Sent: 2021-08-30 12:24 PM
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
Importance: High

Hey there Evelyn,
For your urgent approval, please see the edits I am proposing to this PA on ivermectin, in tracked changes – just to highlight clinical trial as the appropriate route to access, and that HC would review a submission should one come in,
Let me know what you think,
P

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Sent: 2021-08-30 12:03 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Cc: Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; MacKay, Ian (HC/SC) <ian.mackay@hc-sc.gc.ca>; Chang, Vivian (HC/SC) <vivian.chang@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>; Legare, Carole (HC/SC) <carole.legare@hc-sc.gc.ca>; Keene, Daniel (HC/SC) <daniel.keene@hc-sc.gc.ca>
Subject: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19
Importance: High

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

From: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Sent: 2021-08-30 11:58 AM
To: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-

sc.gc.ca>
Cc: Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; MacKay, Ian (HC/SC) <ian.mackay@hc-sc.gc.ca>; Chang, Vivian (HC/SC) <vivian.chang@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>; Legare, Carole (HC/SC) <carole.legare@hc-sc.gc.ca>; Keene, Daniel (HC/SC) <daniel.keene@hc-sc.gc.ca>
Subject: RE: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

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

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

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

Thank you!
P

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

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Sent: 2021-08-30 11:35 AM
To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>
Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Hi Aldege,

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

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

Will wait for TPD to chime in.

Thanks!

Mimi

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Sent: 2021-08-30 11:25 AM
To: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-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 Enforment Branch
Health Canada / Government of Canada
Mimi.Lin@hc-sc.gc.ca / Tel: (343)573-2580

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

From: Lin, Mimi (HC/SC)
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
Date: 2021-08-30 2:47:04 PM
Attachments: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200 (002)_TPDDGO (002)_HPCRM approved.docx

---

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-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, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>
Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: Issue IU - Do not use ivermectin for treatment of COVID-19

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

---

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

Good morning Aldege,

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

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

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

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

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

Please advise,

Mimi

Mimi Lin
(she/elle)

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

Conseillère principale ministériel de conformité et d'application de la loi,
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Santé Canada / Gouvernement du Canada
Mimi.Lin@hc-sc.gc.ca / Tél: (343)573-2580

From: Renart-McGowan, Isabel (HC/SC)
To: Sharma, Supriya (HC/SC)
Subject: FW: NOTE FROM TPD: For review/ADM approval: 21-007306-134 - MIN CORR - Potential effectiveness of ivermectin for the treatment of COVID-19 patients
Date: 2021-07-09 4:24:00 PM
Attachments: 21-007306-134 - HPFB Input.docx
Approval Slip - 21-007306-134.pdf
21-007306-134.pdf

Hello Supriya,

We got the ivermectin response back. TPD has added in a bullet referring to the meta-analysis, in addition to the one referenced in the original letter. They did not include the structure you were looking for (as per my email) but I believe they were trying to balance it with the article referring to in the original letter. Please let me know what you think.

Thanks,
Isabel

From: Racine, Natalie (HC/SC) <natalie.racine@canada.ca> **On Behalf Of** HPFB Briefing / Informations DGPSA (HC/SC)
Sent: 2021-07-09 12:05 PM
To: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>; HPFB Briefing / Informations DGPSA (HC/SC) <hc.hpfb.briefing-informations.dgpsa.sc@canada.ca>
Cc: Zimmermann, Margaret (HC/SC) <margaret.zimmermann@canada.ca>
Subject: RE: NOTE FROM TPD: For review/ADM approval: 21-007306-134 - MIN CORR - Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Hi Isabel,

See revised version of the response.
I have reattached the incoming for ease of reference.

Thx,
Nat

From: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Sent: 2021-07-05 12:27 PM
To: HPFB Briefing / Informations DGPSA (HC/SC) <hc.hpfb.briefing-informations.dgpsa.sc@canada.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@canada.ca>
Subject: RE: NOTE FROM TPD: For review/ADM approval: 21-007306-134 - MIN CORR - Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Hello Natalie,

I discussed this with Supriya. She would still like the meta-analysis referenced briefly. The bullets could look like this:

- Today we do not have sufficient information to support…
- A recent meta-analysis has demonstrated similar findings…
- PHAC is currently doing a more in-depth review…
- We will continue to evaluate the situation as more information becomes available…

Would you please send this back down to TPD. I'll give Phil a heads up.

Cheers,
Isabel

From: Racine, Natalie (HC/SC) <natalie.racine@canada.ca> **On Behalf Of** HPFB Briefing / Informations DGPSA (HC/SC)
Sent: 2021-07-02 1:55 PM
To: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>; HPFB Briefing / Informations DGPSA (HC/SC) <hc.hpfb.briefing-informations.dgpsa.sc@canada.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@canada.ca>
Subject: NOTE FROM TPD: For review/ADM approval: 21-007306-134 - MIN CORR - Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Isabel/Clarke,

I just received this note from TPD:
TPD should not be referencing a specific literature article in the response – literature review is not the role of the regulator, PHAC is undertaking an extensive literature review on this topic. Furthermore, there are several academic articles on this topic, not just this one, and referencing just one would open us up to perceived cherry-picking and selection bias. Enquiries related to literature review on this topic should go to the Emerging Evidence group at PHAC".

Please advise on next steps. I have reattached the draft response and incoming for ease of reference.

Thx
Nat

From: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Sent: 2021-06-29 3:34 PM
To: HPFB Briefing / Informations DGPSA (HC/SC) <hc.hpfb.briefing-informations.dgpsa.sc@canada.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@canada.ca>
Subject: SENT FOR REVISION: For review/ADM approval: 21-007306-134 - MIN CORR - Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Hello Sylvie,

Would you please send this one back with the following request:

Please reference the meta-analysis on Ivermectin released yesterday in the response: https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab591/6310839

Thanks!

From: Desjardins2, Sylvie (HC/SC) <sylvie.desjardins2@canada.ca> **On Behalf Of** HPFB Briefing / Informations DGPSA (HC/SC)
Sent: 2021-06-29 2:08 PM
To: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Cc: HPFB Briefing / Informations DGPSA (HC/SC) <hc.hpfb.briefing-informations.dgpsa.sc@canada.ca>
Subject: For review/ADM approval: 21-007306-134 - MIN CORR - Potential effectiveness of ivermectin for the treatment of COVID-19 patients

FOR REVIEW/ADM APPROVAL

MECS#: 21-007306-134 **Date Received in ADMO:** June 29, 2021

Type of Document: : MIN Corr – Branch Input - MP **Requested by:** ECD **Date:** June 24, 2021 **Prepared by:** TPD **Subject:** : Potential effectiveness of ivermectin for the treatment of COVID-19 patients **Due Dates** **ADMO:** **MBU/ECD:** **Action Required:**	**Comments:** **Special Instructions / Instructions spéciales:** Link for Journal https://journals.lww.com/americantherapeutics/Abstract/9000/Ivermectin_for_Prevention_and_Treatment_of.98040.aspx As per PHAC (This issue is not within PHAC's purview. Please redirected)/ Back to HPFB again - Please audit trail input & approval slip to ECDCST-CST when done. Thanks ** pls note link to journal in Special Instructions** *This section to be used by Correspondence Unit for Compliance Report.* o On time o Overdue by _____ Days Reasons for delays: Delays within ADMO:

Please sign the approval sheet. ********** Has been reviewed by Editor/Writer - **Date** YES or NO (pls circle) Antidote - French Review RDIMS# N/A Has been reviewed by **Issues Mgmt/Advisor**: YES or NO (please circle) - **Date** Flag to Advisor Once Signed (EA to inform Advisor as docket is returned to HPFB-Briefing to finalize) **Advisor & Correspondence Unit** Comments (if any): *please add a date after your comments	

Sylvie Desjardins
Correspondence Officer / Agente à la correspondance
HPFB-Briefing / Informations-DGPSA
Assistant Deputy Minister's Office / Bureau du sous-ministre adjoint
Health Products and Food Branch / Direction générale des produits de santé et des aliments
(613) 769-0861

From: Renart-McGowan, Isabel (HC/SC)
To: Mineau, Philippe (HC/SC)
Subject: FW: NOTE FROM TPD: For review/ADM approval: 21-007306-134 - MIN CORR - Potential effectiveness of ivermectin for the treatment of COVID-19 patients
Date: 2021-07-05 12:28:00 PM

Morning,

Chatted with Supriya. She would like this to still be mentioned. See my email to briefing below. She knows that PHAC is doing a more in-depth review but still wants the meta-analysis mentioned.

Thanks,
I

From: Renart-McGowan, Isabel (HC/SC)
Sent: 2021-07-05 12:27 PM
To: HPFB Briefing / Informations DGPSA (HC/SC) <hc.hpfb.briefing-informations.dgpsa.sc@canada.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@canada.ca>
Subject: RE: NOTE FROM TPD: For review/ADM approval: 21-007306-134 - MIN CORR - Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Hello Natalie,

I discussed this with Supriya. She would still like the meta-analysis referenced briefly. The bullets could look like this:

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- A recent meta-analysis has demonstrated similar findings...
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- We will continue to evaluate the situation as more information becomes available...

Would you please send this back down to TPD. I'll give Phil a heads up.

Cheers,
Isabel

From: Racine, Natalie (HC/SC) <natalie.racine@canada.ca> **On Behalf Of** HPFB Briefing / Informations DGPSA (HC/SC)
Sent: 2021-07-02 1:55 PM
To: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>; HPFB Briefing / Informations DGPSA (HC/SC) <hc.hpfb.briefing-informations.dgpsa.sc@canada.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@canada.ca>
Subject: NOTE FROM TPD: For review/ADM approval: 21-007306-134 - MIN CORR - Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Isabel/Clarke,

I just received this note from TPD:
TPD should not be referencing a specific literature article in the response – literature review is not the role of the regulator, PHAC is undertaking an extensive literature review on this topic. Furthermore, there are several academic articles on this topic, not just this one, and referencing just one would open us up to perceived cherry-picking and selection bias. Enquiries related to literature review on this topic should go to the Emerging Evidence group at PHAC".

Please advise on next steps. I have reattached the draft response and incoming for ease of reference.

Thx
Nat

From: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Sent: 2021-06-29 3:34 PM
To: HPFB Briefing / Informations DGPSA (HC/SC) <hc.hpfb.briefing-informations.dgpsa.sc@canada.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@canada.ca>
Subject: SENT FOR REVISION: For review/ADM approval: 21-007306-134 - MIN CORR - Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Hello Sylvie,

Would you please send this one back with the following request:

Please reference the meta-analysis on Ivermectin released yesterday in the response: https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab591/6310839

Thanks!

From: Desjardins2, Sylvie (HC/SC) <sylvie.desjardins2@canada.ca> **On Behalf Of** HPFB Briefing / Informations DGPSA (HC/SC)
Sent: 2021-06-29 2:08 PM
To: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Cc: HPFB Briefing / Informations DGPSA (HC/SC) <hc.hpfb.briefing-informations.dgpsa.sc@canada.ca>
Subject: For review/ADM approval: 21-007306-134 - MIN CORR - Potential effectiveness of ivermectin for the treatment of COVID-19 patients

FOR REVIEW/ADM APPROVAL

MECS#: 21-007306-134 **Date Received in ADMO:** June 29, 2021

Type of Document: : MIN Corr – Branch Input - MP **Requested by:** ECD **Date:** June 24, 2021 **Prepared by:** TPD **Subject:** : Potential effectiveness of ivermectin for the treatment of COVID-19 patients **Due Dates** **ADMO:** **MBU/ECD:** **Action Required:** **Please sign the approval sheet.** ********** Has been reviewed by Editor/Writer - **Date** YES or NO (pls circle) Antidote - French Review RDIMS# N/A Has been reviewed by **Issues Mgmt/Advisor**: YES or NO (please circle) - **Date** Flag to Advisor Once Signed (EA to inform Advisor as docket is returned to HPFB-Briefing to finalize)	**Comments:** **Special Instructions / Instructions spéciales:** Link for Journal https://journals.lww.com/americantherapeutics/Abstract/9000/Ivermectin_for_Prevention_and_Treatment_of.98040.aspx As per PHAC (This issue is not within PHAC's purview. Please redirected)/ Back to HPFB again - Please audit trail input & approval slip to ECDCST-CST when done. Thanks ** pls note link to journal in Special Instructions** *This section to be used by Correspondence Unit for Compliance Report.* o On time o Overdue by _____ Days Reasons for delays: Delays within ADMO:

Advisor & Correspondence Unit Comments (if any): *please add a date after your comments	

Sylvie Desjardins

Correspondence Officer / Agente à la correspondance
HPFB-Briefing / Informations-DGPSA
Assistant Deputy Minister's Office / Bureau du sous-ministre adjoint
Health Products and Food Branch / Direction générale des produits de santé et des aliments
(613) 769-0861

DOCKET #: 21-007306 -134

Subject: Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Date of Correspondence: June 23, 2021

The Therapeutic Products Directorate suggests the following for Branch Input to the above-mentioned correspondence.

- Health Canada is closely monitoring all potential therapeutic treatments and vaccines in development in Canada and abroad.

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECTOL has been marketed in Canada since 2018.

- 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.

- Thank you for forwarding the article from the *American Journal of Therapeutics*, "Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines", which found that there was moderate-certainty evidence that large reductions in COVID-19 deaths are possible using ivermectin.

- A different article,"Ivermectin for the treatment of COVID-19: A systematic review and meta-analysis of randomized controlled trials" published in the journal *Clinical Infectious Diseases*, found that ivermectin did not reduce all-cause mortality, length of stay or viral clearance in randomized clinical trials in COVID-19 patients with mostly mild disease.

- Generally, because many of the Randomized Clinical Trials on ivermectin have been small and thus lack power and precision in the estimates, there is low or very low certainty in the results related to COVID-19 outcomes.

- Health Canada and the Public Health Agency of Canada will continue to evaluate the situation as more information becomes available.

DOCKET #: 21-004640 – 502

Subject: Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Date of Correspondence: April 22, 2021

The Therapeutic Products Directorate suggests the following for Branch Input to the above-mentioned correspondence.

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECOTL has been marketed in Canada since 2018.

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

- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Heath 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

- 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: Mineau, Philippe (HC/SC)
To: Soo, Evelyn (HC/SC)
Cc: Peate, Jaspyn (HC/SC)
Subject: FW: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19
Date: 2021-08-30 12:23:44 PM
Attachments: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200 (002)_TPDDGO.docx
Importance: High

Hey there Evelyn,

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

Let me know what you think,

P

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Sent: 2021-08-30 12:03 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Cc: Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; MacKay, Ian (HC/SC) <ian.mackay@hc-sc.gc.ca>; Chang, Vivian (HC/SC) <vivian.chang@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>; Legare, Carole (HC/SC) <carole.legare@hc-sc.gc.ca>; Keene, Daniel (HC/SC) <daniel.keene@hc-sc.gc.ca>
Subject: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19
Importance: High

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

From: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Sent: 2021-08-30 11:58 AM
To: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>; Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>

Cc: Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; MacKay, Ian (HC/SC) <ian.mackay@hc-sc.gc.ca>; Chang, Vivian (HC/SC) <vivian.chang@hc-sc.gc.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>; Legare, Carole (HC/SC) <carole.legare@hc-sc.gc.ca>; Keene, Daniel (HC/SC) <daniel.keene@hc-sc.gc.ca>
Subject: RE: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Hey there Mimi, hey Aldege,

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

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

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

Thank you!
P

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

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Sent: 2021-08-30 11:35 AM
To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>
Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19

Hi Aldege,

We have no reason to believe consumers have/are purchasing ivermectin for human use to treat COVID-19 as human use products require a prescription. Like the title, the messaging could be to not use any form of ivermectin to treat/prevent COVID-19. The US FDA article

focuses on describing the ingredient general and then advising on how vet use products should not be used on humans.

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

Will wait for TPD to chime in.

Thanks!

Mimi

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Sent: 2021-08-30 11:25 AM
To: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-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 Enforment Branch

Health Canada / Government of Canada

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

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

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

Santé Canada / Gouvernement du Canada

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

From:	Legare, Carole (HC/SC)
To:	Bellefeuille, Aldege (HC/SC); 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); Keene, Daniel (HC/SC)
Subject:	RE: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19
Date:	2021-08-30 12:46:05 PM
Attachments:	ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200 OCT.docx

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

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

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Will wait for TPD to chime in.

Thanks!

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

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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

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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. STROMECOTL has been marketed in Canada since 2018.

- Health Canada is closely monitoring all potential therapeutic treatments and vaccines in development in Canada and abroad, including products such as ivermectin that are being use outside of their authorized indication (off-label use), as potential treatments for COVID-19.
- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Heath 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.

- At this time, no ivermectin manufacturer has made an application for this drug to be approved for the treatment or prevention of COVID-19. Therefore, the effectiveness of ivermectin as a therapeutic option for COVID-19 has not been evaluated by Health Canada.

- For drugs that have potential to be helpful in treating COVID-19, Health Canada encourages drug manufacturers to conduct clinical trials. This would provide an opportunity for the healthcare community to collect information on the effectiveness of the treatment and its associated risks. Evidence from adequately powered well-designed studies is needed to determine whether ivermectin might be helpful in preventing or treating COVID-19.

- A list of all clinical trials approved for the prevention or treatment of COVID-19 can be found on Health Canada's website: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-clinical-trials/list-authorized-trials.html

- In Canada, clinical trials for COVID-19 are facilitated under an Interim Order, which was signed by the Minister of Health on May 23, 2020: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/notice-interim-order.html

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

- To date, Health Canada has not received any clinical trial application for studying the safety and efficacy of ivermectin for the prevention or treatment of COVID-19. However, Health Canada is aware that such clinical trials may be planned or underway internationally.

- Following the clinical trial stage, companies can choose between two different authorization pathways for COVID-19-related drugs and vaccines: existing regulatory pathways outlined in the *Food and Drug Regulations* or the Interim Order pathway for COVID-19-related drugs and vaccines, which was signed by the Minister of Health and came into effect on September 16, 2020: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs/note.html

- This interim order facilitates timely access for Canadians to drugs and vaccines that have demonstrated the ability to diagnose, prevent, treat or cure COVID-19. It introduces temporary regulations to expedite the authorization for importing, selling and advertising COVID-19-related drugs without compromising patient safety.

- Health Canada's position on ivermectin is aligned with that of other regulators. Ivermectin has not been approved by the FDA or the EMA for the prevention or treatment of COVID-19.

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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 - Do not use ivermectin for treatment of COVID-19
Date: 2021-08-30 11:57:54 AM
Attachments: COVID - Ivermectin - Direct Reply.docx

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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,

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Date: 2021-08-30 12:03:31 PM
Attachments: ROEB_PA_Ivermectin and COVID-19_2021-08_30_1200.docx
Importance: High

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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, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>
Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: Issue IU - Do not use ivermectin for treatment of COVID-19

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

---

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

Good morning Aldege,

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

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

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

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

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

Please advise,

Mimi

Mimi Lin

(she/elle)

Senior Corporate Regulatory Compliance & Enforcement Advisor,

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

Health Canada / Government of Canada

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

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

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

Santé Canada / Gouvernement du Canada

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

DOCKET #: 21-010085-916

Subject: Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Date of Correspondence: July 14, 2021

The Therapeutic Products Directorate suggests the following for Branch Input to the above-mentioned correspondence.

- Health Canada is closely monitoring all potential therapeutic treatments and vaccines in development in Canada and abroad.

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECOTL has been marketed in Canada since 2018.

- 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.

- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be marketed, it does not issue treatment recommendations or guidelines. Heath 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.

- 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

- 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: Farah, Jacqueline (HC/SC)
To: Mineau, Philippe (HC/SC)
Subject: RE: 21-001394 - 120 for / pour: Direct Reply/Réponse directe
Date: 2021-02-24 8:25:00 AM
Attachments: image001.gif
image002.gif

I know eh! so annoying

Jacqueline Farah
(she | elle)
Executive Correspondence Officer / Agente de la correspondance exécutive
Director General's Office / Bureau du directeur général
Therapeutic Products Directorate / Direction des produits thérapeutiques
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
jacqueline.farah@canada.ca / Cell.: 343-552-4415

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-02-24 8:20 AM
To: Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>
Subject: RE: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Bahahaha so they actioned it again? I thought the incoming looked familiar... :p

---

From: Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>
Sent: 2021-02-24 8:04 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Omg I went to send this one and was so confused how it was already actioned and realised admo sent this one on Feb 16 and we already responded to this same letter... so I'll ignore this one.. and send it back as fyi

Jacqueline Farah
(she | elle)
Executive Correspondence Officer / Agente de la correspondance exécutive
Director General's Office / Bureau du directeur général
Therapeutic Products Directorate / Direction des produits thérapeutiques
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
jacqueline.farah@canada.ca / Cell.: 343-552-4415

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

Sent: 2021-02-23 4:08 PM
To: Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>
Subject: FW: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Hey jacquie,
This one is approved but use the original you sent me – no changes (Bruce doesn't want to use the Merck info) – I changed the Ydrive version back,
Thank you!
P

From: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Sent: 2021-02-23 3:58 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Hi Philippe,

I would keep the Merck line out for the moment.

Thanks.

B

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-02-23 11:08 AM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Subject: FW: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Hey there Bruce,

For approval another Ivermectin reply,

Of note, I added the paragraph on the MERCK statement issued last week:

The manufacturer of ivermectin in Canada, Merck, has also issued a public statement (available at https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/) on the use of ivermectin during the COVID-19 pandemic, stating that:

"It is important to note that, to-date, [MERCK's] analysis has identified:

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

Let me know what you think,
P

From: Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>
Sent: 2021-02-22 3:13 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Subject: FW: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Hi Phil,

Direct Reply re – Ivermectin.

I attached a draft response

Due ECD March 2

Thanks,

Jacqueline Farah
(she | elle)
Executive Correspondence Officer / Agente de la correspondance exécutive
Director General's Office / Bureau du directeur général
Therapeutic Products Directorate / Direction des produits thérapeutiques
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
jacqueline.farah@canada.ca / Cell.: 343-552-4415

From: Christa Racicot <christa.racicot@hc-sc.gc.ca>
Sent: 2021-02-22 3:05 PM
To: Beattie, Deborah (HC/SC) <deborah.beattie@canada.ca>; Cain, Francoise (HC/SC) <francoise.cain@canada.ca>; Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>; Mattia-Pepin, Isabelle (HC/SC) <isabelle.mattia-pepin@canada.ca>; Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Audit Trail / Suivi de vérification
Ministerial Correspondence / Correspondance ministérielle

Subject / Sujet: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

21-001394 - 120

Send From / Envoyé de	Send To / Envoyé a	Date Sent / Date de l'envoi	Bring Forward / Rappel
HPFB-ADM-ADMO Christa Racicot/HC-SC/GC/CA	**Organization/Organisme** HPFB-TPD-DGO **Person/Personne** Deborah Beattie/HC-SC/GC/CA	2021-02-22	**Due Date/Date d'échéance** 2021-03-02

Special Instructions / Instructions spéciales: Direct Reply Week 6 (2021)
Document Status / Statut du dossier: Closed/Fermé
Action / Intervention: Direct Reply/Réponse directe

Comment / Commentaires:
Scan copy to Final response in MECS and audit trail to ECDCST when done. Thanks

Here is the link to document / Voici le lien au document:

The documents provided to you may contain personal information.
If you have received these documents in error, notify the MECS-USER-SUPPORT group immediately.

Les documents qui vous sont fournis peuvent contenir des renseignements personnels.
Si vous avez reçu ces documents par erreur, avisez immédiatement le groupe courriel des MECS-USER-SUPPORT.

Created By / Créé par: Christa Racicot
Date Created / Créé le: 2021-02-22

DOCKET #: 21-105260-958

Subject: Ivermectin

The following paragraphs are for inclusion in the response to the above-mentioned docket:

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 authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECOTL has been marketed in Canada since 2018.

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

- The manufacturer of ivermectin in Canada, Merck, has also issued a public statement (available at https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/) on the use of ivermectin during the COVID-19 pandemic, stating that:

  "It is important to note that, to-date, [MERCK's] analysis has identified:
  - *No scientific basis for a potential therapeutic effect against COVID-19 from pre-clinical studies;*
  - *No meaningful evidence for clinical activity or clinical efficacy in patients with COVID-19 disease, and;*
  - *A concerning lack of safety data in the majority of studies."*

- 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. Heath 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

- 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: Renart-McGowan, Isabel (HC/SC)
To: Stewart, John Patrick (HC/SC)
Subject: RE: CTs for ivermectin
Date: 2021-01-29 11:07:34 AM

Great, thank you.

From: Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>
Sent: 2021-01-29 11:06 AM
To: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Subject: RE: CTs for ivermectin

Thanks for following up on this Isabel.

No further information need from my perspective.

Thanks again.

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
613-957-6466

From: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Sent: 2021-01-29 11:04 AM
To: Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>; Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Cc: Loo, Wayne (HC/SC) <wayne.loo@canada.ca>; Mattia-Pepin, Isabelle (HC/SC) <isabelle.mattia-pepin@canada.ca>
Subject: FW: CTs for ivermectin

Hello Pat/Bruce,

I confirmed that there are no COVID-related CTs for ivermectin in Canada. We likely have had some bioequivalence studies, as per Carole. If you would like to see that list, let me know. For now, I told her to stand down.

Thanks,
I

From: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Sent: 2021-01-29 10:15 AM
To: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Subject: RE: CTs for ivermectin

Not for COVID. Is that what you were looking for?
I believe we have had some for bioequivalence studies before. I could get the list for you, if you need.

Carole

From: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Sent: 2021-01-29 10:03 AM
To: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Subject: CTs for ivermectin

Morning Carole,

We were wondering if there have been any CTs for ivermectin in Canada. I did a quick search online and couldn't find one. Just wanted to double check with you.

Thanks!
Isabel

DOCKET #: 21-007306 -134

Subject: Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Date of Correspondence: June 23, 2021

The Therapeutic Products Directorate suggests the following for Branch Input to the above-mentioned correspondence.

- Health Canada is closely monitoring all potential therapeutic treatments and vaccines in development in Canada and abroad.

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECOTL has been marketed in Canada since 2018.

- 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.

- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be marketed, it does not issue treatment recommendations or guidelines. Heath 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.

- 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

- 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.

DOCKET #: 21-003888 - 297

Subject: Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Date of Correspondence: January 22, 2021

The Therapeutic Products Directorate suggests the following for Branch Input to the above-mentioned correspondence.

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECOTL has been marketed in Canada since 2018.

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

- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Heath 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

- 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.

DOCKET #: 21-007306-134

Subject: Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Date of Correspondence: June 23, 2021

The Therapeutic Products Directorate suggests the following for Branch Input to the above-mentioned correspondence.

- Health Canada is closely monitoring all potential therapeutic treatments and vaccines in development in Canada and abroad.

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECOTL has been marketed in Canada since 2018.

- 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.

- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be marketed, it does not issue treatment recommendations or guidelines. Heath 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.

- 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

- 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.

DOCKET #: 21-007306 -134

Subject: Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Date of Correspondence: June 23, 2021

The Therapeutic Products Directorate suggests the following for Branch Input to the above-mentioned correspondence.

- Health Canada is closely monitoring all potential therapeutic treatments and vaccines in development in Canada and abroad.

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECOTL has been marketed in Canada since 2018.

- 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.

- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be marketed, it does not issue treatment recommendations or guidelines. Heath 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.

- 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

- 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: Renart-McGowan, Isabel (HC/SC)
To: Legare, Carole (HC/SC)
Subject: RE: CTs for ivermectin
Date: 2021-01-29 10:15:33 AM

No, this is what I needed. Thank you! Happy Friday!

From: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Sent: 2021-01-29 10:15 AM
To: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Subject: RE: CTs for ivermectin

Not for COVID. Is that what you were looking for?
I believe we have had some for bioequivalence studies before. I could get the list for you, if you need.

Carole

From: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Sent: 2021-01-29 10:03 AM
To: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Subject: CTs for ivermectin

Morning Carole,

We were wondering if there have been any CTs for ivermectin in Canada. I did a quick search online and couldn't find one. Just wanted to double check with you.

Thanks!
Isabel

DOCKET #: 21-003889 - 224

Subject: Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Date of Correspondence: December 16, 2020

The Therapeutic Products Directorate suggests the following for Branch Input to the above-mentioned correspondence.

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECOTL has been marketed in Canada since 2018.

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

- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Heath 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

- 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: Stewart, John Patrick (HC/SC)
To: Mineau, Philippe (HC/SC); Peate, Jaspyn (HC/SC); Randall, Bruce (HC/SC); Soo, Evelyn (HC/SC)
Subject: FW: Clippings
Date: 2021-08-30 9:19:16 AM

fyi

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: Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>
Sent: 2021-08-30 9:18 AM
To: Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Sharma, Supriya (HC/SC) <supriya.sharma@hc-sc.gc.ca>; Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>; Robinson2, Kelly (HC/SC) <kelly.robinson2@canada.ca>; Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>
Subject: RE: Clippings

Risk comms are being developed. Kelly, will let you liaise with Linsey Hollett and Cathy Lafkas on this.

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: Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>
Sent: 2021-08-30 9:16 AM
To: Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>; Sharma, Supriya (HC/SC) <supriya.sharma@hc-sc.gc.ca>; Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>; Robinson2, Kelly (HC/SC) <kelly.robinson2@canada.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>
Subject: RE: Clippings

We've responded to many media requests and MP queries on this since, so there should be standard lines. We also normally point to FDA and WHO statements.

From: Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>
Sent: 2021-08-30 8:53 AM
To: Sharma, Supriya (HC/SC) <supriya.sharma@hc-sc.gc.ca>; Stewart, John Patrick (HC/SC)

<john.patrick.stewart@hc-sc.gc.ca>; Robinson2, Kelly (HC/SC) <kelly.robinson2@canada.ca>
Cc: Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>
Subject: FW: Clippings

Pls see below. Do we have ML on this? What about issuing a letter to health professionals? We should discuss our comms approach on this issue at our covid check-in this aft, with cpab.

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: Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>
Sent: 2021-08-30 8:48 AM
To: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>; Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Cc: Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>
Subject: RE: Clippings

Also see below link to Global news video story, which speaks to US FDA communications on this.

https://www.youtube.com/watch?v=3OA3C0eMKFg

Eric Bélair
Associate Assistant Deputy Minister / Sous-ministre adjoint délégué
Strategic Policy Branch / Direction générale de la politique stratégique
Health Canada / Santé Canada
343-552-1733
eric.belair@hc-sc.gc.ca

From: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>
Sent: 2021-08-30 8:46 AM
To: Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>; Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Cc: Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>
Subject: RE: Clippings

Thanks Eric, I missed that one! I am copying Manon, Linsey and Stefania as there may be post market follow up that is in train.
Pam

From: Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>
Sent: 2021-08-30 8:42 AM
To: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>
Cc: Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>
Subject: Clippings

Hi Pam:

Just wanted to make sure you had seen this one:

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

Eric Bélair
Associate Assistant Deputy Minister / Sous-ministre adjoint délégué
Strategic Policy Branch / Direction générale de la politique stratégique
Health Canada / Santé Canada
343-552-1733
eric.belair@hc-sc.gc.ca

DIRECT REPLY:

Dear XX,

Thank you for your letter dated XX, 2021, regarding Ivermectin as a potential treatment for Covid-19 in Canada. [Your correspondence was forwarded to my organization for response.] Apologies for the delay in responding.

Health Canada is closely tracking all potential therapeutic treatments, vaccines, diagnostic tests, medical devices, and disinfectants currently available and in development in Canada and abroad. Every day, we are adding to our knowledge of COVID-19, keeping pace with the rapid growth of new scientific evidence as it emerges.

Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECTOL has been marketed in Canada since 2018.

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.

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. Heath 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 (this is referred to as "off-label use"), based on other sources of information such as medical literature. Off-label use falls under the practice of medicine and is regulated at the provincial and territorial level.

For drugs that have potential to be helpful in treating COVID-19, Health Canada encourages drug manufacturers to conduct clinical trials. This would provide an opportunity for the healthcare community to collect information on the effectiveness of the treatment and its associated risks. Evidence from well-designed studies is needed to determine whether ivermectin 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. 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.

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.

I hope that this information is helpful, and I thank you for writing to share your views.

Sincerely,

HPFB INPUT BULLETS

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 authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECOTL has been marketed in Canada since 2018.

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

- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Heath 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

- 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: Dinakaran, Deborah (HC/SC)
To: MacKay, Ian (HC/SC); Chang, Vivian (HC/SC); Peate, Jaspyn (HC/SC); Legare, Carole (HC/SC); Keene, Daniel (HC/SC)
Cc: Mineau, Philippe (HC/SC); Badenduck, Lucas (HC/SC); BMS ORM Risk / BSM BGR Risque (HC/SC)
Subject: FW: URGENT: For Review - PA - Do not use ivermectin for treatment of COVID-19
Date: 2021-08-30 11:47:36 AM

Good Day to all,

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

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

Thanking you in advance,

Deborah

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Sent: 2021-08-30 11:35 AM
To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>
Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.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-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

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.

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

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

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

---

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

Good morning Aldege,

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

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

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

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

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

Please advise,

Mimi

Mimi Lin

(she/elle)

Senior Corporate Regulatory Compliance & Enforcement Advisor,

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

Health Canada / Government of Canada

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

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

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

Santé Canada / Gouvernement du Canada

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

From: Soo, Evelyn (HC/SC)
To: Mineau, Philippe (HC/SC)
Cc: Peate, Jaspyn (HC/SC)
Subject: RE: URGENT: For Approval - PA - Do not use ivermectin for treatment of COVID-19
Date: 2021-08-30 12:40:53 PM

Hi Phil

Just some minor edits for consideration to clarify the message.

Thanks
Evelyn

From: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Sent: 2021-08-30 12:24 PM
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
Importance: High

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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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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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.

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

There have been multiple media articles indicating consumers may be purchasing ivermectin (veterinary version) to treat COVID-19. Ivermectin, an antiparasitic agent, is not recommended for

prophylaxis or treatment of coronavirus disease 2019 (COVID-19. The idea of using ivermectin to treat COVID-19 seems to have returned and be more apparent in West Coast Canada. In addition, MHPD STARS received multiple advertising complaints on this matter.

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

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

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

Please advise,

Mimi

Mimi Lin
(she/elle)

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

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

From: Mineau, Philippe (HC/SC)
To: Soo, Evelyn (HC/SC)
Cc: Peate, Jaspyn (HC/SC)
Subject: RE: For Review: Health Portfolio Hot Issues | POUR ACTION: Enjeux importants du portefeuille de la santé
Date: 2021-08-30 1:53:21 PM

Ok thanks for confirming!

It would be nice for the media to focus on AMR more though hey? Instead of horse medicine and alkyl nitrite poppers?

P

From: Soo, Evelyn (HC/SC) <evelyn.soo@hc-sc.gc.ca>
Sent: 2021-08-30 1:50 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Cc: Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>
Subject: RE: For Review: Health Portfolio Hot Issues | POUR ACTION: Enjeux importants du portefeuille de la santé

Damn, not hot enough! ☺☺

Yeah I am not sure where they psychedelics are but if it does come up, I think we will be ready!

Very interesting list for sure.
Evelyn

From: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Sent: 2021-08-30 1:46 PM
To: Soo, Evelyn (HC/SC) <evelyn.soo@hc-sc.gc.ca>
Cc: Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>
Subject: RE: For Review: Health Portfolio Hot Issues | POUR ACTION: Enjeux importants du portefeuille de la santé

Though incredibly serious, I'm not sure AMR is "hot" enough for a "first 5 days" note and speaking points? I think we're trying to identify issues that might come up in the media, need very fast response etc. – same with psychedelics?
P

From: Soo, Evelyn (HC/SC) <evelyn.soo@hc-sc.gc.ca>
Sent: 2021-08-30 1:42 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Cc: Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>
Subject: RE: For Review: Health Portfolio Hot Issues | POUR ACTION: Enjeux importants du portefeuille de la santé

Hi Phil

I agree – but wondering if psilocybin is one to be added and/or AMR?

Thanks
Evelyn

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Sent: 2021-08-30 1:38 PM
To: Soo, Evelyn (HC/SC) <evelyn.soo@hc-sc.gc.ca>
Cc: Peate, Jaspyn (HC/SC) <jaspyn.peate@hc-sc.gc.ca>
Subject: FW: For Review: Health Portfolio Hot Issues | POUR ACTION: Enjeux importants du portefeuille de la santé

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From: Alwani, Kiran (HC/SC) <kiran.alwani@hc-sc.gc.ca>
Sent: 2021-08-30 1:07 PM
To: Beregszaszy, Rita (HC/SC) <rita.beregszaszy@hc-sc.gc.ca>; Gillham-Eisen, Liz Anne (HC/SC) <liz.anne.gillham-eisen@hc-sc.gc.ca>; David, Saira (HC/SC) <saira.david@hc-sc.gc.ca>; Rahim, Hamida (HC/SC) <hamida.rahim@hc-sc.gc.ca>; Dion, Catherine (HC/SC) <catherine.dion@hc-sc.gc.ca>; Anoop, Poovadan (HC/SC) <poovadan.anoop@hc-sc.gc.ca>; Vu, Thanh (HC/SC) <thanh.vu@hc-sc.gc.ca>; Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>; Poulin, Manon L (HC/SC) <manon.l.poulin@hc-sc.gc.ca>; HC.F MHPD Action Requests F.SC <mhpd_action_requests@hc-sc.gc.ca>; HC.F MDD Issues / DIM Enjeux F.SC <hc.mddissues-dimenjeux.sc@hc-sc.gc.ca>; McGrath, Eva (HC/SC) <eva.mcgrath@hc-sc.gc.ca>; NNHPD DGO Corr / BDG DPSNSO (HC/SC) <nnhpd.dgo.corr-bdg.dpsnso@hc-sc.gc.ca>; Fougere, Derek (HC/SC) <derek.fougere@hc-sc.gc.ca>; McGuire, Meghan (HC/SC) <meghan.mcguire@hc-sc.gc.ca>; Food_DGO_Issues / Aliment_BDG_Enjeux (HC/SC) <food_dgo_issuesaliment_bdg_enjeux.sc@hc-sc.gc.ca>; Campsall, Danielle (HC/SC) <danielle.campsall@hc-sc.gc.ca>; Bell, Emily (HC/SC) <emily.bell@hc-sc.gc.ca>; Davis, Meggan (HC/SC) <meggan.davis@hc-sc.gc.ca>; Sunquist, Sean (HC/SC) <sean.sunquist@hc-sc.gc.ca>; Hebert, Sybil (HC/SC) <sybil.hebert@hc-sc.gc.ca>; Dion, Catherine (HC/SC) <catherine.dion@hc-sc.gc.ca>; Bruce, Andrea (HC/SC) <andrea.bruce@hc-sc.gc.ca>; Yousufzhai, Maham (HC/SC)

<maham.yousufzhai@hc-sc.gc.ca>
Cc: Kirjan, Christine (HC/SC) <christine.kirjan@hc-sc.gc.ca>; Zaman, Muhammad (HC/SC) <muhammad.zaman@hc-sc.gc.ca>
Subject: For Review: Health Portfolio Hot Issues | POUR ACTION: Enjeux importants du portefeuille de la santé

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Thanks so much,
Kiran

From: Julien, Julie (HC/SC) <julie.julien@hc-sc.gc.ca> **On Behalf Of** Aung-Thin, Pamela (HC/SC)
Sent: 2021-08-30 11:55 AM
To: De Sousa, Edward (HC/SC) <edward.desousa@hc-sc.gc.ca>; Weber, KendalL (HC/SC) <kendal.weber@hc-sc.gc.ca>; Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>; Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>; Sabourin, Pierre (HC/SC) <pierre.sabourin@hc-sc.gc.ca>; Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>; Chan, Isabella (HC/SC) <isabella.chan@hc-sc.gc.ca>; Bogden, Jacqueline (HC/SC) <jacqueline.bogden@hc-sc.gc.ca>; Nix, Shannon (HC/SC) <shannon.nix@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Brander, Peter (HC/SC) <peter.brander@hc-sc.gc.ca>; Nasrallah, Michel (HC/SC) <michel.nasrallah@hc-sc.gc.ca>; Jeffrey, Heather (HC/SC) <heather.jeffrey@hc-sc.gc.ca>; Srivastava, Raman (HC/SC) <raman.srivastava@hc-sc.gc.ca>; MacDonald, Cameron (HC/SC) <cameron.macdonald@hc-sc.gc.ca>; Hum, Ryan (HC/SC) <ryan.hum@hc-sc.gc.ca>; Johnstone, Christopher (HC/SC) <christopher.johnstone@hc-sc.gc.ca>; Aubertin-Giguere, Sebastien (HC/SC) <sebastien.aubertin-giguere@hc-sc.gc.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@phac-aspc.gc.ca>; Poliquin, Guillaume (PHAC/ASPC) <guillaume.poliquin@phac-aspc.gc.ca>; Kropp, Rhonda (PHAC/ASPC) <rhonda.kropp@phac-aspc.gc.ca>; Levesque, Kaili (PHAC/ASPC) <kaili.levesque@hc-sc.gc.ca>; Gagnon, Luc (PHAC/ASPC) <luc.gagnon@phac-aspc.gc.ca>; Diogo, Brigitte (PHAC/ASPC) <brigitte.diogo@phac-aspc.gc.ca>; Lutfallah, Jennifer (PHAC/ASPC) <jennifer.lutfallah@phac-aspc.gc.ca>; Evans, Cindy (PHAC/ASPC) <cindy.evans@phac-aspc.gc.ca>; St-Aubin, Candice (PHAC/ASPC) <candice.st-aubin@phac-aspc.gc.ca>; Romano, Anna (PHAC/ASPC) <anna.romano@phac-aspc.gc.ca>; Krumins, Martin (PHAC/ASPC) <martin.krumins@phac-aspc.gc.ca>; Borys, Shelley (PHAC/ASPC) <shelley.borys@phac-aspc.gc.ca>; Pearson, Michael (PHAC/ASPC) <michael.pearson@phac-aspc.gc.ca>; Beresford-Green, Debbie (HC/SC) <debbie.beresford-green@hc-sc.gc.ca>

Cc: ADMO CPAB / BSMA DGCAP (HC/SC) <admocpab-bsmadgcap@hc-sc.gc.ca>; Kenney, Katie (HC/SC) <katie.kenney@hc-sc.gc.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>
Subject: FOR ACTION: Health Portfolio Hot Issues | POUR ACTION: Enjeux importants du portefeuille de la santé

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Many thanks for your assistance and collaboration.

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Pam Aung Thin
Assistant Deputy Minister/Sous-Ministre Adjointe (acting/par interim)
Communications and Public Affairs / communications et affaires publiques
Health Canada/Santé Canada
Mobile: 613-878-3379
Pamela.aung-thin@hc-sc.gc.ca

From: Soo, Evelyn (HC/SC)
To: Mineau, Philippe (HC/SC)
Cc: Peate, Jaspyn (HC/SC)
Subject: RE: For Review: Health Portfolio Hot Issues | POUR ACTION: Enjeux importants du portefeuille de la santé
Date: 2021-08-30 1:42:02 PM

Hi Phil

I agree – but wondering if psilocybin is one to be added and/or AMR?

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Evelyn

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<danielle.campsall@hc-sc.gc.ca>; Bell, Emily (HC/SC) <emily.bell@hc-sc.gc.ca>; Davis, Meggan (HC/SC) <meggan.davis@hc-sc.gc.ca>; Sunquist, Sean (HC/SC) <sean.sunquist@hc-sc.gc.ca>; Hebert, Sybil (HC/SC) <sybil.hebert@hc-sc.gc.ca>; Dion, Catherine (HC/SC) <catherine.dion@hc-sc.gc.ca>; Bruce, Andrea (HC/SC) <andrea.bruce@hc-sc.gc.ca>; Yousufzhai, Maham (HC/SC) <maham.yousufzhai@hc-sc.gc.ca>
Cc: Kirjan, Christine (HC/SC) <christine.kirjan@hc-sc.gc.ca>; Zaman, Muhammad (HC/SC) <muhammad.zaman@hc-sc.gc.ca>
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To: De Sousa, Edward (HC/SC) <edward.desousa@hc-sc.gc.ca>; Weber, KendalL (HC/SC) <kendal.weber@hc-sc.gc.ca>; Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>; Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>; Sabourin, Pierre (HC/SC) <pierre.sabourin@hc-sc.gc.ca>; Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>; Chan, Isabella (HC/SC) <isabella.chan@hc-sc.gc.ca>; Bogden, Jacqueline (HC/SC) <jacqueline.bogden@hc-sc.gc.ca>; Nix, Shannon (HC/SC) <shannon.nix@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Brander, Peter (HC/SC) <peter.brander@hc-sc.gc.ca>; Nasrallah, Michel (HC/SC) <michel.nasrallah@hc-sc.gc.ca>; Jeffrey, Heather (HC/SC) <heather.jeffrey@hc-sc.gc.ca>; Srivastava, Raman (HC/SC) <raman.srivastava@hc-sc.gc.ca>; MacDonald, Cameron (HC/SC) <cameron.macdonald@hc-sc.gc.ca>; Hum, Ryan (HC/SC) <ryan.hum@hc-sc.gc.ca>; Johnstone, Christopher (HC/SC) <christopher.johnstone@hc-sc.gc.ca>; Aubertin-Giguere, Sebastien (HC/SC) <sebastien.aubertin-giguere@hc-sc.gc.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@phac-aspc.gc.ca>; Poliquin, Guillaume (PHAC/ASPC) <guillaume.poliquin@phac-aspc.gc.ca>; Kropp, Rhonda (PHAC/ASPC) <rhonda.kropp@phac-aspc.gc.ca>; Levesque, Kaili (PHAC/ASPC) <kaili.levesque@hc-sc.gc.ca>; Gagnon, Luc (PHAC/ASPC) <luc.gagnon@phac-aspc.gc.ca>; Diogo, Brigitte (PHAC/ASPC) <brigitte.diogo@phac-aspc.gc.ca>; Lutfallah, Jennifer (PHAC/ASPC) <jennifer.lutfallah@phac-aspc.gc.ca>; Evans, Cindy (PHAC/ASPC) <cindy.evans@phac-aspc.gc.ca>; St-Aubin, Candice (PHAC/ASPC) <candice.st-aubin@phac-aspc.gc.ca>; Romano, Anna (PHAC/ASPC) <anna.romano@phac-

aspc.gc.ca>; Krumins, Martin (PHAC/ASPC) <martin.krumins@phac-aspc.gc.ca>; Borys, Shelley (PHAC/ASPC) <shelley.borys@phac-aspc.gc.ca>; Pearson, Michael (PHAC/ASPC) <michael.pearson@phac-aspc.gc.ca>; Beresford-Green, Debbie (HC/SC) <debbie.beresford-green@hc-sc.gc.ca>
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Communications and Public Affairs / communications et affaires publiques
Health Canada/Santé Canada
Mobile: 613-878-3379
Pamela.aung-thin@hc-sc.gc.ca

From: Renart-McGowan, Isabel (HC/SC)
To: Randall, Bruce (HC/SC)
Subject: RE: CTs for ivermectin
Date: 2021-01-29 11:07:51 AM

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thanks

From: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Sent: 2021-01-29 11:05 AM
To: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>
Cc: Loo, Wayne (HC/SC) <wayne.loo@canada.ca>; Mattia-Pepin, Isabelle (HC/SC) <isabelle.mattia-pepin@canada.ca>
Subject: RE: CTs for ivermectin

Thanks Isabel.

BE studies aren't necessary.

B

From: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Sent: 2021-01-29 11:04 AM
To: Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>; Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Cc: Loo, Wayne (HC/SC) <wayne.loo@canada.ca>; Mattia-Pepin, Isabelle (HC/SC) <isabelle.mattia-pepin@canada.ca>
Subject: FW: CTs for ivermectin

Hello Pat/Bruce,

I confirmed that there are no COVID-related CTs for ivermectin in Canada. We likely have had some bioequivalence studies, as per Carole. If you would like to see that list, let me know. For now, I told her to stand down.

Thanks,
I

From: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Sent: 2021-01-29 10:15 AM
To: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Subject: RE: CTs for ivermectin

Not for COVID. Is that what you were looking for?
I believe we have had some for bioequivalence studies before. I could get the list for you, if you

need.

Carole

From: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Sent: 2021-01-29 10:03 AM
To: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Subject: CTs for ivermectin

Morning Carole,

We were wondering if there have been any CTs for ivermectin in Canada. I did a quick search online and couldn't find one. Just wanted to double check with you.

Thanks!
Isabel

From: Randall, Bruce (HC/SC)
To: Bettle, Megan (HC/SC); Mineau, Philippe (HC/SC); Stewart, John Patrick (HC/SC)
Cc: Legare, Carole (HC/SC); Soo, Evelyn (HC/SC)
Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment
Date: 2021-03-26 11:45:04 AM

I don't believe so as it was never expected to come in for review. Feel free to pick and chose as not all may be necessary.

Here are our standard lines as well as FDA, EMA, Alberta and Merck links. Nothing new from our side.

https://www.ema.europa.eu/en/news/ema-advises-against-use-ivermectin-prevention-treatment-covid-19-outside-randomised-clinical-trials
https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19
https://www.albertahealthservices.ca/assets/info/ppih/if-ppih-covid-19-sag-ivermectin-in-treatment-and-prevention-rapid-review.pdf
https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/

Thanks!
B

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug approved by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECOTL has been marketed in Canada since 2018.

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

- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Heath Canada has no jurisdiction over how health care professionals prescribe drugs once they are approved.

- Healthcare practitioners may prescribe drugs, including ivermectin, outside of their authorized indications (off-label use), based on other sources of information such as medical literature. Off-label use falls under the practice of medicine and is regulated at the provincial and territorial level.

- However, at this time, no ivermectin manufacturer has made an application for this drug to be approved for the treatment or prevention of COVID-19. Therefore, the effectiveness of ivermectin as a therapeutic option for COVID-19

has not been evaluated by Health Canada.

- For drugs that have potential to be helpful in treating COVID-19, Health Canada encourages drug manufacturers to conduct clinical trials. This would provide an opportunity for the healthcare community to collect information on the effectiveness of the treatment and its associated risks. Evidence from well-designed studies is needed to determine whether ivermectin might be helpful in preventing or treating COVID-19.

- A list of all clinical trials approved for the prevention or treatment of COVID-19 can be found on Health Canada's website: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-clinical-trials/list-authorized-trials.html

- In Canada, clinical trials for COVID-19 are facilitated under an Interim Order, which was signed by the Minister of Health on May 23, 2020: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/notice-interim-order.html

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

- To date, Health Canada has not received any clinical trial application for studying the safety and efficacy of ivermectin for the prevention or treatment of COVID-19. However, Health Canada is aware that such clinical trials may be planned or underway internationally.

- Following the clinical trial stage, companies can choose between two different authorization pathways for COVID-19-related drugs and vaccines: existing regulatory pathways outlined in the *Food and Drug Regulations* or the Interim Order pathway for COVID-19-related drugs and vaccines, which was signed by the Minister of Health and came into effect on September 16, 2020: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs/note.html

- This interim order facilitates timely access for Canadians to drugs and vaccines that have demonstrated the ability to diagnose, prevent, treat or cure COVID-19. It introduces temporary regulations to expedite the authorization for importing, selling and advertising COVID-19-related drugs without compromising patient safety.

- Health Canada's position on ivermectin is aligned with that of other regulators. Ivermectin has not been approved by the U.S. Food and Drug Administration or the European Medicines Agency for the prevention or treatment of COVID-19.

From: Bettle, Megan (HC/SC) <megan.bettle@canada.ca>
Sent: 2021-03-26 11:42 AM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>
Cc: Legare, Carole (HC/SC) <carole.legare@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>
Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment

I will throw together something really short. I assume there's been no product brief done previously?

From: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Sent: 2021-03-26 10:53 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>; Bettle, Megan (HC/SC) <megan.bettle@canada.ca>
Cc: Legare, Carole (HC/SC) <carole.legare@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>
Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment

Hi Megan,

We can help inform response from any CTs or pre-market discussions, however I believe PHAC was responsible for tracking potential therapies. I know Merck has come out with a position saying they don't have evidence that it's effective. We have our current stock lines.

Bruce

From: Smith4, Melissa (HC/SC) <melissa.smith4@canada.ca>
Sent: 2021-03-26 10:17 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>; Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Bettle, Megan (HC/SC) <megan.bettle@canada.ca>
Subject: DM Request - Update on Ivermectin in the context of COVID-19 treatment

Good morning TPD and Megan,

The DM has requested, by COB today, a summary of what we know about Ivermectin studies and use as COVID-19 treatment. This request is triggered by [redacted] to ask

if HC is systematically tracking it.

Megan – would you mind reaching out to Kaili's group to see if they've been tracking and thus would have input to provide?

Thanks,
Melissa

DOCKET #: 21-007306 -134

Subject: Potential effectiveness of ivermectin for the treatment of COVID-19 patients

Date of Correspondence: June 23, 2021

The Therapeutic Products Directorate suggests the following for Branch Input to the above-mentioned correspondence.

- Health Canada is closely monitoring all potential therapeutic treatments and vaccines in development in Canada and abroad.

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECTOL has been marketed in Canada since 2018.

- 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.

- Thank you for forwarding the article from the *American Journal of Therapeutics*, "Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines", which found that there was moderate-certainty evidence that large reductions in COVID-19 deaths are possible using ivermectin.

- A different article,"Ivermectin for the treatment of COVID-19: A systematic review and meta-analysis of randomized controlled trials" published in the journal *Clinical Infectious Diseases*, found that ivermectin did not reduce all-cause mortality, length of stay or viral clearance in randomized clinical trials in COVID-19 patients with mostly mild disease.

- Generally, because many of the Randomized Clinical Trials on ivermectin have been small and thus lack power and precision in the estimates, there is low or very low certainty in the results related to COVID-19 outcomes.

- Health Canada and the Public Health Agency of Canada will continue to evaluate the situation as more information becomes available.

DOCKET #: 21-003891-802

Subject: Potential effectiveness of Ivermectin for the treatment of COVID-19 patients

Date of Correspondence: December 9, 2020

The Therapeutic Products Directorate suggests the following for Branch Input to the above-mentioned correspondence.

- Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECOTL has been marketed in Canada since 2018.

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

- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Heath 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

- 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: Bellefeuille, Aldege (HC/SC)
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); 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
Date: 2021-08-30 2:53:32 PM

Thank you.

From: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Sent: 2021-08-30 2:53 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>; 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

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 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

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 >>

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

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

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

From: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>
Sent: 2021-08-30 9:50 AM
To: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>; BMS ORM Risk / BSM BGR Risque (HC/SC) <bmsormrisk-bsmbgrrisque@hc-sc.gc.ca>; Dinakaran, Deborah (HC/SC) <deborah.dinakaran@hc-sc.gc.ca>; Badenduck, Lucas (HC/SC) <lucas.badenduck@hc-sc.gc.ca>
Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: Issue IU - Do not use ivermectin for treatment of COVID-19
Importance: High

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

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

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

Thank you!

Mimi

From: Bellefeuille, Aldege (HC/SC) <aldege.bellefeuille@hc-sc.gc.ca>
Sent: 2021-08-30 9:31 AM
To: Lin, Mimi (HC/SC) <mimi.lin@hc-sc.gc.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@hc-sc.gc.ca>
Cc: Schmidt, Stephanie (HC/SC) <stephanie.schmidt@hc-sc.gc.ca>; Lejmi Mrad, Rim (HC/SC) <rim.lejmimrad@hc-sc.gc.ca>; Kearns-Justin, Dayna (HC/SC) <dayna.kearns-justin@hc-sc.gc.ca>
Subject: RE: Issue IU - Do not use ivermectin for treatment of COVID-19

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

---

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

Good morning Aldege,

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

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

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

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

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

Please advise,

Mimi

Mimi Lin
(she/elle)

Senior Corporate Regulatory Compliance & Enforcement Advisor,
Health Product Compliance & Enforcement Unit / Regulatory Operations and Enforment Branch
Health Canada / Government of Canada
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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)
To: Genier, Anne (HC/SC); HC.F TPD Media Requests F.SC; HC.F MHPD Action Requests F.SC
Cc: Aboueid, Suzane (HC/SC); Nahum, Marilyne (HC/SC); Francis-Lamb, Laura (HC/SC); Zaman, Muhammad (HC/SC)
Subject: RE: For HPFB-TBD input: Media Query: Toronto Star ([redacted]Use of Ivermectin to treat COVID-19 + incident report
Date: 2021-09-08 1:30:44 PM

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
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- - -
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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. STROMECOTL has been marketed in Canada since 2018.

- Health Canada is closely monitoring all potential therapeutic treatments and vaccines in development in Canada and abroad, including products such as ivermectin that are being use outside of their authorized indication (off-label use), as potential treatments for COVID-19.
- While Health Canada issues market authorizations for drugs and approves the conditions for which the drugs are to be used, it does not issue treatment recommendations or guidelines. Heath 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.

- At this time, no ivermectin manufacturer has made an application for this drug to be approved for the treatment or prevention of COVID-19. Therefore, the effectiveness of ivermectin as a therapeutic option for COVID-19 has not been evaluated by Health Canada.

- For drugs that have potential to be helpful in treating COVID-19, Health Canada encourages drug manufacturers to conduct clinical trials. This would provide an opportunity for the healthcare community to collect information on the effectiveness of the treatment and its associated risks. Evidence from well-designed studies is needed to determine whether ivermectin might be helpful in preventing or treating COVID-19.

- A list of all clinical trials approved for the prevention or treatment of COVID-19 can be found on Health Canada's website: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-clinical-trials/list-authorized-trials.html

- In Canada, clinical trials for COVID-19 are facilitated under an Interim Order, which was signed by the Minister of Health on May 23, 2020: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/notice-interim-order.html

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

- To date, Health Canada has not received any clinical trial application for studying the safety and efficacy of ivermectin for the prevention or treatment of COVID-19. However, Health Canada is aware that such clinical trials may be planned or underway internationally.

- Following the clinical trial stage, companies can choose between two different authorization pathways for COVID-19-related drugs and vaccines: existing regulatory pathways outlined in the *Food and Drug Regulations* or the Interim Order pathway for COVID-19-related drugs and vaccines, which was signed by the Minister of Health and came into effect on September 16, 2020: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs/note.html

- This interim order facilitates timely access for Canadians to drugs and vaccines that have demonstrated the ability to diagnose, prevent, treat or cure COVID-19. It introduces temporary regulations to expedite the authorization for importing, selling and advertising COVID-19-related drugs without compromising patient safety.

- Health Canada's position on ivermectin is aligned with that of other regulators. Ivermectin has not been approved by the U.S. Food and Drug Administration or the European Medicines Agency for the prevention or treatment of COVID-19.

From: Mineau, Philippe (HC/SC)
To: Lingohr, Erika (PHAC/ASPC)
Cc: Peate, Jaspyn (HC/SC)
Subject: RE: FYI - Ivermectin info from June 3
Date: 2021-07-05 9:36:52 AM

Ok awesome thanks for the update Erika!
I
don't think there's a huge rush over here, better to take our time and do a solid job of it ☺ - we are still hoping that a good comprehensive PHAC review can be used to communicate more effectively with stakeholders / Canadians when they write in,

Cheers!
P

From: Lingohr, Erika (PHAC/ASPC) <erika.lingohr@canada.ca>
Sent: 2021-07-05 9:32 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: FYI - Ivermectin info from June 3

Thanks Philippe – always nice to have a few sunny days off; hope you got to enjoy as well.

Unfortunately due to the short week, and more complicated nature of this review than originally anticipated, we were not able to complete it last week as planned! I've been assured it will be available by the end of the week, and am trying to see if an early draft can be shared with you for reference. I'll share updates as soon as possible.

Thanks for the details on new reviews below – I've passed them along should it be possible to include them, or at least confirm there is no conflicting evidence detailed.

Erika

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

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-07-05 9:24 AM
To: Waddell, Lisa (PHAC/ASPC) <lisa.waddell@canada.ca>
Cc: OCSO Evidence / BCSC Données Probantes (PHAC/ASPC) <phac.ocsoevidence-bcscdonneesprobantes.aspc@canada.ca>; Peate, Jaspyn (HC/SC) <jaspyn.peate@canada.ca>; Lingohr, Erika (PHAC/ASPC) <erika.lingohr@canada.ca>
Subject: RE: FYI - Ivermectin info from June 3

Hey there Lisa, hope you had a great weekend,

Just wondering how the review related to ivermectin is going? Just got wind of a couple of newly published meta-analyses...

Ivermectin for the treatment of COVID-19: A systematic review and meta-analysis of randomized controlled trials | Clinical Infectious Diseases | Oxford Academic (oup.com)
Ivermectin for Prevention and Treatment of COVID-19 Infectio... : American Journal of Therapeutics (lww.com)

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] 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
  - Ivemectin 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 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)

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. STROMECOTL has been marketed in Canada since 2018.

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- 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-

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: Nahum, Marilyne (HC/SC)
To: Mineau, Philippe (HC/SC); Genier, Anne (HC/SC); HC.F TPD Media Requests F.SC; HC.F MHPD Action Requests F.SC
Cc: Aboueid, Suzane (HC/SC); Francis-Lamb, Laura (HC/SC); Zaman, Muhammad (HC/SC)
Subject: RE: For HPFB-TBD input: Media Query: Toronto Star [redacted] Use of Ivermectin to treat COVID-19 + incident report
Date: 2021-09-08 1:42:22 PM

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>
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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, E/CE: media@hc-sc.gc.ca

From: Renart-McGowan, Isabel (HC/SC)
To: Loo, Wayne (HC/SC)
Subject: RE: Controversy Flares Over Ivermectin for COVID-19
Date: 2021-01-22 3:42:37 PM

☺

From: Loo, Wayne (HC/SC) <wayne.loo@canada.ca>
Sent: 2021-01-22 3:42 PM
To: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Subject: RE: Controversy Flares Over Ivermectin for COVID-19

Thanks!

From: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Sent: 2021-01-22 3:26 PM
To: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Cc: Loo, Wayne (HC/SC) <wayne.loo@canada.ca>
Subject: RE: Controversy Flares Over Ivermectin for COVID-19

Very interesting, also reminds me of the remdesivir debates. Thank you for including me. Looping in Wayne as well.

Have a lovely weekend. ☺

From: Legare, Carole (HC/SC) <carole.legare@canada.ca>
Sent: 2021-01-22 1:40 PM
To: Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>; Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>; Punch, Vincent (HC/SC) <vincent.punch@canada.ca>
Cc: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Subject: Controversy Flares Over Ivermectin for COVID-19

Still much debate

https://www.medscape.com/viewarticle/944440?src=WNL_mdpls_210122_mscpedit_wir&uac=68877MJ&spon=17&impID=3146929&faf=1

Carole

From: Randall, Bruce (HC/SC)
To: Bettle, Megan (HC/SC); Mineau, Philippe (HC/SC); Stewart, John Patrick (HC/SC)
Cc: Legare, Carole (HC/SC); Soo, Evelyn (HC/SC)
Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment
Date: 2021-03-26 11:45:04 AM

I don't believe so as it was never expected to come in for review. Feel free to pick and chose as not all may be necessary.

Here are our standard lines as well as FDA, EMA, Alberta and Merck links. Nothing new from our side.

https://www.ema.europa.eu/en/news/ema-advises-against-use-ivermectin-prevention-treatment-covid-19-outside-randomised-clinical-trials
https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19
https://www.albertahealthservices.ca/assets/info/ppih/if-ppih-covid-19-sag-ivermectin-in-treatment-and-prevention-rapid-review.pdf
https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/

Thanks!
B

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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.

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- To date, Health Canada has not received any clinical trial application for studying the safety and efficacy of ivermectin for the prevention or treatment of COVID-19. However, Health Canada is aware that such clinical trials may be planned or underway internationally.

- Following the clinical trial stage, companies can choose between two different authorization pathways for COVID-19-related drugs and vaccines: existing regulatory pathways outlined in the *Food and Drug Regulations* or the Interim Order pathway for COVID-19-related drugs and vaccines, which was signed by the Minister of Health and came into effect on September 16, 2020: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs/note.html

- This interim order facilitates timely access for Canadians to drugs and vaccines that have demonstrated the ability to diagnose, prevent, treat or cure COVID-19. It introduces temporary regulations to expedite the authorization for importing, selling and advertising COVID-19-related drugs without compromising patient safety.

- Health Canada's position on ivermectin is aligned with that of other regulators. Ivermectin has not been approved by the U.S. Food and Drug Administration or the European Medicines Agency for the prevention or treatment of COVID-19.

From: Bettle, Megan (HC/SC) <megan.bettle@canada.ca>
Sent: 2021-03-26 11:42 AM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>
Cc: Legare, Carole (HC/SC) <carole.legare@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>
Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment

I will throw together something really short. I assume there's been no product brief done previously?

From: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Sent: 2021-03-26 10:53 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>; Bettle, Megan (HC/SC) <megan.bettle@canada.ca>
Cc: Legare, Carole (HC/SC) <carole.legare@canada.ca>; Soo, Evelyn (HC/SC) <evelyn.soo@canada.ca>
Subject: RE: DM Request - Update on Ivermectin in the context of COVID-19 treatment

Hi Megan,

We can help inform response from any CTs or pre-market discussions, however I believe PHAC was responsible for tracking potential therapies. I know Merck has come out with a position saying they don't have evidence that it's effective. We have our current stock lines.

Bruce

From: Smith4, Melissa (HC/SC) <melissa.smith4@canada.ca>
Sent: 2021-03-26 10:17 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>; Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Bettle, Megan (HC/SC) <megan.bettle@canada.ca>
Subject: DM Request - Update on Ivermectin in the context of COVID-19 treatment

Good morning TPD and Megan,

The DM has requested, by COB today, a summary of what we know about Ivermectin studies and use as COVID-19 treatment. This request is triggered by [redacted] to the DM to ask

if HC is systematically tracking it.

Megan – would you mind reaching out to Kaili's group to see if they've been tracking and thus would have input to provide?

Thanks,
Melissa

From: Randall, Bruce (HC/SC)
To: Mineau, Philippe (HC/SC)
Subject: RE: For HPFB-TBD input: Media Query: Toronto Star [redacted] Use of Ivermectin to treat COVID-19 + incident report
Date: 2021-09-08 1:27:00 PM

Ok, thanks

From: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
Sent: 2021-09-08 1:27 PM
To: Randall, Bruce (HC/SC) <bruce.randall@hc-sc.gc.ca>
Subject: RE: For HPFB-TBD input: Media Query: Toronto Star [redacted] Use of Ivermectin to treat COVID-19 + incident report

Hey Bruce,

Yes agreed, we haven't seen anything about actual reports of use, but honestly I wouldn't know if MHPD would have this either. The advisory mentioned people using the veterinary ivermectin, and that was in reference to those news articles... I can send this info back to CPAB?
P

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?

Health Canada

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To: Mineau, Philippe (HC/SC) <philippe.mineau@hc-sc.gc.ca>
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Don't know if this is us or MHPD?

We have seen correspondence but no actual reports.

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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?

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Approved by:

Anne Génier

Senior Media Relations Advisor, Communication and Public Affairs Branch
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- - -
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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

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Pinard, Mike (HC/SC)

From: Superle, Tamy (HC/SC)
Sent: 2021-09-02 5:35 PM
To: Robinson, Kelly (HC/SC); Houston, Laura (HC/SC)
Cc: Derry, Mélanie (HC/SC)
Subject: RE: Call with Manon

Hi all,

Manon is interested in the adverse events reports on ivermectin use (during and pre-COVID). The background is the ongoing discussion on how ensure that the message out gets out about the dangers of ivermectin. I haven't talked to Manon directly about this meeting, but I suspect that's what she would like to discuss.

Tamy

From: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Sent: 2021-09-02 5:17 PM
To: Houston, Laura (HC/SC) <laura.houston@hc-sc.gc.ca>
Cc: Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>; Derry, Mélanie (HC/SC) <melanie.derry@hc-sc.gc.ca>
Subject: RE: Call with Manon

Thanks, do we have any background information for this call?

From: Houston, Laura (HC/SC) <laura.houston@hc-sc.gc.ca>
Sent: 2021-09-02 4:19 PM
To: Robinson, Kelly (HC/SC) <kelly.robinson@hc-sc.gc.ca>
Cc: Superle, Tamy (HC/SC) <tamy.superle@hc-sc.gc.ca>
Subject: Call with Manon

I have sked for 1800 as Manon has a mtg from 1700 to 1800. If however that meeting ends earlier, the call could happen sooner. I will give you a heads up if that happens, okay?

Merci!

Laura

Laura J. Houston, CAPM
(pronouns: she, her | pronoms : elle, elle)
Management Executive Assistant to the Associate Assistant Deputy Minister /
Adjointe exécutive de gestion à la sous ministre adjointe déléguée
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Immeuble Graham Spry Building
250, avenue Lanark Avenue
Ottawa, Ontario K1A 0K9
Email / courriel laura.houston@canada.ca
Tel: (343) 553-4723

From: Legare, Carole (HC/SC)
Sent: 2021-01-22 1:40 PM
To: Stewart, John Patrick (HC/SC); Randall, Bruce (HC/SC); Soo, Evelyn (HC/SC); Punch, Vincent (HC/SC)
Cc: Renart-McGowan, Isabel (HC/SC)
Subject: Controversy Flares Over Ivermectin for COVID-19

Still much debate

https://www.medscape.com/viewarticle/944440?src=WNL_mdpls_210122_mscpedit_wir&uac=68877MJ&spon=17&impID=3146929&faf=1

Carole

From: Soo, Evelyn (HC/SC)
Sent: 2021-03-19 3:25 PM
To: Kukulski, Filip (HC/SC); Punch, Vincent (HC/SC); McLean, Martin (HC/SC)
Subject: FW: COVID-19 Related: [redacted]: EMA communication: EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials
Attachments: Ivermectin - 03-2021 - public health communication.docx

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Follow Up Flag: Follow up
Flag Status: Flagged

FYI

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

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

From: Srivastava, Tanya (HC/SC) <tanya.srivastava@canada.ca> **On Behalf Of** MHPD_International / DPSC_International (HC/SC)
Sent: 2021-03-19 8:08 AM
To: Abdelmesih, Mariam (HC/SC) <mariam.abdelmesih@canada.ca>; Alhaddad, Saj (HC/SC) <saj.alhaddad@canada.ca>; Bawolak, Marie-Therese (HC/SC) <marie-therese.bawolak@canada.ca>; Campbell, Catherine (HC/SC) <catherine.campbell@canada.ca>; Chen2, Yong (HC/SC) <yong.chen2@canada.ca>; Chretien, Louise (HC/SC) <louise.chretien@canada.ca>; Comarova, Natalia (HC/SC) <natalia.comarova@canada.ca>; Dai, Jiazhen Minnie (HC/SC) <jiazhenminnie.dai@canada.ca>; del Campo, Eduardo (HC/SC) <eduardo.delcampo@canada.ca>; Djulus, Josephine (HC/SC) <josephine.djulus@canada.ca>; Duguay, David (HC/SC) <david.duguay@canada.ca>; Eng, David (HC/SC) <david.eng@canada.ca>; Filfil, Rana (HC/SC) <rana.filfil@canada.ca>; Hazelwood, Tracey (HC/SC) <tracey.hazelwood@canada.ca>; HC.F HPF MHPD OPEDA F.SC <HPF_MHPD_OPEDA@canada.ca>; HC.F MHPD BBRS Assistants / MHPD BBRA Assistants F.SC <hc.mhpdbbrsassistants-mhpdbbraassistants.sc@canada.ca>; HC.F MHPD BBRS Management / MHPD BBRA Management F.SC <hc.mhpdbbrsmanagement-mhpdbbramanagement.sc@canada.ca>;

HC.F MHPD HPSEB Managers / DPSC HPSEB Gestionnaires F.SC <hc.mhpdhpsebmanagers-dpschpsebgestionnaires.sc@canada.ca>; HC.F MHPD MPB MANAGEMENT F.SC <hc.mhpdmpbmanagement.sc@canada.ca>; HC.F MHPD MPB SCIENTIFIC STAFF F.SC <hc.mhpdmpbscientificstaff.sc@canada.ca>; HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@canada.ca>; MBBNHPB ENVIROSCANS / BPBBSNC (HC/SC) <hc.mbbnhpb.enviroscans-bpbbsnc.sc@canada.ca>; Meszaros, Michele (HC/SC) <michele.meszaros@canada.ca>; MHPD_International / DPSC_International (HC/SC) <hc.mhpd_international-dpsc_international.sc@canada.ca>; MPB RPM / GPR BPPC (HC/SC) <hc.mpb.rpm-gpr.bppc.sc@canada.ca>; Murty, Hima (HC/SC) <hima.murty@canada.ca>; Plante, Isabelle (HC/SC) <isabelle.plante@canada.ca>; Rose, Jhona (HC/SC) <jhona.rose@canada.ca>; Salem, Myriam (HC/SC) <myriam.salem@canada.ca>; Shehata, Marlene (HC/SC) <marlene.shehata@canada.ca>; Sleno, Rory (HC/SC) <rory.sleno@canada.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@canada.ca>; Springuel, Pascale (HC/SC) <pascale.springuel@canada.ca>; Tremblay, Patrice (HC/SC) <patrice.tremblay@canada.ca>; Williams, Lee (HC/SC) <lee.williams@canada.ca>; Xu, Xiao (HC/SC) <xiao.xu@canada.ca>; Yammine, Elena (HC/SC) <elena.yammine@canada.ca>

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

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

Dear all,

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

Kindest regards,

Tanya

Tanya Srivastava

Junior Policy Analyst
Bureau of Strategic Engagement and Integrated Management Services
Marketed Health Products Directorate
Health Products and Food Branch
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Email: tanya.srivastava@canada.ca
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Analyste de politiques junior
Bureau de la mobilisation stratégique et des services de gestion intégrée
Direction des produits de santé commercialisés
Direction générale des produits de santé et des aliments

Santé Canada
Courriel: tanya.srivastava@canada.ca
hc.mhpd_international-dpsc_international.sc@canada.ca

Dear Colleagues,

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

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

Best regards,

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

www.ema.europa.eu

Follow us:

[redacted]

[redacted]

Emerging Evidence on COVID-19

Evidence Brief of Ivermectin

Introduction

Is there evidence that Ivermectin is an efficacious treatment for COVID-19?

Ivermectin is a broad-spectrum anti parasitic agent approved in Canada to treat intestinal strongyloidiasis and onchocerciasis, tropical parasitic infections, and is considered safe at dosages <200 ug/kg (1, 2). Its use in the treatment of COVID-19 is not currently recommended by Health Canada, Food and Drug Administration of the USA, the Pan American Health Organization (PAHO) or the World Health Organization (WHO) except in clinical trials (1-4). However, it has been explored for use in COVID-19 due to its antiviral activity *in vitro* against a range of viruses including SARS-CoV-2 (5, 6). The suggested mechanism of action is that ivermectin inhibits and disrupts binding of the SARS-CoV-2 S protein at the ACE-2 receptor (7). Ivermectin was not included in the WHO SOLIDARITY trial for repurposing drugs for COVID-19, some authors suggest this is because the anti-viral effects seen *in vitro* would require nine times the recommended dosage of ivermectin (5). Dosages evaluated across studies were generally <200 ug/kg with some dosing 2 – 3 times 200 ug/kg and ranged from a single dose to treatment over several days up to 14 days. This review summarises systematic reviews and new randomized controlled trials (RCTs) on the efficacy and safety of ivermectin compared to a standard of care or placebo for the prevention of infection with SARS-CoV-2 (post-exposure prophylaxis) and for use as a treatment of COVID-19 cases receiving either inpatient or outpatient care published up to July 5, 2021.

Key Points

- The WHO updated its living guidelines March 31, 2021 to include ivermectin (1) and currently does not recommend the use of ivermectin for the treatment of COVID-19 due to low certainty in the evidence and the availability of other more efficacious treatments.
- Eight systematic or rapid reviews on ivermectin as a therapeutic including two guidelines documents from WHO and PAHO that were underpinned by synthesis research are summarized below. Three systematic reviews summarized the literature on prophylactic use of ivermectin to prevent COVID-19.
- There was variability in the meta-analyses between reviews due to variability in studies included. Across meta-analyses some syntheses included randomized controlled trials (RCTs) only, others restricted to RCTs with low risk of bias, while others included observational studies of both prospective and retrospective design.
    - Moderate/high risk of bias RCTs frequently had inadequate randomization and/or allocation concealment.
    - Many of the RCTs on ivermectin have been small and thus lack power and precision in the estimates.
- There is low or very low certainty in the results for all COVID-19 outcomes, which are summarized below.

Mortality:

- Meta-analyses on the prevention of mortality with ivermectin treatment are inconsistent and had very low to moderate certainty depending on the analysis. The meta-analyses with the most restrictive inclusion criteria (e.g., RCTs of low risk of bias) did not report an association with mortality, whereas those that included RCTs of moderate/high risk of bias or non-RCTs reported an association as shown in the PAHO rapid review (2).

  No association with mortality:

  - 28-day mortality RR 0.33 (95% 0.01-8.14) from 3 RCTs/ 60 day mortality RR 2.00 (0.18-21.91) from 1 RCT (8).
  - RR 0.94 (95%CI 0.51-1.73) from 4 RCTs at low risk of bias / RR 0.32 (95%CI 0.16-0.64) from 6 RCTs at moderate/high risk of bias (2).
  - RR 0.37 (95%CI 0.12 to 1.13) from 5 RCTs, very low certainty of evidence and the subgroup analysis showed a reduction in mortality across 3 RCTs at high risk of bias (RR 0.18, 95%CI 0.07-0.49) (9).

  Reduced mortality:

  - OR 0.19 (95%CI 0.09-0.36) from 7 RCTs very low certainty (1).
  - RR 0.38 (95%CI 0.19 -0.73) from 15 studies (RCT and observational studies) moderate certainty evidence, this persisted only for mild/moderate cases (RR 0.24, 95%CI 0.06-0.94) in subgroup analysis (10).
  - RR 0.31 (95%CI 0.15–0.62) from 8 RCTs that persisted only for mild/moderate COVID-19 (RR 0.15, 95%CI 0.03-0.67) in a sub-group analysis (11).
  - OR 0.39 (95%CI 0.22-0.70) from 22 studies (RCT, observational, descriptive) and very low certainty in the evidence. Clinical trials only (OR 0.32, 95%CI 0.15-0.65) had similar results and the authors note that the benefit of ivermectin treatment was only seen in mild/moderate cases (12).

Severe disease:

- Ivermectin was not shown to reduce the risk of symptomatic disease, hospitalization or mechanical ventilation, or length of stay (1, 2, 8-10, 12-14).
  - One meta-analysis reported reduced severity of COVID-19 (RR 0.43 [95% CI 0.23–0.81], I2=65%, p = 0.008, 8 RCTs, n=1638), in the subgroup analysis reduced severity was only associated with mild/moderate cases (RR 0.44, 95%CI 0.22–0.85) (11).

Time to symptom resolution:

- Conflicting results for symptom resolution or improvement were reported across analyses with many reporting no difference (1).
  - RR 1 (95%CI 0.9-1.11, I^2=30%) 2 RCTs low risk of bias and moderate certainty of evidence vs. RR 1.35 (95%CI 1.16-1.57) 6 RCTS of moderate/high risk of bias (2).

Time to PCR negative:

- Time to viral clearance was similar between ivermectin and controls in several analyses (1, 9, 14).
  - Faster time to PCR negative (HR 2.70, 95%CI 1.21- 6.04, 1 RCT) in mild cases, an outcome reported in only 1 of 18 included RCTs, very low certainty (8).
  - Higher PCR negative rate (RR 1.23, 95% CI 1.01–1.51) from 9 RCTs, low certainty and shorter time to PCR negative (mean difference [MD] −3.29, 95%CI −5.69, −0.89) from 6 studies (11).
  - Compared to Lopinavir-Ritonavir, the ivermectin treatment group had a faster time to PCR negative (HR 2.02, 95%CI 1.28-3.18) among hospitalized cases in 1 RCT (8).

Severe adverse events:

- There is no evidence that there was an association between ivermectin treatment and severe adverse events (1, 2, 8-10, 12-14).

Prophylactic use to prevent COVID-19:

- Three systematic reviews report on the RCTs and/or clinical trials on prophylaxis have shown some protective effect of ivermectin supplementation however, the certainty in this evidence is very low to low:
  - Ivermectin prophylaxis reduced COVID-19 infection by 86% (95%CI 79-91%, 3 studies, 738 participants) – low certainty of evidence (10).
  - Ivermectin alone on suspected, probable, or laboratory confirmed COVID-19 infections (159 fewer per 1000, 165 fewer to 144 fewer) remain very uncertain (15).
  - A protective effect of ivermectin supplementation to prevent symptomatic COVID-19 (RR 0.13, 95%CI 0.08-0.21, 1 RCT) or confirmed COVID-19 (RR 0.20, 95%CI 0.04-0.89, 1 RCT) very low certainty of evidence (8).

On-going ivermectin and COVID-19 research:

- There are currently at least 66 trials registered to study treatment of COVID-19 with ivermectin.

Overview of the Evidence

Systematic reviews of RCTs and RCTs published since the last SR search date were included in this evidence brief. Systematic reviews were evaluated using the AMSTAR tool for systematic reviews (16).

CONTENTS

THERAPEUTIC USE

Therapeutic use of ivermectin in the treatment of COVID-19 has been studied in several clinical trials and a wide range of severities and outcomes have been reported. Several reviews report moderate/high risk of bias in many of the RCTs examining ivermectin treatment. To minimize the bias in the analyses some authors analysed low risk of bias RCTs separate from moderate/high risk of bias RCTs (2, 9) and in some analyses authors have limited analysis to RCTs (1, 11, 12), while others have included multiple study designs in one meta-analysis (10, 12, 13). There are also websites that collect and meta-analyse the literature on ivermectin without conducting a systematic review process. These were excluded from this evidence brief, but are listed in the appendix for reference.

Most RCTs on ivermectin as a therapeutic were small, which impact power and precision of the results and many were at risk of bias due to inappropriate randomization or inadequate allocation concealment. Thus, the studies included in each meta-analysis differed from one systematic review to the next and for a few outcomes (e.g., mortality) the analyses were conflicting.

Table 1: Treatment of COVID-19 with ivermectin (n=8 systematic/rapid reviews and 1 new RCT)

STUDY	METHOD	KEY OUTCOMES
Evidence-Based Guidelines		
WHO Living guideline on Therapeutics for COVID-19 (1) Mar 2021	The living guideline is underpinned by a systematic review process with GRADE certainty of evidence. 16 RCTs (2407 participants) were included and all other study designs were excluded. Many RCTs did not report on patient-important outcomes. Meta-analysis and sub-group analysis was conducted on ivermectin dosages There are few RCTs available on ivermectin and RCTs are small with few events. Relative to alternative treatment options, there is a high degree of uncertainty in the evidence. *See figure in appendix.*	Recommendation: WHO recommends not to use ivermectin in patents with COVID-19 except in the context of a clinical trial. This recommendation applies to patients with any disease severity and any duration of symptoms. A recommendation to only use a drug in the setting of clinical trials is appropriate when there is very low certainty evidence and future research has a large potential for reducing uncertainty about the effects of the intervention and for doing so at reasonable cost. For most key outcomes, including mortality, mechanical ventilation, hospital admission, duration of hospitalization and viral clearance, the panel considered the evidence of very low certainty *(Summary of Findings table in Appendix)*. Evidence was rated as very low certainty primarily because of very serious imprecision for most outcomes: the aggregate

		data had wide confidence intervals and/or very few events. There were also serious concerns related to risk of bias for some outcomes, specifically lack of blinding, lack of trial pre-registration, and lack of outcome reporting for one trial that did not report mechanical ventilation despite pre-specifying it in their protocol (publication bias). Ivermectin used to treat COVID-19: more than 66 RCTs planning to enrol more than 12 000 participants (range 24 - 2724) are registered or ongoing. Note: The meta-analysis results for mortality OR 0.19 (95%CI 0.09-0.36, from 7 RCTs n=1419 observations).
Pan American Health Organization (PAHO) Living Update of COVID-19 Therapeutic Options (2) Rapid Review May 2021	The rapid review follows systematic review methodology and uses the Living OVerview of Evidence (L·OVE; https://iloveevidence.com) platform to identify studies for inclusion in this review. Studies included up to May 6, 2021. RCTs of therapeutic interventions for COVID-19 were included. The outcomes focused on were comparative effectiveness studies that provide evidence on outcomes of crucial importance to patients (mortality, invasive mechanical ventilation, symptom resolution or improvement, infection [prophylaxis studies] and severe adverse events) Meta-analysis: Random effects meta-analysis was performed. Where significant heterogeneity existed, subgroup analysis by risk of bias was performed considering: 1) Risk of bias (high/moderate vs low risk of bias), 2) Disease severity (mild, moderate, severe or critical); and 3) Intervention's characteristics. A risk of bias assessment was applied to RCTs focusing on randomization, allocation concealment, blinding,	28 RCTs (4837 cases, mild to severe) and most were very small RCTs with a small number of events (low power and high imprecision). • 17 did not report any clinically important outcomes. • 11 of those studies reported on clinically important outcomes. • Methodological limitations in studies that reported clinically important outcomes included inappropriate randomization or allocation concealment. Results: • Ivermectin may not significantly reduce mortality, RR 0.94 (95%CI 0.51 to 1.73 I^2 =1%); RD - 0.96% (95%CI -7.8% to 11.7%); low certainty based on 4 low risk of bias studies. High risk of bias RCTs (n=6) showed significant protection from mortality (RR 0.32, 95%CI 0.16-0.64, I^2 = 39%), 2/6 found an association within study. • It is uncertain if ivermectin affects mechanical ventilation requirements, RR 0.89 (95%CI 0.38 to 2.07); RD -1.9% (95%CI -10.7% to 18.5%); very low certainty based on 4 low risk of bias RCTs. • Ivermectin probably does not improve symptom resolution or improvement, RR 1 (95%CI 0.9-1.11, I^2=30%); RD 0% (95%CI -6%-6.6%); moderate certainty based on 2 RCTS with low risk of bias. 2/6 high risk of

	attrition, or other biases relevant to the estimates of effect. The GRADE approach was used to assess the certainty on the body of evidence for every comparison on an outcome basis.	bias RCTs found an association symptom improvement (RR 1.35, 95%CI 1.16-1.57, I^2=60%). • It is uncertain if ivermectin affects symptomatic infection, RR 0.22 (95%CI 0.09 to 0.53); RD -13.6% (95%CI -15.8% to -8.2%); very low certainty based on 4 low risk of bias studies. • It is uncertain if ivermectin affects hospitalizations in non-severe patients, RR 0.66 (95%CI 0.69 to 2.30); RD 2.5% (95%CI -6% to 9.6%); very low certainty from 1 RCT at low risk of bias. • It is uncertain if there are severe adverse events (RR 1.04, 95%CI 0.32 – 3.38); very low certainty from 4 low risk of bias RCTs.
Synthesis Research		
COVID nma (2021) (8) Living Systematic Review June 2021* NA*	Current up to June 24, 2021. This is a living summary of RCTs on pharmacological interventions that also considers outcomes on clinical improvement, mortality, viral negative conversion, serious adverse events, as well as time to these events. Meta-analysis is conducted for each outcome. The Cochrane Risk of Bias 2.0 tool is used assess risk of bias and GRADE is used to assess the certainty of the evidence. Results are updated weekly.	26 RCTs have investigated ivermectin. 8 high risk of bias and 18 with some concerns. Trial size was 32-476 people. No significant outcomes of treatment were reported in studies varying the dosage of ivermectin, for 4 RCTs on ivermectin vs. hydroxychloroquine or 1 RCT on Ivermectin+Doxycycline vs Hydroxychloroquine+Azithromycin. Outcomes with at least one significant result: MILD CASES • 1/18 RCTs on ivermectin vs. placebo reported faster time to PCR negative (HR 2.70, 95%CI 1.21- 6.04, 1 RCT) in mild cases. No other outcomes were significant. • 1/4 RCTs on ivermectin+Doxycyclin vs.placebo showed better clinical improvement in the placebo group (RR 0.63, 95%CI 0.45-0.87) and faster time to clinical improvement (HR 0.51, 95%CI 0.32-0.81) in the placebo group. HOSPITALIZED CASES • 1 RCT on ivermectin+Doxycycline vs. ivermectin reported more adverse

		events in the ivermectin+Doxycycline group (RR 1.69, 95%CI 1.15- 2.49). • 1 RCT on ivermectin vs. Lopinavir-Ritonavir reported faster time to PCR negative (HR= 2.02, 95%CI 1.28-3.18) among hospitalized patients in the ivermectin group. GRADE for the ivermectin outcomes ranged from very low to moderate certainty.
Bryant (2021) (10) Systematic Review Jun 2021* (AMSTAR rating high)	Search date April 26, 2021. RCTs and quasi-RCTs were included. Objective was to assess the efficacy of ivermectin treatment in reducing mortality, and in chemoprophylaxis, among people with, or at high risk of, COVID-19 infection. Secondary outcomes included hospital stay, admission to hospital/ICU and adverse outcomes. Cochrane Risk of Bias 2.0 was used. GRADE was used to assess the certainty of the evidence.	24 RCTs (n=3406 participants) met the inclusion criteria- 22 studies on treatment. • Across 15 RCTs ivermectin reduced risk of death to 2.3% vs. 7.8% among hospitalized cases (RR 0.38, 95%CI 0.19 - 0.73, I^2=49%, 15 studies) – moderate certainty evidence. This was robust in a sensitivity analysis. • For moderate/mild COVID the reduced risk of mortality RR 0.24 (95%CI 0.06 -0.94) and no association for severe COVID-19 RR 0.51 (95%CI 0.22 – 1.14). • Deterioration of disease status RR 0.35 (0.19-0.65, 7 studies). • No benefit from ivermectin was identified in prevention of ICU admission or mechanical ventilation- very low /low certainty of evidence. • No association with adverse events – low certainty.
Roman (2021) (9) Systematic Review May 2021* (AMSTAR rating high)	Search conducted March 22, 2021 for Published and preprint randomized controlled trials (RCTs) assessing ivermectin treatment effects on COVID-19 adult patients. Primary outcomes were all-cause mortality, length of stay (LOS), and adverse events (AE). Secondary outcomes included viral clearance and severe AEs. Risk of bias (RoB) conducted with the Cochrane RoB 2·0 tool. Meta-analysis was conducted. Subgroup analyses by severity of disease and RoB, and sensitivity	Ten RCTs (n=1173) were included. RCTs sample size ranged from 24 to 398 patients, and severity of COVID-19 disease was mild in 8 RCTs, moderate in one RCT, and mild and moderate in one RCT. • Ivermectin did not reduce all-cause mortality vs. controls (RR 0.37, 95%CI 0.12 to 1.13, I^2=16%, 5 RCTs, very low QoE-Quality of Evidence). ○ A significant reduction in mortality was seen across 3 RCTs at high risk of bias (RR 0.18, 95%CI 0.07-0.49; RoB p for interaction=0.1)

	analyses by time of follow-up were conducted.	○ Sensitivity analyses excluding RCTs with follow up <21 days showed no difference in all-cause mortality. • Ivermectin did not reduce LOS vs. controls (MD 0.72 days, 95%CI -0.86 to 2.29, I^2=0%, 3 RCTs, very low QoE). • Severe adverse effects were similar between ivermectin and controls (RR 0.95, 95%CI 0.85 to 1.07, I^2=0%, 3 RCTs, low QoE). • Viral clearance was similar between ivermectin and controls (RR 0.96, 95%CI 0.79 to 1.16, I2 =0%, 4 RCTs low QoE).
Hariyanto (2021) (11) Systematic Review (AMSTAR rating moderate)	Search date May 10, 2021. Published RCTs on COVID-19 and ivermectin as a treatment for COVID-19 cases were included. Outcomes: severe COVID-19, mortality, negative RT-PCR test results rate, time to negative RT-PCR test results, symptoms alleviations rate, time to symptoms alleviations and time to hospital discharge. The quality of the study was assessed using Jadad scale assessment tool for clinical trial studies. Overall meta-analysis included all studies regardless of the COVID-19 severity included in the study. Sub-group analysis separating mild/moderate and severe COVID was conducted and is noted in key observations where heterogeneity was explained or only one subgroup remained significant. Several outcomes had high heterogeneity >60% that was not explained by sub-group analysis. This variability in the outcome reduces our confidence that the meta-analytic summary represents the true value, thus the value would be expected to change with additional research.	19 RCTs with 2768 COVID-19 patients were included (10 open-label and 9 double blinded). Ivermectin was associated with: • Reduction in severity of COVID-19 (RR 0.43 [95% CI 0.23–0.81], I^2=65%, p = 0.008, 8 studies, n=1638). ○ Sub-group analysis was only significant for mild/moderate COVID-19: RR 0.44 [95%CI 0.22–0.85], p= 0.01, I^2= 47%, n = 1294. • Reduction of mortality (RR 0.31 [95% CI 0.15–0.62], p = 0.001, I^2=40%, 8 studies, n-1726). ○ Sub-group analysis of mild/moderate COVID-19 only: RR 0.15 [95%CI 0.03–0.67], p = 0.01, I^2 = 0%, n = 1169. ○ Sub group analysis of severe COVID-19: RR 0.41 [95%CI 0.16–1.04], p = 0.06, I^2 = 58%, n = 377. • Higher negative RT-PCR test results rate (RR 1.23 [95% CI 1.01–1.51], p = 0.04, I^2=91%, 9 studies, n=1205). • Shorter time to negative RT-PCR test results (mean difference [MD] −3.29 [95% CI −5.69, −0.89], p = 0.007, I^2=96%, 6 studies, n=782). • Higher symptoms alleviations rate (RR 1.23 [95% CI 1.03−1.46], p = 0.02, I^2=85%, 8 studies, n=1535). • Shorter time to symptoms alleviations (MD −0.68 [95% CI −1.07,-0.29], p = 0.0007, I^2=68%, 6 studies, n=950).

		○ Sub-group analysis of mild/moderate COVID-19 only: MD −0.65 (95% CI −1.12, −0.18), p = 0.007, I^2 = 0%, 4 studies, n = 701. ○ Sub group analysis of severe COVID-19: MD −1.00 [95% CI −1.14, −0.86), p < 0.00001, I2 = 0%, 1 study, n = 69. • Shorter time to hospital discharge (MD −2.66 [95%CI −4.49, -0.82], p = 0.004, I^2=98%, 7 studies, n=1032). Ivermectin administered to mild/moderate cases had a greater benefit of reducing severity and morality.
Karale (2021) *preprint* (12) Systematic Review May 2021* (AMSTAR rating moderate)	Search date Feb 2020 to Mar 27, 2021 Primary outcomes were overall mortality, need for intensive care unit (ICU) admission; secondary outcomes were - adverse effects, need for mechanical ventilation. Random-effects meta-analysis was conducted. Cochrane ROB and and NIH quality assessment tools were used and evidence was GRADED for certainty. 38 studies were included (n=15002) 19 RCTs, 14 observational, 6 case series; 30 included in the meta-analysis.	Mortality is reported in 22 studies: • Mortality overall: The odds of mortality in the ivermectin group were significantly lower compared to control group (OR 0.39, 95%CI 0.22-0.70, p=0.002; I^2=81%) but evidence was graded very low. • Mortality clinical trials: Subgroup analysis of 15 clinical trials (RCTs N=12, Non-RCTs N=3) and observed similar mortality benefit (OR 0.32, 95%CI 0.15-0.65, p=0.002; I^2 =65%). • Mortality benefit was not observed in severe/critical cases, thus ivermectin was only indicated as possibly beneficial to mild/moderate cases. Severity outcomes ICU admission (n=5 studies) and Mechanical ventilation (n=9) were not associated with ivermectin. Adverse events are reported in 10 studies: • Adverse events in the ivermectin treatment arms were not associated with treatment in 17 studies (245/973) vs control group (234/945). We did not find an association between ivermectin and rate of adverse events as compared to controls (OR 0.92, 95%CI 0.64- 1.33, p=0.67; I^2 =14%).
Murchu (2021) (13) Systematic review Jun 2021*	Search date January 6, 2021. Clinical trials (RCT or nRCT) were included and risk of bias assessment was conducted using the Cochrane RoB 2.0 and the certainty of evidence was assessed with GRADE.	One study on a combination intervention of oral ivermectin plus doxycycline, conducted in Iraq (n=96). Treatment: 200 µg/kg ivermectin orally daily for 2 to 3 days and 100 mg oral doxycycline twice daily for 5 to 10 days plus standard therapy.

(AMSTAR rating moderate)	The review assessed ambulatory treatments for COVID-19. 8 RCTs were included, only one was on an ivermectin plus Doxycycline treatment.	• Mean time to recovery in patients with mild/moderate disease was 6.34 days (SD = 2.4) in the intervention group compared with 13.66 days (SD = 6.4) in the control group ($P < 0.01$). • Progression to severe disease or mortality and adverse reactions did not occur in this study.
New RCTs		
Vallejos (2021) (14) RCT Aug 2020 – Feb 2021 Argentina	RCT double-blind, placebo-controlled study (n=501) "IVERCORCOVID19" ivermectin treatment to prevent hospitalization in individuals with early COVID-19 cases. Dose was according to weight: mean dose 192.37 µg/kg/day (SD ± 24.56) up to 80kg received 12mg/d for 2 days. >80kg received 18mg/d for 2 days. >110kg received 24mg/d for 2 days. Mean age was 42 years (SD ± 15.5) and the median time since symptom onset to the inclusion was 4 days [interquartile range 3-6]. ClinicalTrials.gov (NCT04529525)	• Hospitalizations: 14/250 (5.6%) ivermectin group vs. 21/251 (8.4%) placebo group (OR 0.65; 95%CI 0.32-1.31; p = 0.227). • Time to hospitalization was not statistically different between groups. • The mean time from study enrollment to invasive mechanical ventilation was 5.25 days (SD ± 1.71) in ivermectin group vs. 10 days (SD ± 2) in placebo group, (p = 0.019). • No statistically significant differences in the other secondary outcomes including polymerase chain reaction test negativity and safety outcomes.

LTE= letter to editor, * the date or location is based on citation information. QoE= quality of evidence

PROPHYLAXIS

Three systematic reviews report on the RCTs and/or clinical trials on prophylaxis have shown some protective effect of ivermectin supplementation however, the certainty in this evidence is very low to low.

Table 2: Prophylaxis (n=3)

Systematic review		
Bartoszko (2021) (15) Living Systematic Review May 2021*	Search date Feb 2020 to Mar 27, 2021 Included randomised trials of people at risk of covid-19 who were assigned to receive prophylaxis or no prophylaxis (standard care or placebo). Random effects Bayesian network meta-analysis was performed. Risk of bias was assessed by a modification of the Cochrane risk of bias	There was serious risk of bias and very serious imprecision for each outcome, thus there is very low certainty in this evidence. • The effects of ivermectin combined with iota-carrageenan on laboratory confirmed COVID-19 (52 fewer per 1000, 58 fewer to 37 fewer).

(AMSTAR quality high)	2.0 tool and GRADE was applied for the certainty of evidence.	• Ivermectin alone on laboratory confirmed COVID-19 infection (50 fewer per 1000, 59 fewer to 16 fewer). • Ivermectin alone on suspected, probable, or laboratory confirmed COVID-19 infection (159 fewer per 1000, 165 fewer to 144 fewer), remains very uncertain.
Bryant (2021) (10) Systematic Review Jun 2021* (AMSTAR rating high)	Search date April 26, 2021. RCTs and quasi-RCTs were included. Objective was to assess the efficacy of ivermectin treatment in reducing mortality, and in chemoprophylaxis, among people with, or at high risk of, COVID-19 infection. Secondary outcomes included hospital stay, admission to hospital/ICU and adverse outcomes. Cochrane Risk of Bias 2.0 was used. GRADE was used to assess the certainty of the evidence.	24 RCTs (n=3406 participants) met the inclusion criteria – 3 studies on prophylaxis. • Ivermectin prophylaxis reduced COVID-19 infection by 86% (95%CI 79-91%, 3 studies, 738 participants); low certainty of evidence.
COVID nma (2021) (8) Living Systematic Review June 2021* NA*	Current up to June 2021. This is a living summary of RCTs on pharmacological interventions. The outcomes considered were clinical improvement, mortality, viral negative conversion, serious adverse events, as well as time to these events. Meta-analysis is conducted for each outcome. The Cochrane Risk of Bias 2.0 tool is used assess risk of bias and GRADE is used to assess the certainty of the evidence. Results are updated weekly. 4 RCTs investigated ivermectin as a preventative treatment.	Ivermectin vs. placebo: 2 RCTS • A protective effect of ivermectin supplementation to prevent symptomatic COVID-19 (RR 0.13, 95%CI 0.08-0.21, 1 RCT) or confirmed COVID-19 (RR 0.20, 95%CI 0.04-0.89, 1 RCT); very low certainty of evidence. Ivermectin vs. Vitamin C: 1 RCT • No difference in incidence of symptomatic or confirmed COVID-19, adverse events, hospitalization, ICU admission or mortality. Ivermectin+Iota-Carrageenan vs. Placebo: 1 RCT • Ivermectin +Iota-Carrageenan reduced the risk of confirmed COVID-19 (RR 0.13, 95%CI 0.04-0.47), risk of symptomatic COVID-19 (RR 0.04, 95%CI 0.01-0.30), and there was no mortality in either group.

Methods:

A daily scan of the literature (published and pre-published) is conducted by the Emerging Science Group, PHAC. The scan has compiled COVID-19 literature since the beginning of the outbreak and is updated daily. Searches to retrieve relevant COVID-19 literature are conducted in Pubmed, Scopus, BioRxiv, MedRxiv, ArXiv,

SSRN, Research Square and cross-referenced with the COVID-19 information centers run by Lancet, BMJ, Elsevier, Nature and Wiley. The daily summary and full scan results are maintained in a refworks database and an excel list that can be searched. Targeted keyword searching is conducted within these databases to identify relevant citations on COVID-19 and SARS-COV-2. Search term used included: ivermectin.
This review contains research published up to July 5, 2021.
Each potentially relevant reference was examined to confirm it had relevant data and relevant data is extracted into the review.

Peer-review

This document underwent peer-review by a subject matter expert, and editorial and science to policy review by the Office of the Chief Science Officer.

Prepared by: Lisa Waddell, NML, Emerging Science Group, PHAC.

Knowledge mobilized by the Office of the Chief Science Officer: phac.ocsoevidence-bcscdonneesprobantes.aspc@canada.ca

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APPENDIX

Figure: WHO Living Guidelines on Therapeutics: Network meta-analysis figure indicates that the data and studies supporting the data for Ivermectin is weak.

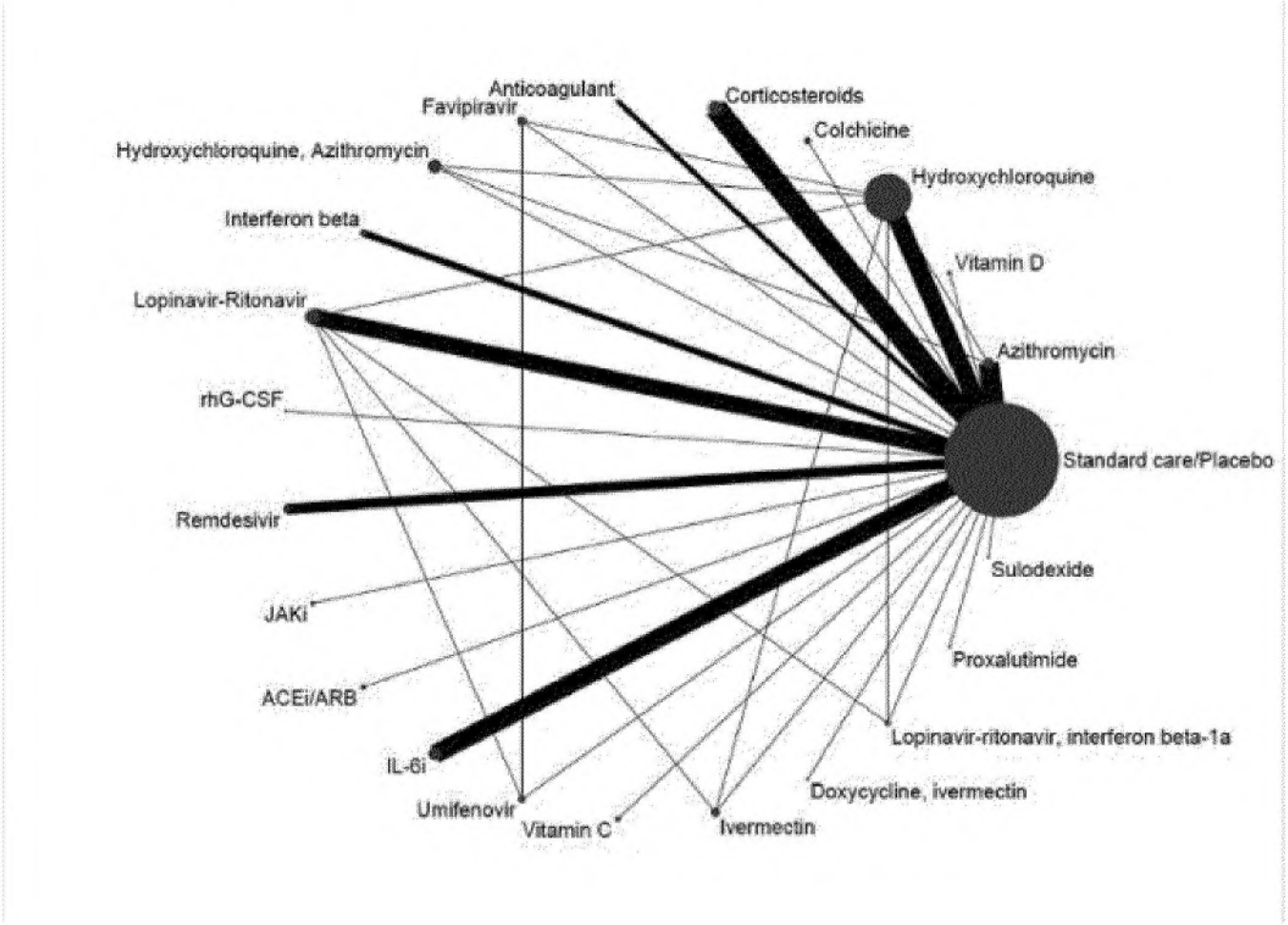


Table: WHO Living Guidelines on Therapeutics: The summary of findings analysis conducted on RCT trial on Ivermectin.

Clinical question/ PICO

Population: Patients with COVID-19 infection (all disease severities)
Intervention: Ivermectin
Comparator: Usual care

Summary

Outcome Timeframe	Study results and measurements	Absolute effect estimates Standard care	 Ivermectin	Certainty of the evidence (Quality of evidence)	Plain text summary
Mortality	Odds ratio 0.19 (CI 95% 0.09 - 0.36) Based on data from 1,419 patients in 7 studies. [1] (Randomized controlled)	70 per 1000	14 per 1000 Difference: **56 fewer** per 1000 (CI 95% 63 fewer - 44 fewer)	Very Low Due to serious risk of bias and very serious imprecision [2]	The effect of ivermectin on mortality is uncertain.
Mechanical ventilation	Odds ratio 0.51 (CI 95% 0.12 - 1.77) Based on data from 687 patients in 5 studies. (Randomized controlled)	20 per 1000	10 per 1000 Difference: **10 fewer** per 1000 (CI 95% 18 fewer - 15 more)	Very Low Due to very serious imprecision and publication bias [3]	The effect of ivermectin on mechanical ventilation is uncertain.
Viral clearance 7 days	Odds ratio 1.62 (CI 95% 0.95 - 2.86) Based on data from 625 patients in 6 studies. (Randomized controlled)	500 per 1000	618 per 1000 Difference: **118 more** per 1000 (CI 95% 13 fewer - 241 more)	Low Due to serious inconsistency and imprecision [4]	Ivermectin may increase or have no effect on viral clearance.
Hospital admission (outpatients only)	Odds ratio 0.36 (CI 95% 0.08 - 1.48) Based on data from 398 patients in 1 studies. (Randomized controlled)	50 per 1000	18 per 1000 Difference: **32 fewer** per 1000 (CI 95% 47 fewer - 23 more)	Very Low Due to extreme imprecision [5]	The effect of ivermectin on hospital admission is uncertain.
Serious adverse events	Odds ratio 3.07 (CI 95% 0.77 - 12.09) Based on data from 584 patients in 3 studies. (Randomized controlled)	9 per 1000	27 per 1000 Difference: **18 more** per 1000 (CI 95% 2 fewer - 89 more)	Low Due to very serious imprecision [6]	Ivermectin may increase the risk of serious adverse events leading to drug discontinuation.

Outcome Timeframe	Study results and measurements	Absolute effect estimates Standard care	Absolute effect estimates Ivermectin	Certainty of the evidence (Quality of evidence)	Plain text summary
Time to clinical improvement	Measured by: days Lower better Based on data from: 633 patients in 2 studies. (Randomized controlled)	11 days (Mean)	10.5 days (Mean) Difference: MD 0.5 fewer (CI 95% 1.7 fewer - 1.1 more)	Low Due to very serious imprecision [7]	Ivermectin may have little or no difference on time to clinical improvement
Duration of hospitalization	Measured by: days Lower better Based on data from: 252 patients in 3 studies. (Randomized controlled)	12.8 days (Mean)	11.7 days (Mean) Difference: MD 1.1 fewer (CI 95% 2.3 fewer - 0.1 more)	Very Low Due to serious imprecision, inconsistency and serious risk of bias [8]	The effect of ivermectin on hospital length of stay is uncertain.
Time to viral clearance	Measured by: days Lower better Based on data from: 559 patients in 4 studies. (Randomized controlled)	7.3 days (Mean)	5.7 days (Mean) Difference: MD 1.6 fewer (CI 95% 4.1 fewer - 3 more)	Very Low Due to very serious imprecision and serious risk of bias. [9]	We are uncertain whether ivermectin improves or worsen time to viral clearance

1. Systematic review (3). **Baseline/comparator:** Control arm of reference used for intervention. We elected to use the control arm of the WHO solidarity trial, reflecting usual care across countries participating in the trial.
2. **Risk of bias: Serious.** The large trial contributing most of the effect estimate was driven by studies that were not blinded.. **Inconsistency: No serious. Indirectness: No serious. Imprecision: Very Serious.** The number of total events was very small.. **Publication bias: No serious.**
3. **Inconsistency: No serious. Indirectness: No serious. Imprecision: Very Serious.** Very few events and credible intervals that include both important benefit and harm.. **Publication bias: Serious.**
4. **Inconsistency: Serious.** The point estimates varied widely and credible intervals do not substantially overlap.. **Indirectness: No serious. Imprecision: Serious.** Credible interval includes no effect.. **Publication bias: No serious.**
5. **Inconsistency: No serious. Indirectness: No serious. Imprecision: Very Serious.** Credible interval includes important benefit and harm.. **Publication bias: No serious.**
6. **Inconsistency: No serious. Indirectness: No serious. Imprecision: Serious.** Credible interval includes little to no difference.. **Publication bias: No serious.**
7. **Inconsistency: No serious. Indirectness: No serious. Imprecision: Very Serious. Publication bias: No serious.**
8. **Risk of bias: Serious.** Result driven by one study that was not blinded.. **Inconsistency: Serious.** Despite overlapping confidence intervals, point estimates discrepant.. **Indirectness: No serious. Imprecision: Serious.** Credible intervals include no difference.. **Publication bias: No serious.**
9. **Risk of bias: Serious.** Concerns around risk of bias.. **Inconsistency: No serious. Indirectness: No serious. Imprecision: Very Serious.** Credible interval includes important benefit and important harm.. **Publication bias: No serious.**

Table: Evidence Synthesis sources that are websites and reports that were identified, but are not summarized above due to identified limitations:

Source	Methods	Key outcomes
Ivermectin for COVID-19: real-time meta-analysis of 60 studies. https://ivmmeta.com Living Meta-analysis Accessed July 6, 2021	• Their on-going search strategy is sensitive to the identification of relevant literature. • Primary Outcome: not stated.	A list of 61 studies are included as of July 6, 2021; there are short descriptions of each study in the appendix as well as the outcomes extracted for that study. These include: - Early treatment

	• All study designs included. • No risk of bias assessment of the included studies. • Meta-analysis conducted with no definition of heterogeneity. • Arbitrarily broad inclusion criteria, and no specific outcomes stated for inclusion led to a high number of RCTs identified, however few report clinically relevant outcomes and participants.	- Late treatment - Prophylaxis Several meta-analysis results are included, however meta-analyses merge together study designs and different outcomes, which is not appropriate.
Lawrie (2021) Report (not peer reviewed). Ivermectin reduces the risk of death from COVID-19 -a rapid review and meta-analysis in support of the recommendation of the Front Line COVID-19 Critical Care Alliance. Published: 5 January 2021. DOI: 10.13140/RG.2.2.27751.88486. Accessed June 25, 2021	This rapid review and meta-analysis followed many steps of conducting rapid reviews. Search strategy not specified, references taken from a website: Primary Outcome: death Study design: RCT and observational studies included. Risk of Bias: ROBINS-I for non-randomized studies of interventions and the Cochrane handbook for randomized trials. Meta-analysis methods: Random effects meta-analysis and heterogeneity was evaluated by I^2 and was assessed by visual inspection of forest plots. Study designs were pooled together (not appropriate), and no analysis by risk of bias was conducted. Studies examined were those included by Kory 2021.	15 studies (2 reported two studies), 10 randomized controlled trials and 7 controlled observational studies (6 considered low, 9 moderate and 2 high risk of bias.) Outcome RR CERTAINTY (# studies): • Mortality: RR 0.17 (95% 0.08 to 0.35) MODERATE (5 studies) • Condition improvement (mild to moderate COVID19) RR 1.34 (1.22 to 1.48) MODERATE (5 studies) • Condition improvement (severe COVID-19) RR 1.88 (1.54 to 2.30) LOW (1 study) • Condition deterioration RR 0.47 (0.29 to 0.77) MODERATE (4 studies) • Admission to ICU RR 0.11 (0.01 to 0.80) LOW (1 study) • Prophylaxis to prevent COVID-19 infection RR 0.12 (0.08 to 0.18) MODERATE (4 studies) NOTE: Lawrie excluded 12 of the 27 studies considered by Kory.

Kory (2021) Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19. American Journal of Therapeutics Review May 2021 (Journal not indexed, identified in grey literature search) Previous preprint version posted on this site: https://covid19criticalcare.com/	This is a review with meta-analysis and there are no methods. Primary Outcome: time to clinical recovery and mortality. Included study: RCT and observational studies. Published peer-reviewed studies, preprints, expert meta-analyses, and numerous epidemiological analyses of regions with Ivermectin distribution campaigns. Meta-analyses are not underpinned by a systematic review. There is no protocol, no inclusion criteria, no information on search or risk of bias assessment.	27 studies included, meta-analyses based on 18 randomized controlled treatment trials of Ivermectin in COVID-19 have found large, statistically significant reductions in mortality, time to clinical recovery, and time to viral clearance. Furthermore, results from numerous controlled prophylaxis trials report significantly reduced risks of contracting COVID-19 with the regular use of Ivermectin.

To:	Sleno, Rory (HC/SC)
Cc:	Canada Vigilance (HC/SC); Morrison, Heather (HC/SC)
Subject:	Correspondence form Marketed Health Products Directorate- CV-2021-156 -urgent (COVID-19)- Ivermectin
Attachments:	Canada Vigilance Request Form_ivermectin.docx

Dear Rory,

Please find attached a response on behalf of the **Canada Vigilance Program**. In order to avoid large email files, your search results are saved (PDF documents; Excel documents only for search results with more than 2 AR reports) 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 **March 4th , 2021 , a search o**f the **Canada Vigilance Program Database** has been conducted.

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

Search #1:

1. Serious reports received for **Ivermectin** with a ***suspected*** role**;**
2 All reported reactions.
3. Reports received and entered into the database from **January 1, 2020 to March 4th, 2021*.**

7 reports were retrieved with the parameters of search #1.

* ***Please note*** that there may be reports which have been received but not yet processed and entered into the database. New and additional information may be available at a later date.

The summary 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-2021-156

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.

Thank you,

Nicoleta

From: Sleno, Rory (HC/SC) <rory.sleno@canada.ca>
Sent: 2021-03-05 4:40 PM
To: Canada Vigilance (HC/SC) <hc.canada.vigilance.sc@canada.ca>
Subject: CV search request - urgent (COVID-19)

Hello,

Please find enclosed an urgent CV search request. This is related to COVID-19 signal detection.

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

Canada Vigilance
Summary of Reported Adverse Reactions

Search Criteria

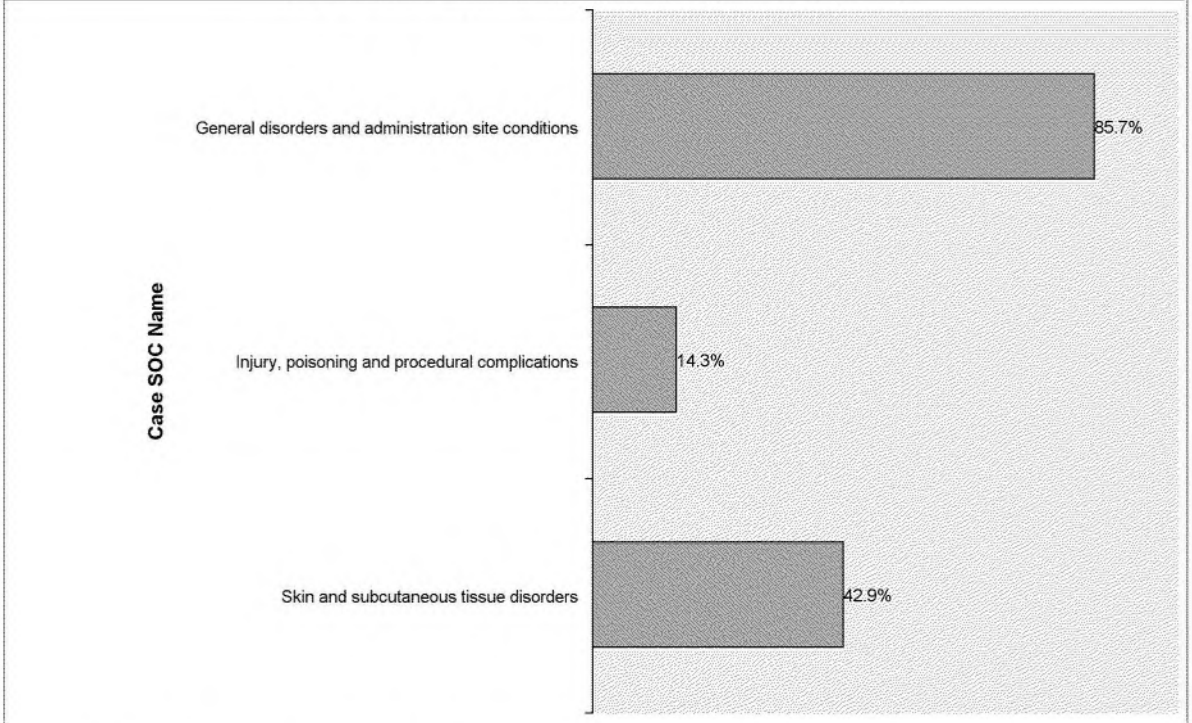
Report Runtime	2021-03-05 - 10:50 PM 16.3 minutes
Range for Initial Date Received	2020-01-01 to 2021-03-04
AER No(s)	All
Country of Occurence	Domestic
Case Serious?	All
Case Outcome	All
Report Source	All
Source Company Unit	All
Patient Gender	All
Range for Age (years)	All
Reporter Type	All
Product Role	Suspect
Product Class	All
Product Description	All
DIN/NPN	All
Active Ingredient(s)	IVERMECTIN ivermectine ivermectin
Dosage Form	All
Route of Administration	All
ATC	All
ATC Pattern	All
Reaction PTs	All
SMQ(s)	--
SMQ MedDRA Version	--
SMQ Broad or Narrow Search	NA
AER(s) have at least one Preferred	**Term related to the following (multi-axial concept)**
System Organ Class	All
High Level Group Term	All
High Level Term	All

CAVEAT: This summary is based on information from adverse event reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement. (10/2007)

Report Runtime 2021-03-05 - 10:34:07 PM
Initial Date of Receipt 2020-01-01 to 2021-03-04
Total Number of Reports 7 Reports

Canada Vigilance
Summary of Reported Adverse Reactions

Occurrences by Primary System Organ Class (SOC)



Total No. of Reports: (Denominator)	7

Number of reports (percentage) with one or more reaction terms in the SOC(s) above

MedDRA V23.1

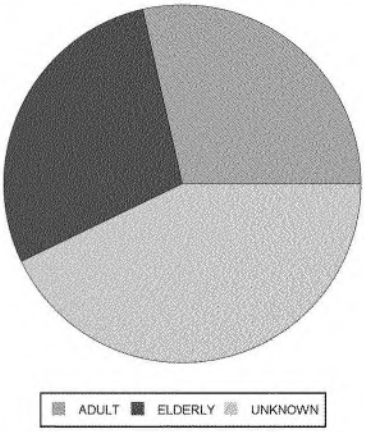
Age Group

ADULT	2
ELDERLY	2
UNKNOWN	3

Patient Sex

Female	5	71.43 %
Male	2	28.57 %

Age Group



The Definition for age groups has been taken from the International Conference on Harmonization (ICH) and have been defined as follows:
- Infant - greater than 27 days and less than 2 years
- Child - greater or equal to 2 and less than 12 years
- Adolescent - greater or equal to 12 and less than 19 years
- Adult - greater or equal to 19 and less than 65 years
- Elderly - greater or equal to 65 years

Reason for Seriousness

Death	0
LifeThreatening	0
Hospitalisation Required	0
Disability	0
Congenital Anomaly	0

Serious Reports

Not Serious	7

Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime 2021-03-05 - 10:34:07 PM
Initial Date of Receipt 2020-01-01 to 2021-03-04
Total Number of Reports 7 Reports

AER No (Version)	Comments
000908111 (0)	
000908115 (0)	
000916662 (1)	
000933599 (0)	
000938012 (0)	
000938422 (0)	
000938758 (0)	
Total: 7	

Summary of Selected Fields for Market Authorization Holders

Report Runtime 2021-03-05 - 10:34:07 PM
Initial Date of Receipt 2020-01-01 to 2021-03-04
Total Number of Reports 7 Reports

Aer No	Serious?	Reporter Type	Source	MAH No	Outcome	Notes
000908111	Not Serious	Consumer/other non health professional	MAH		Unknown	
000908115	Not Serious	Consumer/other non health professional	MAH		Unknown	
000916662	Not Serious	Pharmacist	MAH		Unknown	
000933599	Not Serious	Consumer/other non health professional	MAH		Not recovered/not resolved	
000938012	Not Serious	Consumer/other non health professional	MAH		Unknown	
000938422	Not Serious	Pharmacist	Community		Recovered/resolved	
000938758	Not Serious	Pharmacist	Community		Unknown	
Total 7						

Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2021-03-05 - 10:34:07 PM
Initial Date of Receipt: 2020-01-01 to 2021-03-04
Total Number of Reports: 7 Reports

No Duplicate or Linked Reports

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Source Country	Type of Report	Reporter Type
000908111	0	2020-01-20	2020-01-20	MAH		Canada	Spontaneous	Consumer/other non health professional

Record Type	Link Aer No

Serious Report?
Not Serious

Death:	N/A	Disability:	N/A	Congenital Anomaly:	N/A
Life Threatening:	N/A	Hospitalization:	N/A	Other Medically Imp Condition:	N/A

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
ROSIVER	Suspect	Cream	Topical	1.0000 Dosage forms		

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Drug ineffective	MedDRA V23.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2021-03-05 - 10:34:07 PM
Initial Date of Receipt: 2020-01-01 to 2021-03-04
Total Number of Reports: 7 Reports

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Source Country	Type of Report	Reporter Type
000908115	0	2020-01-20	2020-01-20	MAH		Canada	Spontaneous	Consumer/other non health professional

Record Type	Link Aer No

Serious Report?
Not Serious

Death:	N/A	Disability:	N/A	Congenital Anomaly:	N/A
Life Threatening:	N/A	Hospitalization:	N/A	Other Medically Imp Condition:	N/A

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
ROSIVER	Suspect	Cream	Topical	1.0000 Dosage forms		1 Months

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Drug ineffective	MedDRA V23.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2021-03-05 - 10:34:07 PM
Initial Date of Receipt: 2020-01-01 to 2021-03-04
Total Number of Reports: 7 Reports

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Source Country	Type of Report	Reporter Type
000916662	1	2020-05-08	2020-10-08	MAH		Canada	Spontaneous	Pharmacist

Record Type	Link Aer No

Serious Report?
Not Serious

Death:	N/A	Disability:	N/A	Congenital Anomaly:	N/A
Life Threatening:	N/A	Hospitalization:	N/A	Other Medically Imp Condition:	N/A

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Unknown

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
ROSIVER	Suspect	Cream	Topical	1.0000 Dosage forms		

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Condition aggravated	MedDRA V23.1	
Drug ineffective	MedDRA V23.1	
Rash	MedDRA V23.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2021-03-05 - 10:34:07 PM
Initial Date of Receipt: 2020-01-01 to 2021-03-04
Total Number of Reports: 7 Reports

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Source Country	Type of Report	Reporter Type
000933599	0	2020-11-25	2020-11-25	MAH		Canada	Spontaneous	Consumer/other non health professional

Record Type	Link Aer No

Serious Report?
Not Serious

Death:	N/A	Disability:	N/A	Congenital Anomaly:	N/A
Life Threatening:	N/A	Hospitalization:	N/A	Other Medically Imp Condition:	N/A

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male			Not recovered/not resolved

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
METROGEL	Suspect	GEL	Topical		1 every 1 Days	
ROSIVER	Suspect	Cream	Topical		2 every 1 Days	
blood pressure pill	Concomitant					
VITAMIN C	Concomitant	NOT SPECIFIED				
VITAMIN D	Concomitant	NOT SPECIFIED				

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Drug ineffective	MedDRA V23.1	
Off label use	MedDRA V23.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2021-03-05 - 10:34:07 PM
Initial Date of Receipt: 2020-01-01 to 2021-03-04
Total Number of Reports: 7 Reports

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Source Country	Type of Report	Reporter Type
000938012	0	2021-01-29	2021-01-29	MAH		Canada	Spontaneous	Consumer/other non health professional

Record Type	Link Aer No

Serious Report?
Not Serious

Death:	N/A	Disability:	N/A	Congenital Anomaly:	N/A
Life Threatening:	N/A	Hospitalization:	N/A	Other Medically Imp Condition:	N/A

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
ROSIVER	Suspect	Cream	Topical			

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Adverse event	MedDRA V23.1	
Drug ineffective	MedDRA V23.1	

Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2021-03-05 - 10:34:07 PM
Initial Date of Receipt: 2020-01-01 to 2021-03-04
Total Number of Reports: 7 Reports

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Source Country	Type of Report	Reporter Type
000938422	0	2021-01-29	2021-01-29	Community		Canada	Spontaneous	Pharmacist

Record Type	Link Aer No

Serious Report?
Not Serious

Death:	N/A	Disability:	N/A	Congenital Anomaly:	N/A
Life Threatening:	N/A	Hospitalization:	N/A	Other Medically Imp Condition:	N/A

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female	[redacted]	[redacted]	Recovered/resolved

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
ONRELTEA	Suspect	GEL	Topical		2 every 1 Days	20 Days
ROSIVER	Suspect	Cream	Topical		1 every 1 Days	20 Days

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Erythema	MedDRA V23.1	10 Days
Skin burning sensation	MedDRA V23.1	

Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2021-03-05 - 10:34:07 PM
Initial Date of Receipt: 2020-01-01 to 2021-03-04
Total Number of Reports: 7 Reports

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Source Country	Type of Report	Reporter Type
000938758	0	2021-02-03	2021-02-03	Community		Canada	Spontaneous	Pharmacist

Record Type	Link Aer No

Serious Report?
Not Serious

Death:	N/A	Disability:	N/A	Congenital Anomaly:	N/A
Life Threatening:	N/A	Hospitalization:	N/A	Other Medically Imp Condition:	N/A

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Unknown

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
ROSIVER	Suspect	Cream	Topical		1 every 1 Days	

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Condition aggravated	MedDRA V23.1	
Drug ineffective	MedDRA V23.1	
Rosacea	MedDRA V23.1	

Lot Number and Expiration Date Information available for Products in this Line Listing

Aer No	Source	Serious	Product Description	Lot Number	Expiration Date Text
000916662	MAH	Not Serio	ROSIVER	9414244	/07/2021
000938422	Community	Not Serio	ONRELTEA	9516008	-OCT-2021
000938422	Community	Not Serio	ROSIVER	0414019	-MAR-2020

2

Indications for all products

Aer No	Product Description	Product Flag	Indication
000908111	ROSIVER	Suspect	Rosacea
000908115	ROSIVER	Suspect	Rosacea
000916662	ROSIVER	Suspect	Rosacea
000933599	METROGEL	Suspect	Rosacea
000933599	ROSIVER	Suspect	Rosacea
000938012	ROSIVER	Suspect	Product used for unknown indication
000938422	ONRELTEA	Suspect	Rosacea
000938422	ROSIVER	Suspect	Rosacea
000938758	ROSIVER	Suspect	Rosacea

Indications for all products

Product As Reported for Suspect Products only

Aer No	Product Description (Name of product as displayed in the database)	Product as Reported (Name of product as reported by the Reporter)
000908111	ROSIVER	rosiver
000908115	ROSIVER	rosiver
000916662	ROSIVER	rosiver
000933599	blood pressure pill	blood pressure pill
000933599	METROGEL	metrogel
000933599	ROSIVER	rosiver
000933599	VITAMIN C	vitamin c
000933599	VITAMIN D	vitamin d
000938012	ROSIVER	rosiver
000938422	ONRELTEA	Onreltea Gel
000938422	ROSIVER	Rosiver
000938758	ROSIVER	Rosiver

7

Please discard this report before distributing this Document

Known Dupl./Link AER(s)

Type	Aer No	Dupl./Link case AER No
Count:		

Case(s) without Reaction Terms

Aer No	Workflow

Case(s) in Workflow

Aer No	Workflow

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Aer No	Version No	Init Rec Date	Follow-up Rec Date	Report Type	Report Feature	Source	MAH No	Seriousness	Congenital Anomaly Code	Death Code	Disability Code	Hosp Required C
2	000908111	0.00	2020-01-20	2020-01-20	Spontaneous	Adverse event	MAH		Not Serious				
3	000908115	0.00	2020-01-20	2020-01-20	Spontaneous	Adverse event	MAH		Not Serious				
4	000916662	1.00	2020-05-08	2020-10-08	Spontaneous		MAH		Not Serious				
5	000916662	1.00	2020-05-08	2020-10-08	Spontaneous		MAH		Not Serious				
6	000916662	1.00	2020-05-08	2020-10-08	Spontaneous		MAH		Not Serious				
7	000933599	0.00	2020-11-25	2020-11-25	Spontaneous		MAH		Not Serious				
8	000933599	0.00	2020-11-25	2020-11-25	Spontaneous		MAH		Not Serious				
9	000933599	0.00	2020-11-25	2020-11-25	Spontaneous		MAH		Not Serious				
10	000933599	0.00	2020-11-25	2020-11-25	Spontaneous		MAH		Not Serious				
11	000933599	0.00	2020-11-25	2020-11-25	Spontaneous		MAH		Not Serious				
12	000933599	0.00	2020-11-25	2020-11-25	Spontaneous		MAH		Not Serious				
13	000933599	0.00	2020-11-25	2020-11-25	Spontaneous		MAH		Not Serious				

	N	O	P	Q	R	S	T	U	V	W	X	Y	Z
1	Life Threatening	Other Medically I	Outcome	Age Group	Age (years)	Sex	Height	Height Unit	Weight	Weight Unit	Medically Confirmed	Reporter Type	Product Flag
2		2	Unknown		0.000000	Female					No	Consumer/other non health professional	Suspect
3		2	Unknown		0.000000	Female					No	Consumer/other non health professional	Suspect
4			Unknown		70.000000	Male					Yes	Pharmacist	Suspect
5			Unknown		70.000000	Male					Yes	Pharmacist	Suspect
6			Unknown		70.000000	Male					Yes	Pharmacist	Suspect
7			Not recovered/not resolved		79.000000	Male					No	Consumer/other non health professional	Suspect
8			Not recovered/not resolved		79.000000	Male					No	Consumer/other non health professional	Suspect
9			Not recovered/not resolved		79.000000	Male					No	Consumer/other non health professional	Suspect
10			Not recovered/not resolved		79.000000	Male					No	Consumer/other non health professional	Suspect
11			Not recovered/not resolved		79.000000	Male					No	Consumer/other non health professional	Concomitant
12			Not recovered/not resolved		79.000000	Male					No	Consumer/other non health professional	Concomitant
13			Not recovered/not resolved		79.000000	Male					No	Consumer/other non health professional	Concomitant

	AA	AB	AC	AD	AE	AF	AG
1	**Trade Name**	**Form of Admin**	**Dosing**	**Route Admin**	**Frequency**	**Therapy Duration**	**Therapy Duration Unit**
2	ROSIVER	Cream	1.0000 Dosage forms	Topical			
3	ROSIVER	Cream	1.0000 Dosage forms	Topical		1	Months
4	ROSIVER	Cream	1.0000 Dosage forms	Topical			
5	ROSIVER	Cream	1.0000 Dosage forms	Topical			
6	ROSIVER	Cream	1.0000 Dosage forms	Topical			
7	ROSIVER	Cream		Topical	2 every 1 Days		
8	ROSIVER	Cream		Topical	2 every 1 Days		
9	METROGEL	GEL		Topical	1 every 1 Days		
10	METROGEL	GEL		Topical	1 every 1 Days		
11	blood pressure pill						
12	blood pressure pill						
13	VITAMIN C	NOT SPECIFIED					

	AH	AI	AJ	AK	AL	AM
1	**Product Indications**	**Case SOC Name**	**PT Name**	**Reaction Meddra V**		
2	(01) Rosacea	General disorders and administration site conditions	Drug ineffective	MedDRA V23.1		
3	(01) Rosacea	General disorders and administration site conditions	Drug ineffective	MedDRA V23.1		
4	(01) Rosacea	General disorders and administration site conditions	Condition aggravated	MedDRA V23.1		
5	(01) Rosacea	General disorders and administration site conditions	Drug ineffective	MedDRA V23.1		
6	(01) Rosacea	Skin and subcutaneous tissue disorders	Rash	MedDRA V23.1		
7	(01) Rosacea	General disorders and administration site conditions	Drug ineffective	MedDRA V23.1		
8	(01) Rosacea	Injury, poisoning and procedural complications	Off label use	MedDRA V23.1		
9	(02) Rosacea	General disorders and administration site conditions	Drug ineffective	MedDRA V23.1		
10	(02) Rosacea	Injury, poisoning and procedural complications	Off label use	MedDRA V23.1		
11	(03)	General disorders and administration site conditions	Drug ineffective	MedDRA V23.1		
12	(03)	Injury, poisoning and procedural complications	Off label use	MedDRA V23.1		
13	(04)	General disorders and administration site conditions	Drug ineffective	MedDRA V23.1		

	A	B	C	D	E	F	G	H	I	J	K	L	M
14	000933599	0.00	2020-11-25	2020-11-25	Spontaneous		MAH		Not Serious				
15	000933599	0.00	2020-11-25	2020-11-25	Spontaneous		MAH		Not Serious				
16	000933599	0.00	2020-11-25	2020-11-25	Spontaneous		MAH		Not Serious				
17	000938012	0.00	2021-01-29	2021-01-29	Spontaneous		MAH		Not Serious				
18	000938012	0.00	2021-01-29	2021-01-29	Spontaneous		MAH		Not Serious				
19	000938422	0.00	2021-01-29	2021-01-29	Spontaneous		Community		Not Serious	2	2	2	2
20	000938422	0.00	2021-01-29	2021-01-29	Spontaneous		Community		Not Serious	2	2	2	2
21	000938422	0.00	2021-01-29	2021-01-29	Spontaneous		Community		Not Serious	2	2	2	2
22	000938422	0.00	2021-01-29	2021-01-29	Spontaneous		Community		Not Serious	2	2	2	2
23	000938758	0.00	2021-02-03	2021-02-03	Spontaneous		Community		Not Serious	2	2	2	2
24	000938758	0.00	2021-02-03	2021-02-03	Spontaneous		Community		Not Serious	2	2	2	2
25	000938758	0.00	2021-02-03	2021-02-03	Spontaneous		Community		Not Serious	2	2	2	2
26													

	N	O	P	Q	R	S	T	U	V	W	X	Y	Z
14			Not recovered/not resolved		79.000000	Male					No	Consumer/other non health professional	Concomitant
15			Not recovered/not resolved		79.000000	Male					No	Consumer/other non health professional	Concomitant
16			Not recovered/not resolved		79.000000	Male					No	Consumer/other non health professional	Concomitant
17			Unknown		0.000000	Female					No	Consumer/other non health professional	Suspect
18			Unknown		0.000000	Female					No	Consumer/other non health professional	Suspect
19	2	2	Recovered/resolved		32.000000	Female	173.000000	Centimeter	63.500000	Kilogram	Yes	Pharmacist	Suspect
20	2	2	Recovered/resolved		32.000000	Female	173.000000	Centimeter	63.500000	Kilogram	Yes	Pharmacist	Suspect
21	2	2	Recovered/resolved		32.000000	Female	173.000000	Centimeter	63.500000	Kilogram	Yes	Pharmacist	Suspect
22	2	2	Recovered/resolved		32.000000	Female	173.000000	Centimeter	63.500000	Kilogram	Yes	Pharmacist	Suspect
23	2	2	Unknown		58.000000	Female					Yes	Pharmacist	Suspect
24	2	2	Unknown		58.000000	Female					Yes	Pharmacist	Suspect
25	2	2	Unknown		58.000000	Female					Yes	Pharmacist	Suspect
26													

	AA	AB	AC	AD	AE	AF	AG
14	VITAMIN C	NOT SPECIFIED					
15	VITAMIN D	NOT SPECIFIED					
16	VITAMIN D	NOT SPECIFIED					
17	ROSIVER	Cream		Topical			
18	ROSIVER	Cream		Topical			
19	ROSIVER	Cream		Topical	1 every 1 Days	20	Days
20	ROSIVER	Cream		Topical	1 every 1 Days	20	Days
21	ONRELTEA	GEL		Topical	2 every 1 Days	20	Days
22	ONRELTEA	GEL		Topical	2 every 1 Days	20	Days
23	ROSIVER	Cream		Topical	1 every 1 Days		
24	ROSIVER	Cream		Topical	1 every 1 Days		
25	ROSIVER	Cream		Topical	1 every 1 Days		
26							

	AH	AI	AJ	AK	AL	AM
14	(04)	Injury, poisoning and procedural complications	Off label use	MedDRA V23.1		
15	(05)	General disorders and administration site conditions	Drug ineffective	MedDRA V23.1		
16	(05)	Injury, poisoning and procedural complications	Off label use	MedDRA V23.1		
17	(01) Product used for unknown indication	General disorders and administration site conditions	Adverse event	MedDRA V23.1		
18	(01) Product used for unknown indication	General disorders and administration site conditions	Drug ineffective	MedDRA V23.1		
19	(01) Rosacea	Skin and subcutaneous tissue disorders	Erythema	MedDRA V23.1		
20	(01) Rosacea	Skin and subcutaneous tissue disorders	Skin burning sensation	MedDRA V23.1		
21	(02) Rosacea	Skin and subcutaneous tissue disorders	Erythema	MedDRA V23.1		
22	(02) Rosacea	Skin and subcutaneous tissue disorders	Skin burning sensation	MedDRA V23.1		
23	(01) Rosacea	General disorders and administration site conditions	Condition aggravated	MedDRA V23.1		
24	(01) Rosacea	General disorders and administration site conditions	Drug ineffective	MedDRA V23.1		
25	(01) Rosacea	Skin and subcutaneous tissue disorders	Rosacea	MedDRA V23.1		
26						

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Aer No	Version No	Init Rec Date	Follow-up Rec Date	Report Type	Report Feature	Source	MAH No	Seriousness	Congenital Anomaly Code	Death Code	Disability Code	Hosp Required Code
2	000908111	0.00	2020-01-20	2020-01-20	Spontaneous	Adverse event	MAH		Not Serious				
3	000908115	0.00	2020-01-20	2020-01-20	Spontaneous	Adverse event	MAH		Not Serious				
4	000916662	1.00	2020-05-08	2020-10-08	Spontaneous		MAH		Not Serious				
5	000933599	0.00	2020-11-25	2020-11-25	Spontaneous		MAH		Not Serious				
6	000938012	0.00	2021-01-29	2021-01-29	Spontaneous		MAH		Not Serious				
7	000938422	0.00	2021-01-29	2021-01-29	Spontaneous		Community		Not Serious	2	2	2	2
8	000938758	0.00	2021-02-03	2021-02-03	Spontaneous		Community		Not Serious	2	2	2	2
9													

	N	O	P	Q	R	S	T	U	V	W	X	Y
1	Life Threatening Code	Other Medically Imp Cond Code	Outcome	Age Group	Age (years)	Sex	Height	Height Unit	Weight	Weight Unit	Medically Confirmed	Reporter Type
2		2	Unknown		0.000000	Female					No	Consumer/other non health professional
3		2	Unknown		0.000000	Female					No	Consumer/other non health professional
4			Unknown		70.000000	Male					Yes	Pharmacist
5			Not recovered/not resolved		79.000000	Male					No	Consumer/other non health professional
6			Unknown		0.000000	Female					No	Consumer/other non health professional
7	2	2	Recovered/resolved		32.000000	Female	173.000000	Centimeter	63.500000	Kilogram	Yes	Pharmacist
8	2	2	Unknown		58.000000	Female					Yes	Pharmacist
9												

	Z	AA	AB	AC
1	**Trade Name**	**Product Therapy details**	**Product Indications**	**Reaction Terms**
2	(01-S) ROSIVER	(01) Cream, 1 Dosage forms, Topical,	(01) Rosacea	(1) SOC: General disorders and administration site conditions PT: Drug ineffective
3	(01-S) ROSIVER	(01) Cream, 1 Dosage forms, Topical, for 1 Months	(01) Rosacea	(1) SOC: General disorders and administration site conditions PT: Drug ineffective
4	(01-S) ROSIVER	(01) Cream, 1 Dosage forms, Topical,	(01) Rosacea	(3) SOC: General disorders and administration site conditions PT: Drug ineffective (2) SOC: General disorders and administration site conditions PT: Condition aggravated (1) SOC: Skin and subcutaneous tissue disorders PT: Rash
5	(01-S) ROSIVER (02-S) METROGEL (03-C) blood pressure pill (04-C) VITAMIN C (05-C) VITAMIN D	(01) Cream, , Topical, 2 every 1 Days (02) GEL, , Topical, 1 every 1 Days (03) , , , (04) NOT SPECIFIED, , , (05) NOT SPECIFIED, , ,	(01) Rosacea (02) Rosacea (03) (04) (05)	(1) SOC: General disorders and administration site conditions PT: Drug ineffective (2) SOC: Injury, poisoning and procedural complications PT: Off label use
6	(01-S) ROSIVER	(01) Cream, , Topical,	(01) Product used for unknown indication	(2) SOC: General disorders and administration site conditions PT: Adverse event (1) SOC: General disorders and administration site conditions PT: Drug ineffective
7	(01-S) ROSIVER (02-S) ONRELTEA	(01) Cream, , Topical, 1 every 1 Days for 20 Days (02) GEL, , Topical, 2 every 1 Days for 20 Days	(01) Rosacea (02) Rosacea	(2) SOC: Skin and subcutaneous tissue disorders PT: Skin burning sensation (1) SOC: Skin and subcutaneous tissue disorders PT: Erythema
8	(01-S) ROSIVER	(01) Cream, , Topical, 1 every 1 Days	(01) Rosacea	(2) SOC: General disorders and administration site conditions PT: Condition aggravated (1) SOC: General disorders and administration site conditions PT: Drug ineffective (3) SOC: Skin and subcutaneous tissue disorders PT: Rosacea
9				

	AD
1	**Reaction Meddra Version**
2	MedDRA V23.1
3	MedDRA V23.1
4	MedDRA V23.1
5	MedDRA V23.1
6	MedDRA V23.1
7	MedDRA V23.1
8	MedDRA V23.1
9	

Canada Vigilance Summary of Reported Adverse Reactions

Search Criteria

Report Runtime	2021-03-05 - 10:50 PM 16.3 minutes
Range for Initial Date Received	2020-01-01 to 2021-03-04
AER No(s)	All
Country of Occurence	Domestic
Case Serious?	All
Case Outcome	All
Report Source	All
Source Company Unit	All
Patient Gender	All
Range for Age (years)	All
Reporter Type	All
Product Role	Suspect
Product Class	All
Product Description	All
DIN/NPN	All
Active Ingredient(s)	IVERMECTIN ivermectine ivermectin
Dosage Form	All
Route of Administration	All
ATC	All
ATC Pattern	All
Reaction PTs	All
SMQ(s)	--
SMQ MedDRA Version	--
SMQ Broad or Narrow Search	NA
AER(s) have at least one Preferred	**Term related to the following (multi-axial concept)**
System Organ Class	All
High Level Group Term	All
High Level Term	All

Bones, Christopher (HC/SC)

From: Cain, Francoise (HC/SC) <francoise.cain@canada.ca>
Sent: 2021-02-18 2:38 PM
To: Mineau, Philippe (HC/SC)
Subject: RE: Ivermectin availability for COVID-19 treatment in Canada as in the U.S.A.

Thanks done!

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-02-18 2:35 PM
To: Cain, Francoise (HC/SC) <francoise.cain@canada.ca>
Subject: RE: Ivermectin availability for COVID-19 treatment in Canada as in the U.S.A.

You can respond with the message below, thank you!
P

Dear [redacted]

Thank you for your letter dated February 18th, 2021, regarding Ivermectin as a potential treatment for Covid-19 in Canada.

Health Canada is closely tracking all potential therapeutic treatments, vaccines, diagnostic tests, medical devices, and disinfectants currently available and in development in Canada and abroad. Every day, we are adding to our knowledge of COVID-19, keeping pace with the rapid growth of new scientific evidence as it emerges.

Ivermectin (brand name STROMECTOL) is an antiparasitic drug authorized by Health Canada for the treatment of parasitic worm infections, specifically intestinal strongyloidiasis and onchocerciasis. STROMECTOL has been marketed in Canada since 2018.

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.

The manufacturer of ivermectin in Canada, Merck, has also issued a public statement (available at https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/) on the use of ivermectin during the COVID-19 pandemic, stating that:

"It is important to note that, to-date, [MERCK's] analysis has identified:

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

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. Heath 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 (this is referred to as "off-label use"), based on other sources of information such as medical literature. Off-label use falls under the practice of medicine and is regulated at the provincial and territorial level.

For drugs that have potential to be helpful in treating COVID-19, Health Canada encourages drug manufacturers to conduct clinical trials. This would provide an opportunity for the healthcare community to collect information on the effectiveness of the treatment and its associated risks. Evidence from well-designed studies is needed to determine whether ivermectin 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. 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.

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.

I hope that this information is helpful, and I thank you for writing to share your views.

Sincerely,

Therapeutic Products Directorate, Health Canada.

From: Cain, Francoise (HC/SC) <francoise.cain@canada.ca>
Sent: 2021-02-18 2:20 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: FW: Ivermectin availability for COVID-19 treatment in Canada as in the U.S.A.

Ivermectin.....

Therefore, for us who are wary of possible future side effects that could be harmful from these vaccines, we now have an effective alternative solution if it is made available in Canada, rather than being forced to be injected by these vaccines.

Not sure he is looking for a response....please advise, thanks

---

From [redacted]
Sent: 2021-02-18 2:07 PM
To: TPD General / Général DPT (HC/SC) <hc.tpdgeneral-generaldpt.sc@canada.ca>
Subject: Ivermectin availability for COVID-19 treatment in Canada as in the U.S.A.

Are you aware that the U.S. NIH (National Institutes of Health), had recently included the drug Ivermectin in its roster for treating COVID-19 along with monoclonal antibodies and convalescent plasma that are currently being used? This drug that has been used to treat parasite infections has now been found to be a miracle drug for treating COVID-19. Dr. Pierre Kory, President of FLCCC and their team of research doctors believe that ivermectin when taken (based on completed surveys), that it attaches to the spiked protein of the corona virus preventing it from affecting our cells as a prophylactic, and also as an anti-inflammatory agent in hospital use (see Dr. Pierre Kory testifies to Senate Committee about Ivermectin, Dec. 8, 2020 on the flccc.net website opening page).

Since several other countries have also adopted this drug into their health care systems, Canada needs to do the same rather than relying totally on the current experimental vaccines to stem the tide of this virus to get our economy back to pre-pandemic conditions. Therefore, for us who are wary of possible future side effects that could be harmful from these vaccines, we now have an effective alternative solution if it is made available in Canada, rather than being forced to be injected by these vaccines.

The following information and links are from the flccc.net website:

NIH (National Institutes of Health) Revises Treatment Guidelines for Ivermectin for the Treatment of COVID-19

Ivermectin is Now a Treatment Option for Health Care Providers!

January 14, 2021 – One week after Dr. Paul Marik and Dr. Pierre Kory – founding members of the Front Line COVID-19 Critical Care Alliance (FLCCC) – along with Dr. Andrew Hill, researcher and consultant to the World Health Organization (WHO), presented their data before the NIH Treatment Guidelines Panel, the NIH has upgraded their recommendation and now considers Ivermectin an option for use in COVID-19.

Their recommendation has now been upgraded to the same level as those for widely used monoclonal antibodies & convalescent plasma, which is a "neither for nor against" recommendation. The significance of this change is that the NIH has decided to no longer recommend against the use of ivermectin in the treatment of COVID-19 by the nation's health care providers. A consequence of this change is that ivermectin has now been made a clear therapeutic option for patients.

https://covid19criticalcare.com/flccc-pressrelease-nih-ivermectin-in-c19-recommendation-change-jan15-2021-final/

PROPHYLAXIS & EARLY OUTPATIENT TREATMENT PROTOCOL FOR COVID-19: https://covid19criticalcare.com/wp-content/uploads/2020/11/FLCCC-Alliance-I-MASKplus-Protocol-ENGLISH.pdf

One page summary of Ivermectin COVID-19 trials---link:

https://covid19criticalcare.com/wp-content/uploads/2020/12/One-Page-Summary-of-the-Clinical-Trials-Evidence-for-Ivermectin-in-COVID-19.pdf

Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19 (31 pages---link). https://osf.io/wx3zn/

[redacted]

From: Mineau, Philippe (HC/SC)
Sent: 2021-02-23 11:08 AM
To: Randall, Bruce (HC/SC)
Subject: FW: 21-001394 - 120 for / pour: Direct Reply/Réponse directe
Attachments: 21-001394-120.pdf
21-001394-120 - Direct Reply - Ivermectin.docx

Hey there Bruce,

For approval another Ivermectin reply,

Of note, I added the paragraph on the MERCK statement issued last week:

The manufacturer of ivermectin in Canada, Merck, has also issued a public statement (available at https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/) on the use of ivermectin during the COVID-19 pandemic, stating that:

"It is important to note that, to-date, [MERCK's] analysis has identified:

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

Let me know what you think,
P

From: Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>
Sent: 2021-02-22 3:13 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Subject: FW: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Hi Phil,

Direct Reply re – Ivermectin.

I attached a draft response

Due ECD March 2

Thanks,

Jacqueline Farah
(she | elle)
Executive Correspondence Officer / Agente de la correspondance exécutive
Director General's Office / Bureau du directeur général
Therapeutic Products Directorate / Direction des produits thérapeutiques

Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
jacqueline.farah@canada.ca / Cell.: 343-552-4415

From: Christa Racicot <christa.racicot@hc-sc.gc.ca>
Sent: 2021-02-22 3:05 PM
To: Beattie, Deborah (HC/SC) <deborah.beattie@canada.ca>; Cain, Francoise (HC/SC) <francoise.cain@canada.ca>; Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>; Mattia-Pepin, Isabelle (HC/SC) <isabelle.mattia-pepin@canada.ca>; Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Health Canada Santé Canada

Canada

Audit Trail / Suivi de vérification
Ministerial Correspondence / Correspondance ministérielle

Subject / Sujet: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

21-001394 - 120

Send From / Envoyé de	Send To / Envoyé a	Date Sent / Date de l'envoi	Bring Forward / Rappel
HPFB-ADM-ADMO Christa Racicot/HC-SC/GC/CA	**Organization/Organisme** HPFB-TPD-DGO **Person/Personne** Deborah Beattie/HC-SC/GC/CA	2021-02-22	**Due Date/Date d'échéance** 2021-03-02

Special Instructions / Instructions spéciales: Direct Reply Week 6 (2021)
Document Status / Statut du dossier: Closed/Fermé
Action / Intervention: Direct Reply/Réponse directe

Comment / Commentaires:
Scan copy to Final response in MECS and audit trail to ECDCST when done. Thanks

Here is the link to document / Voici le lien au document:

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If you have received these documents in error, notify the MECS-USER-SUPPORT group immediately.

Les documents qui vous sont fournis peuvent contenir des renseignements personnels.
Si vous avez reçu ces documents par erreur, avisez immédiatement le groupe courriel des MECS-USER-SUPPORT.

Created By / Créé par: Christa Racicot
Date Created / Créé le: 2021-02-22

From: Mineau, Philippe (HC/SC)
Sent: 2021-02-23 4:08 PM
To: Farah, Jacqueline (HC/SC)
Subject: FW: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

---

Hey jacquie,
This one is approved but use the original you sent me – no changes (Bruce doesn't want to use the Merck info) – I changed the Ydrive version back,
Thank you!
P

From: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Sent: 2021-02-23 3:58 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Hi Philippe,

I would keep the Merck line out for the moment.

Thanks.

B

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-02-23 11:08 AM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Subject: FW: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Hey there Bruce,

For approval another Ivermectin reply,

Of note, I added the paragraph on the MERCK statement issued last week:

The manufacturer of ivermectin in Canada, Merck, has also issued a public statement (available at https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/) on the use of ivermectin during the COVID-19 pandemic, stating that:

"It is important to note that, to-date, [MERCK's] analysis has identified:

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

Let me know what you think,
P

From: Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>
Sent: 2021-02-22 3:13 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>
Subject: FW: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

Hi Phil,

Direct Reply re – Ivermectin.

I attached a draft response

Due ECD March 2

Thanks,

Jacqueline Farah
(she | elle)
Executive Correspondence Officer / Agente de la correspondance exécutive
Director General's Office / Bureau du directeur général
Therapeutic Products Directorate / Direction des produits thérapeutiques
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
jacqueline.farah@canada.ca / Cell.: 343-552-4415

From: Christa Racicot <christa.racicot@hc-sc.gc.ca>
Sent: 2021-02-22 3:05 PM
To: Beattie, Deborah (HC/SC) <deborah.beattie@canada.ca>; Cain, Francoise (HC/SC) <francoise.cain@canada.ca>; Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>; Mattia-Pepin, Isabelle (HC/SC) <isabelle.mattia-pepin@canada.ca>; Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

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Subject / Sujet: 21-001394 - 120 for / pour: Direct Reply/Réponse directe

21-001394 - 120

Send From / Envoyé de	Send To / Envoyé a	Date Sent / Date de l'envoi	Bring Forward / Rappel
HPFB-ADM-ADMO Christa Racicot/HC-SC/GC/CA	**Organization/Organisme** HPFB-TPD-DGO **Person/Personne** Deborah Beattie/HC-SC/GC/CA	2021-02-22	**Due Date/Date d'échéance** 2021-03-02

Special Instructions / Instructions spéciales: Direct Reply Week 6 (2021)
Document Status / Statut du dossier: Closed/Fermé
Action / Intervention: Direct Reply/Réponse directe

Comment / Commentaires:
Scan copy to Final response in MECS and audit trail to ECDCST when done. Thanks

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Si vous avez reçu ces documents par erreur, avisez immédiatement le groupe courriel des MECS-USER-SUPPORT.

Created By / Créé par: Christa Racicot
Date Created / Créé le: 2021-02-22

From: Mineau, Philippe (HC/SC)
Sent: 2021-06-14 9:54 AM
To: Abdulla, Rosemin (HC/SC)
Subject: FW: 21-001396 - 449 for / pour: Direct Reply/Réponse directe
Attachments: 21-001396-449.pdf
21-001396 - 449 - COVID - Ivermectin - Direct Reply.docx

Hey Rosemin, the following response is approved by Bruce and can be sent out,
Thank you!
P

From: Mineau, Philippe (HC/SC)
Sent: 2021-06-07 12:09 PM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>
Subject: FW: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

Hey Pat, hey Bruce,

If you remember, we received some correspondence a couple of weeks ago that accused HC of "blocking access to ivermectin" – I had written to the Dr involved to find out more about how he had been blocked, and he had responded with the email attached ("ivermectin concern").

Long story short, he had prescribed ivermectin, the pharmacy had returned to him with a SAP form, he assumed that HC would not allow it so did not pursue further.

Here are the proposed responses back to the letter-writer, [redacted] I just want to make sure you're both comfortable with these before they get sent.

[redacted]

[redacted]

Let me know what you think,

P

From: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Sent: 2021-05-20 12:11 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Subject: RE: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

Hi Philippe,

Here is the standard direct reply response prepared for this MECS as requested.

Have a wonderful day / Bonne journée

Rosemin
Tel: 613-327-0578

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-05-20 10:15 AM
To: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Subject: RE: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

Yes the standard ivermectin response please,
Thanks,
P

From: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Sent: 2021-05-20 10:07 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Subject: FW: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

Hi Phil,

Enclosed please find the incoming documents for which we have to provide a direct reply re:
Coronavirus - I-MASK + Protocol for Covid-19 Treatment/ Ivermectin

Redirected from PHAC
This was originally Due: to ECDCST on Mar 4 however, it is due whenever done.

Did do want to use the standard direct reply for ivermectin or want to task BGIVD or MDD?

Have a wonderful day / Bonne journée

Rosemin
Tel: 613-327-0578

From: Christa Racicot <christa.racicot@hc-sc.gc.ca>
Sent: 2021-05-20 9:48 AM
To: Beattie, Deborah (HC/SC) <deborah.beattie@canada.ca>; Cain, Francoise (HC/SC) <francoise.cain@canada.ca>; Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>; Mattia-Pepin, Isabelle (HC/SC) <isabelle.mattia-pepin@canada.ca>; Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Subject: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

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Ministerial Correspondence / Correspondance ministérielle

Subject / Sujet: 21-001396 - 449 for / pour: Direct Reply/Réponse directe

21-001396 - 449

Send From / Envoyé de	Send To / Envoyé a	Date Sent / Date de l'envoi	Bring Forward / Rappel
HPFB-ADM-ADMO Christa Racicot/HC-SC/GC/CA	**Organization/Organisme** HPFB-TPD-DGO **Person/Personne** Deborah Beattie/HC-SC/GC/CA	2021-05-20	**Due Date/Date d'échéance** 2021-03-08

Special Instructions / Instructions spéciales: Direct reply week 6 (2021)
Document Status / Statut du dossier: Open/Ouvert
Action / Intervention: Direct Reply/Réponse directe

Comment / Commentaires:
As per PHAC (As per program, this issue is not within PHAC's purview. Please redirected to HC)/ HPFB - Scan copy to Final response in MECS and audit trail to ECDCST when done. Thanks

Here is the link to document / Voici le lien au document:

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Si vous avez reçu ces documents par erreur, avisez immédiatement le groupe courriel des MECS-USER-SUPPORT.

Created By / Créé par: Christa Racicot
Date Created / Créé le: 2021-05-20

From: Mineau, Philippe (HC/SC)
Sent: 2021-05-18 11:14 AM
To: Abdulla, Rosemin (HC/SC)
Subject: FW: 21-005071 - 222 for / pour: Branch Input Required/Information requise de la direction générale
Attachments: 21-005071 - 222 - TPDDGO.docx

Hey Rosemin,
The attached is approved by Bruce, I made some small edits based on specific questions in the incoming (no need to change our standard response on the shared drive),
Thank you!
P

From: Mineau, Philippe (HC/SC)
Sent: 2021-05-18 10:59 AM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Subject: FW: 21-005071 - 222 for / pour: Branch Input Required/Information requise de la direction générale

Hey Bruce, for approval,

This is the standard TPD input on ivermectin,

I added a line about HC not issuing a "best practices" list ("Heath Canada has no jurisdiction over how health care professionals prescribe drugs once they are authorized, and Health Canada does not issue a "best practices" list."), as this is specifically referenced in the incoming.

Cheers,
P

From: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Sent: 2021-05-17 3:32 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Subject: FW: 21-005071 - 222 for / pour: Branch Input Required/Information requise de la direction générale

Hi Phil,

Here is an email re: Coronovirus – ivermectin for the treatment of COVID-19 for branch input. Due by: May 21.

I have prepared a response using standard input text – enclosed.

Thank you.

Have a wonderful day / Bonne journée

Rosemin

Tel: 613-327-0578

From: Christa Racicot <christa.racicot@hc-sc.gc.ca>
Sent: 2021-05-17 3:14 PM
To: Beattie, Deborah (HC/SC) <deborah.beattie@canada.ca>; Cain, Francoise (HC/SC) <francoise.cain@canada.ca>; Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>; Mattia-Pepin, Isabelle (HC/SC) <isabelle.mattia-pepin@canada.ca>; Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Subject: 21-005071 - 222 for / pour: Branch Input Required/Information requise de la direction générale

Health Canada Santé Canada

Canada

Audit Trail / Suivi de vérification
Ministerial Correspondence / Correspondance ministérielle

Subject / Sujet: 21-005071 - 222 for / pour: Branch Input Required/Information requise de la direction générale

21-005071 - 222

Send From / Envoyé de	Send To / Envoyé a	Date Sent / Date de l'envoi	Bring Forward / Rappel
HPFB-ADM-ADMO Christa Racicot/HC-SC/GC/CA	**Organization/Organisme** HPFB-TPD-DGO **Person/Personne** Deborah Beattie/HC-SC/GC/CA	2021-05-17	**Due Date/Date d'échéance** 2021-05-24

Document Status / Statut du dossier: Open/Ouvert
Action / Intervention: Branch Input Required/Information requise de la direction générale

Comment / Commentaires:
Please see incoming and provide branch input by May 21, 2021. Thanks CR

Here is the link to document / Voici le lien au document:

The documents provided to you may contain personal information.
If you have received these documents in error, notify the MECS-USER-SUPPORT group immediately.

Les documents qui vous sont fournis peuvent contenir des renseignements personnels.
Si vous avez reçu ces documents par erreur, avisez immédiatement le groupe courriel des MECS-USER-SUPPORT.

Created By / Créé par: Christa Racicot
Date Created / Créé le: 2021-05-17

From: Mineau, Philippe (HC/SC)
Sent: 2021-06-25 2:18 PM
To: Zimmermann, Margaret (HC/SC)
Cc: Racicot, Christa (HC/SC); Abdulla, Rosemin (HC/SC)
Subject: FW: 21-007306 - 134 for / pour: See note
Attachments: 21-007306-134.pdf

Hey Margaret,

I don't know if your correspondence staff had talked to you about this one,

PHAC is currently undertaking a review of emerging evidence related to ivermectin for COVID-19. As the following correspondence just points us to a new article on ivermectin, and is not asking any questions related to the drug approval process, we really feel it would be better directed to PHAC, as there's nothing TPD can respond to here,

I'm not sure why PHAC correspondence is sending this to HPFB – maybe because so much ivermectin correspondence has been coming our way, and been responded to here. But we really feel this one should go to them,

Thanks!
P

From: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Sent: 2021-06-25 2:02 PM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Cc: Abdulla, Rosemin (HC/SC) <rosemin.abdulla@canada.ca>
Subject: FW: 21-007306 - 134 for / pour: See note

Hi Phil,

The one that we redirected to PHAC's Emerging Evidence group, as they are undertaking a review of emerging evidence related to ivermectin, has been audit trailed back to us with the following note: This request was already sent to PHAC and they redirected it to HPFB. I spoke with the ADMO - Advisor and she requested that TPD please respond. Thank you CR

Please advice what you would like me to do it – task to BGIVD?

Have a wonderful day / Bonne journée

Rosemin
Tel: 613-327-0578

From: Christa Racicot <christa.racicot@hc-sc.gc.ca>
Sent: 2021-06-25 1:57 PM
To: Beattie, Deborah (HC/SC) <deborah.beattie@canada.ca>; Cain, Francoise (HC/SC) <francoise.cain@canada.ca>; Renart-McGowan, Isabel (HC/SC) <isabel.renart-mcgowan@canada.ca>; Mattia-Pepin, Isabelle (HC/SC) <isabelle.mattia-pepin@canada.ca>; Farah, Jacqueline (HC/SC) <jacqueline.farah@canada.ca>; Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Abdulla, Rosemin

(HC/SC) <rosemin.abdulla@canada.ca>
Subject: 21-007306 - 134 for / pour: See note

Health Canada Santé Canada

Canada

Audit Trail / Suivi de vérification
Ministerial Correspondence / Correspondance ministérielle

Subject / Sujet: 21-007306 - 134 for / pour: See note

21-007306 - 134

Send From / Envoyé de	Send To / Envoyé a	Date Sent / Date de l'envoi	Bring Forward / Rappel
HPFB-ADM-ADMO Christa Racicot/HC-SC/GC/CA	**Organization/Organisme** HPFB-TPD-DGO **Person/Personne** Deborah Beattie/HC-SC/GC/CA	2021-06-25	**Due Date/Date d'échéance** 2021-07-12

Document Status / Statut du dossier: Open/Ouvert
Action / Intervention: See note

Comment / Commentaires:
This request was already sent to PHAC and they redirected it to HPFB. I spoke with the ADMO - Advisor and she requested that TPD please respond. Thank you CR

Here is the link to document / Voici le lien au document:

The documents provided to you may contain personal information.
If you have received these documents in error, notify the MECS-USER-SUPPORT group immediately.

Les documents qui vous sont fournis peuvent contenir des renseignements personnels.
Si vous avez reçu ces documents par erreur, avisez immédiatement le groupe courriel des MECS-USER-SUPPORT.

Created By / Créé par: Christa Racicot
Date Created / Créé le: 2021-06-25

From: Mineau, Philippe (HC/SC)
Sent: 2021-07-09 10:23 AM
To: Abdulla, Rosemin (HC/SC)
Subject: FW: 21-007306-134 - HPFB Input.docx
Attachments: 21-007306-134 - HPFB Input.docx

Hey Rosemin,
The attached is approved by Bruce and can be sent up,
Thank you!
P

From: Mineau, Philippe (HC/SC)
Sent: 2021-07-09 10:21 AM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Subject: RE: 21-007306-134 - HPFB Input.docx

Ok will do, thanks!
P

From: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Sent: 2021-07-09 10:04 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: RE: 21-007306-134 - HPFB Input.docx

Hi Phil,

Would ask this line be removed. I am not comfortable speaking on behalf of PHAC and I think the last line captures it in a general way.

- The Public Health Agency of Canada is currently undertaking a more comprehensive review of the available literature, and will be publishing its findings shortly.

Thanks,
B

From: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Sent: 2021-07-08 11:56 AM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Subject: 21-007306-134 - HPFB Input.docx

Hey Bruce, for approval, this is the one we've been talking about where Supriya wants to mention a specific article.

Let me know what you think,
P

From: Mineau, Philippe (HC/SC)
Sent: 2021-07-13 11:58 AM
To: Adlani, Souad (HC/SC); Abdulla, Rosemin (HC/SC)
Subject: FW: 21-008262 - 925 for / pour: Direct Reply/Réponse directe
Attachments: 21-008262-925 - Direct Reply.docx

Hey folks,
The attached version has been approved by Bruce and can be processed,
Thank you!
P

From: Mineau, Philippe (HC/SC)
Sent: 2021-07-13 10:50 AM
To: Randall, Bruce (HC/SC) <bruce.randall@canada.ca>
Subject: FW: 21-008262 - 925 for / pour: Direct Reply/Réponse directe

Hey Bruce, for approval,

This is based on the standard response for ivermectin, but with an emphasis on clinical trials, as the question was "would HC approve a clinical trial" – answer, "Should Health Canada receive a clinical trial application for ivermectin, the application would be reviewed through the same process as all clinical trial applications related to COVID-19."

Let me know what you think,
Thanks!
P

From: Adlani, Souad (HC/SC) <souad.adlani@canada.ca>
Sent: 2021-07-13 9:38 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>
Subject: 21-008262 - 925 for / pour: Direct Reply/Réponse directe

Bonjour Philippe,

Ci-joint un "Incoming" relatif à l'usage de **l'Ivermectin pour le traitement de la COVID -19** pour un « direct reply » **due by July 26.**

J'ai joint aussi une réponse standard adaptée selon la requête. J'ai juste changé l'ordre des paragraphes.

Bonne chance à moi pour ma première MECS ☺ A toi je te souhaite une très bonne journée,

Souad Adlani
(she | elle)
Administrative Assistant / Adjointe administrative

Director General's Office / Bureau du directeur général
Therapeutic Products Directorate / Direction des produits thérapeutiques
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
souad.adlani@canada.ca / Cell.: 343-573-4410

From: Stewart, John Patrick (HC/SC)
Sent: 2021-08-30 9:19 AM
To: Mineau, Philippe (HC/SC); Peate, Jaspyn (HC/SC); Randall, Bruce (HC/SC); Soo, Evelyn (HC/SC)
Subject: FW: Clippings

---

fyi

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: Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>
Sent: 2021-08-30 9:18 AM
To: Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Sharma, Supriya (HC/SC) <supriya.sharma@hc-sc.gc.ca>; Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>; Robinson2, Kelly (HC/SC) <kelly.robinson2@canada.ca>; Bassi, Marilena (HC/SC) <marilena.bassi@hc-sc.gc.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>
Subject: RE: Clippings

Risk comms are being developed. Kelly, will let you liaise with Linsey Hollett and Cathy Lafkas on this.

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: Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>
Sent: 2021-08-30 9:16 AM
To: Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>; Sharma, Supriya (HC/SC) <supriya.sharma@hc-sc.gc.ca>; Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>; Robinson2, Kelly (HC/SC) <kelly.robinson2@canada.ca>
Cc: Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>
Subject: RE: Clippings

We've responded to many media requests and MP queries on this since, so there should be standard lines. We also normally point to FDA and WHO statements.

From: Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>
Sent: 2021-08-30 8:53 AM

To: Sharma, Supriya (HC/SC) <supriya.sharma@hc-sc.gc.ca>; Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>; Robinson2, Kelly (HC/SC) <kelly.robinson2@canada.ca>
Cc: Smith, Melissa (HC/SC) <melissa.smith@hc-sc.gc.ca>; Olsen, Clarke (HC/SC) <clarke.olsen@hc-sc.gc.ca>
Subject: FW: Clippings

Pls see below. Do we have ML on this? What about issuing a letter to health professionals?
We should discuss our comms approach on this issue at our covid check-in this aft, with cpab.

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: Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>
Sent: 2021-08-30 8:48 AM
To: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>; Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Cc: Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>
Subject: RE: Clippings

Also see below link to Global news video story, which speaks to US FDA communications on this.

https://www.youtube.com/watch?v=3OA3C0eMKFg

Eric Bélair
Associate Assistant Deputy Minister / Sous-ministre adjoint délégué
Strategic Policy Branch / Direction générale de la politique stratégique
Health Canada / Santé Canada
343-552-1733
eric.belair@hc-sc.gc.ca

From: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>
Sent: 2021-08-30 8:46 AM
To: Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>; Trombetti, Stefania (HC/SC) <stefania.trombetti@hc-sc.gc.ca>; Bombardier, Manon (HC/SC) <manon.bombardier@hc-sc.gc.ca>; Hollett, Linsey (HC/SC) <linsey.hollett@hc-sc.gc.ca>
Cc: Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>
Subject: RE: Clippings

Thanks Eric, I missed that one! I am copying Manon, Linsey and Stefania as there may be post market follow up that is in train.
Pam

From: Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>
Sent: 2021-08-30 8:42 AM
To: Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@hc-sc.gc.ca>
Cc: Voisin, Jocelyne (HC/SC) <jocelyne.voisin@hc-sc.gc.ca>
Subject: Clippings

Hi Pam:

Just wanted to make sure you had seen this one:

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

Eric Bélair
Associate Assistant Deputy Minister / Sous-ministre adjoint délégué
Strategic Policy Branch / Direction générale de la politique stratégique
Health Canada / Santé Canada
343-552-1733
eric.belair@hc-sc.gc.ca

From: Stewart, John Patrick (HC/SC)
Sent: 2021-08-23 7:52 AM
To: Robinson, Kelly (HC/SC); Sommerer, Sophie (HC/SC)
Cc: Hollett, Linsey (HC/SC); Mineau, Philippe (HC/SC); Peate, Jaspyn (HC/SC)
Subject: FW: [redacted] - Ivermectin signage concern [redacted]
Attachments: FLCCC.net - Jun2021.jpg

Hi Kelly

As this compliant involves what appears to be inappropriate advertising of an approved health product I am forwarding this onto for MHPD's assessment. I have cc'd Linsey Hollet as well.

If you are okay with it, I will respond back to [redacted] indicating receipt of the email and that I have forwarded it onto to MHPD for action.

Thanks.

Pat

Dr. J. Patrick Stewart, MD, CCFP(EM)
Director General/ Directeur général
Therapeutic Products Directorate/ Direction des produits thérapeutiques
Health Products and Food Branch / Direction générale des produits de santé et des aliments
Health Canada / Santé Canada
613-859-2433 (cell)

From: [redacted]
Sent: 2021-08-20 6:44 PM
To: Stewart, John Patrick (HC/SC) <john.patrick.stewart@hc-sc.gc.ca>
Cc: prescription.drug.enquiries / renseignements.drogue.ordonnance (HC/SC) <prescription.drug.enquiries-renseignements.drogue.ordonnance@hc-sc.gc.ca> [redacted]
Subject: [redacted] - Ivermectin signage concern [redacted]

Dear Dr. Stewart,

I am writing to you on behalf of the [redacted] regarding a concern that had been brought to our attention recently involving the advertisement of the use of Ivermectin in treating Covid-19.

[redacted]

Requester agreed to Remove 3rd Party Info

[redacted] has recently received notification from two rural pharmacists about a sign along a rural highway in Manitoba that reads "Ivermectin treats COVID-19 [redacted] I have attached a picture for your review as well. These pharmacists have expressed great concern about this apparent misinformation, placed in a region with extremely poor/low vaccination uptake, combined with the potentially lower educational levels of some residents of the particular area.

In my initial review [redacted]

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.

Requester agreed to Remove 3rd Party Info

Kind regards,

[redacted]

WITHHELD / RETENUE

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

19(1)

Subject to subsection (2), the head of a government institution shall refuse to disclose any record requested under this Act that contains personal information as defined in section 3 of the Privacy Act

Sous réserve du paragraphe (2), le responsable d'une institution fédérale est tenu de refuser la communication de documents contenant les renseignements personnels visés à l'article 3 de la Loi sur la protection des renseignements personnels

From: Soo, Evelyn (HC/SC)
Sent: 2021-03-19 3:26 PM
To: Stewart, John Patrick (HC/SC); Randall, Bruce (HC/SC)
Cc: Mineau, Philippe (HC/SC)
Subject: FW: COVID-19 Related: [redacted] EMA communication: EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials
Attachments: Ivermectin - 03-2021 - public health communication.docx

---

FYI

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

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

From: Srivastava, Tanya (HC/SC) <tanya.srivastava@canada.ca> **On Behalf Of** MHPD_International / DPSC_International (HC/SC)
Sent: 2021-03-19 8:08 AM
To: Abdelmesih, Mariam (HC/SC) <mariam.abdelmesih@canada.ca>; Alhaddad, Saj (HC/SC) <saj.alhaddad@canada.ca>; Bawolak, Marie-Therese (HC/SC) <marie-therese.bawolak@canada.ca>; Campbell, Catherine (HC/SC) <catherine.campbell@canada.ca>; Chen2, Yong (HC/SC) <yong.chen2@canada.ca>; Chretien, Louise (HC/SC) <louise.chretien@canada.ca>; Comarova, Natalia (HC/SC) <natalia.comarova@canada.ca>; Dai, Jiazhen Minnie (HC/SC) <jiazhenminnie.dai@canada.ca>; del Campo, Eduardo (HC/SC) <eduardo.delcampo@canada.ca>; Djulus, Josephine (HC/SC) <josephine.djulus@canada.ca>; Duguay, David (HC/SC) <david.duguay@canada.ca>; Eng, David (HC/SC) <david.eng@canada.ca>; Filfil, Rana (HC/SC) <rana.filfil@canada.ca>; Hazelwood, Tracey (HC/SC) <tracey.hazelwood@canada.ca>; HC.F HPF MHPD OPEDA F.SC <HPF_MHPD_OPEDA@canada.ca>; HC.F MHPD BBRS Assistants / MHPD BBRA Assistants F.SC <hc.mhpdbbrsassistants-mhpdbbraassistants.sc@canada.ca>; HC.F MHPD BBRS Management / MHPD BBRA Management F.SC <hc.mhpdbbrsmanagement-mhpdbbramanagement.sc@canada.ca>;

HC.F MHPD HPSEB Managers / DPSC HPSEB Gestionnaires F.SC <hc.mhpdhpsebmanagers-dpschpsebgestionnaires.sc@canada.ca>; HC.F MHPD MPB MANAGEMENT F.SC <hc.mhpdmpbmanagement.sc@canada.ca>; HC.F MHPD MPB SCIENTIFIC STAFF F.SC <hc.mhpdmpbscientificstaff.sc@canada.ca>; HC.F MHPD OPRAA Management F.SC <hc.mhpd.opraa.management.sc@canada.ca>; MBBNHPB ENVIROSCANS / BPBBSNC (HC/SC) <hc.mbbnhpb.enviroscans-bpbbsnc.sc@canada.ca>; Meszaros, Michele (HC/SC) <michele.meszaros@canada.ca>; MHPD_International / DPSC_International (HC/SC) <hc.mhpd_international-dpsc_international.sc@canada.ca>; MPB RPM / GPR BPPC (HC/SC) <hc.mpb.rpm-gpr.bppc.sc@canada.ca>; Murty, Hima (HC/SC) <hima.murty@canada.ca>; Plante, Isabelle (HC/SC) <isabelle.plante@canada.ca>; Rose, Jhona (HC/SC) <jhona.rose@canada.ca>; Salem, Myriam (HC/SC) <myriam.salem@canada.ca>; Shehata, Marlene (HC/SC) <marlene.shehata@canada.ca>; Sleno, Rory (HC/SC) <rory.sleno@canada.ca>; Sommerer, Sophie (HC/SC) <sophie.sommerer@canada.ca>; Springuel, Pascale (HC/SC) <pascale.springuel@canada.ca>; Tremblay, Patrice (HC/SC) <patrice.tremblay@canada.ca>; Williams, Lee (HC/SC) <lee.williams@canada.ca>; Xu, Xiao (HC/SC) <xiao.xu@canada.ca>; Yammine, Elena (HC/SC) <elena.yammine@canada.ca>
Cc: Robinson2, Kelly (HC/SC) <kelly.robinson2@canada.ca>; Bettle, Megan (HC/SC) <megan.bettle@canada.ca>; Lehman, Kelly (HC/SC) <kelly.lehman@canada.ca>; Hazelwood, Tracey (HC/SC) <tracey.hazelwood@canada.ca>
Subject: COVID-19 Related [redacted] EMA communication: EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials

Dear all,

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

Kindest regards,

Tanya

Tanya Srivastava

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

Analyste de politiques junior
Bureau de la mobilisation stratégique et des services de gestion intégrée
Direction des produits de santé commercialisés
Direction générale des produits de santé et des aliments

Santé Canada
Courriel: tanya.srivastava@canada.ca
hc.mhpd_international-dpsc_international.sc@canada.ca

Dear Colleagues,

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

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

Best regards,

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

www.ema.europa.eu

Follow us:

[redacted]

[redacted]

From: Piecha, Maryanne (HC/SC)
Sent: 2021-05-07 1:28 PM
To: Legare, Carole (HC/SC)
Subject: FW: CTs in Canada for Ivermectin - quetion

Hi Carole
This person called the OCT main line this week requesting for CTs on Ivrmectin.
I contacted Larissa who suggested I send this link to Lisa
https://health-products.canada.ca/ctdb-bdec/index-eng.jsp
She feels she did not find all CTs for Ivermectin and sent me the email below
How should I proceed?
Maryanne

Gouvernement du Canada Government of Canada

Canada

From: [redacted]
Sent: 2021-05-07 1:22 PM
To: Piecha, Maryanne (HC/SC)
Subject: Re: CTs in Canada for Ivermectin

Hi Maryanne,

I would like to request under the freedom of information act:

1. A list of all clinical trials applied for to Health Canada specifically for the use of Ivermectin for Covid.

2. A list of any clinical trials declined by Health Canada specifically for the use of Ivermectin for Covid.

Please note: Due to high volumes response times could be delayed up to 48 hours.

[redacted]

Kindest regards,

[redacted]

Requester agreed to
Remove 3rd Party Info

On Wed, 5 May 2021 at 09:43, Piecha, Maryanne (HC/SC) <maryanne.piecha@canada.ca> wrote:

Hi [redacted]

As discussed please find the weblink for the Clinical Trials below, you can search for Ivermectin:

https://health-products.canada.ca/ctdb-bdec/index-eng.jsp

Thank you

Maryanne Piecha
Executive Assistant to the Director /The Office of Clinical Trials/
Therapeutic Products Directorate/Health Products and Food Branch
Health Canada, Government of Canada
Tel : 343-553-3922
maryanne.piecha@canada.ca

Adjointe exécutive à la Directrice / Bureau des essais cliniques
Direction des produits thérapeutiques/ Direction générale des produits de santé et des aliments
Santé Canada, Gouvernement du Canada
Tel : 343-553-3922
maryanne.piecha@canada.ca

Gouvernement du Canada Government of Canada

Canada

From:	Longo, Maria (HC/SC)
Sent:	2021-08-30 12:16 PM
To:	Sleno, Rory (HC/SC)
Cc:	Morrison, Heather (HC/SC); Canada Vigilance (HC/SC)
Subject:	FW: CV-2021-441: CV search request
Attachments:	Ivermectin_Canada Vigilance Request form_2021-08-30.doc

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 sante et de l'epidemiologie
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-coodinators.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: Stewart, John Patrick (HC/SC)
Sent: 2021-03-26 11:33 AM
To: Randall, Bruce (HC/SC)
Cc: Legare, Carole (HC/SC)
Subject: FW: DM Request - Update on Ivermectin in the context of COVID-19 treatment

---

Hi Bruce

We should also provide some info on the market status of this product, what it is indicated for and the fact that for a long time this therapy was on the SAP

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: Smith4, Melissa (HC/SC) <melissa.smith4@canada.ca>
Sent: 2021-03-26 10:17 AM
To: Mineau, Philippe (HC/SC) <philippe.mineau@canada.ca>; Stewart, John Patrick (HC/SC) <johnpatrick.stewart@canada.ca>; Randall, Bruce (HC/SC) <bruce.randall@canada.ca>; Bettle, Megan (HC/SC) <megan.bettle@canada.ca>
Subject: DM Request - Update on Ivermectin in the context of COVID-19 treatment

Good morning TPD and Megan,

The DM has requested, by COB today, a summary of what we know about Ivermectin studies and use as COVID-19 treatment. This request is triggered by [redacted] to ask if HC is systematically tracking it.

Megan – would you mind reaching out to Kaili's group to see if they've been tracking and thus would have input to provide?

Thanks,
Melissa

From: Legare, Carole (HC/SC)
Sent: 2021-03-08 8:00 AM
To: Soo, Evelyn (HC/SC); Punch, Vincent (HC/SC)
Subject: FW: FDA MedWatch - Why You Should Not Use Ivermectin to Treat or Prevent COVID-19: Consumer Update

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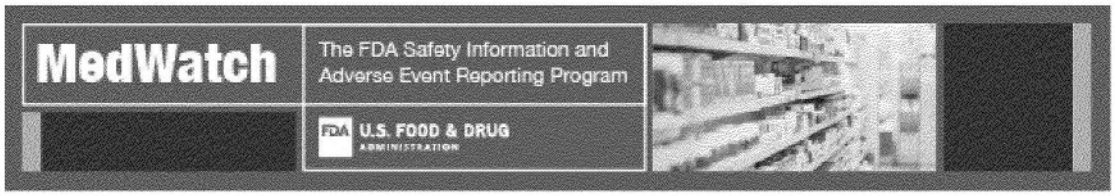
In case you did not get this announcement

From: U.S. Food and Drug Administration <usfda@public.govdelivery.com>
Sent: 2021-03-05 4:12 PM
To: carole_legare@hc-sc.gc.ca
Subject: FDA MedWatch - Why You Should Not Use Ivermectin to Treat or Prevent COVID-19: Consumer Update



MedWatch - The FDA Safety Information and Adverse Event Reporting Program

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

AUDIENCE: Consumer, Health Professional

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

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

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

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

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

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

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

RECOMMENDATIONS:

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

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

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

Read More

From: Stewart, John Patrick (HC/SC)
Sent: 2021-09-13 11:09 AM
To: Mineau, Philippe (HC/SC)
Cc: Randall, Bruce (HC/SC); Soo, Evelyn (HC/SC)
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>; Cropley, Julia (HC/SC) <julia.cropley@hc-sc.gc.ca>
Cc: Manick, Alexis (HC/SC) <alexis.manick@hc-sc.gc.ca>; Burke, Suzanne (HC/SC) <suzanne.burke@hc-sc.gc.ca>
Subject: HPEC Sept 13
Importance: High

Good morning,
Lisa is back tomorrow so this is your last set of HPEG notes from me for now! Have a great day ☺
Kailey

HPEG:

Dr Tam:

- People are ordering another strange covid treatment product (didn't catch the name) – saw on GPHN this morning – will monitor and flag if we need to communicate on this.
    - Comms – dust off lines on COVID treatment in case w need them

From: Mineau, Philippe (HC/SC)
Sent: 2021-07-08 9:26 AM
To: Keeping, Elizabeth (HC/SC)
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

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 [redacted]

I had been reaching out to you to determine how we can better explain to members of the public [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.

Requester agreed to
Remove 3rd Party Info

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,

[redacted]

[redacted]

[redacted]

Let me know if you have any other questions.

Requester agreed to
Remove 3rd Party Info

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]
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