From: s22
To: s22
Subject: RE: Request for assistance by WA Police
Date: Thursday, 27 April 2023 11:06:48 AM
Attachments: image002.png
image003.png
image005.png

Dear s22 ,

Thank you for reaching out to the TGA regarding this case involving ivermectin. As the human medicines regulator, it is not the role of the TGA to advise on veterinary products or provide clinical advice for individuals. The best place to seek clinical information on an individual would be a medical practitioner who prescribes the products or a clinical toxicologist via your forensic medicine services. However, below I have provided some links to information which they may find useful in looking at the case, as well as some general information about how we regulate medicines such as ivermectin.

I also note that as the product involved was a veterinary product, you may wish to see advice from a clinical toxicologist on any excipient (inactive) ingredients used in the product, as they may not be suitable for human use. The APVMA, or Eraquell manufacturer, should be able to provide you with further information on these ingredients if needed.

When considering a medicine for registration, the TGA reviews information on the medicines' safety, quality and efficacy. Prescription medicines, such as ivermectin, are approved for use in certain conditions (therapeutic indication) at identified doses and in particular formulations, which includes both strength of the advice ingredient and composition of the final product, such as a tablet or capsule.

The TGA provides information on the medicine in the form of the product information. This document includes what indications the medicine is approved for, at what doses, as well as safety information. The safety information is from both clinical trials and post-marketing experience. It includes reactions that may occur, but frequently these potential side effects are rare, and may not occur in many individuals who use the product. The product information for ivermectin can be found at: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&q=ivermectin, or be searching the internet for 'pi tga ivermectin'.

Ivermectin is a schedule 4, prescription only, medicine. This means that it is only available with a prescription from a doctor. In September 2021, further restrictions were included in the Poisons Standard which restrict the prescribing of ivermectin to TGA-approved indications by GPs, with prescriptions for other uses limited to certain medical specialties. Further information on these changes can be found at the following links:

- www.tga.gov.au/news/media-releases/new-restrictions-prescribing-ivermectin-covid-19
- www.tga.gov.au/resources/publication/scheduling-decisions-final/notice-amendment-current-poisons-standard-under-paragraph-52d2a-therapeutic-goods-act-1989-0

I trust that this information will be of assistance.
Kind regards,
s22

s22

Director – Adverse Event and Medicine Defects Section

Medicines Regulation Division | Health Products Regulation Group
Pharmacovigilance Branch
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Scherger Drive 1.N. Fairbairn
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: s22 @police.wa.gov.au>
Sent: Thursday, 20 April 2023 9:48 PM
To: s22 @health.gov.au>
Subject: Request for assistance by WA Police

Hello s22 ,

I am a s22 in the Western Australia Police Service and I am currently investigating an incident where a father administered ivermectin (in the form of horse medication - Erequell) to his daughter to treat Covid-19.
I was provided your email address by s22 at APVMA who has been assisting me.
I am hoping to discuss the possible health consequences of his actions with you and also obtain some information from the TGA with regard to adverse effects of ivermectin in humans, how these are determined, and how the drugs are scheduled as a result of these findings.
My mobile number is s22 if you wish to discuss this in person.
I look forward to hearing from you.

Many thanks,

s22

s22 [redacted]

***** In Confidence *****


Think before you print

********** This email message and any attached files may contain information that is confidential and subject of legal privilege intended only for use by the individual or entity to whom they are addressed. If you are not the intended recipient or the person responsible for delivering the message to the intended recipient be advised that you have received this message in error and that any use, copying, circulation, forwarding, printing or publication of this message or attached files is strictly forbidden, as is the disclosure of the information contained therein. If you have received this message in error, please notify the sender immediately and delete it from your inbox.
****

Talking points – Removal of restrictions on prescribing of ivermectin

- Restrictions on the prescribing of ivermectin through its scheduling in the Poisons Standard will be removed from 1 June 2023. This decision was announced by the TGA on 3 May 2023.
- The restrictions were introduced in September 2021 to limit 'off-label' prescribing of oral ivermectin to certain specialists. The restrictions were introduced because of concerns that the prescribing of ivermectin for the claimed prevention or treatment of COVID-19 posed significant public health risks.
- The decision to remove the restrictions is not an endorsement of the off-label prescribing of ivermectin for the treatment or prevention of COVID-19. Rather, it reflects that the safety risks to individuals and public health from its use are now sufficiently low.
- A large number of clinical studies have demonstrated that ivermectin does not improve outcomes in patients with COVID-19. These include studies conducted in different countries and settings.
- The National Clinical Evidence Taskforce (NCET) and many similar bodies around the world, including the World Health Organization, strongly advises against the use of ivermectin for the prevention or treatment of COVID-19.
- Ivermectin has not received regulatory approval in Australia, or by other comparable international regulators, for the treatment or prevention of any respiratory illness, including COVID-19.
- When the restrictions on ivermectin prescribing were introduced in September 2021, the key public health risks of concern included:
    - people prescribed ivermectin for COVID-19 may not get vaccinated or seek medical care if they developed symptoms, and may pose a potential risk to the community through spread of the disease
    - potential adverse effects from ivermectin
    - potential for supply shortages impacting people needing treatment with ivermectin for its TGA-approved indications.
- The key reasons for the decision to remove the restrictions are:
    - medical professionals are now properly informed of the risks of prescribing ivermectin and the abundance of evidence that it is not beneficial for such an off-label indication
    - clinical studies investigating ivermectin for treatment of COVID-19 demonstrate a low-risk of adverse reactions
    - use of ivermectin by some individuals is unlikely to compromise public health because of the high rate of COVID-19 vaccination in Australia
    - there is a low risk of supply shortages of ivermectin that would impact its availability for approved indications.
- The final decision was made in accordance with the statutory process involving advice from the Advisory Committee on Medicines Scheduling (ACMS) and two rounds of public consultation in which all stakeholders had a full opportunity to put forward all concerns and information they wish to be considered about the current prescribing restrictions.

Background

Ivermectin is an anti-parasite medication that is used to treat human and animal diseases.

Ivermectin for oral use (Stromectol) is a Prescription Only (Schedule 4) medicine in the Poisons Standard. It is only approved by the TGA for the treatment of river blindness (onchocerciasis), threadworm of the intestines (intestinal strongyloidiasis), and scabies.

Scabies is particularly widespread in remote Aboriginal and Torres Strait Islander communities. Shortages of ivermectin may therefore disproportionately affect these communities.

Whilst ivermectin was shown in the laboratory environment and some small early clinical studies to potentially be effective against COVID-19 virus, the body of clinical studies including large high quality randomised clinical trials now overwhelmingly shows there is no evidence of it being effective.

On 10 September 2021, restrictions were created in Appendix D of the Poisons Standard to limit 'off-label' prescribing of oral ivermectin, which is a Schedule 4 (Prescription Only) medicine, to specialists in dermatology, gastroenterology and hepatology, infectious diseases, paediatric gastroenterology and hepatology, and paediatric infectious diseases.

This occurred on the advice of the Advisory Committee for Medicines Scheduling (ACMS), due to concerns about off-label prescribing of oral ivermectin for the claimed prevention or treatment of COVID-19 in the context of insufficient evidence.

Following the announcement (10 September 2021), there was significant public interest as well as an increase in media enquiries and FOI requests. The TGA received more than 10,000 enquiries regarding the decision. The behaviour of many callers was inappropriate.

There has also been an ongoing campaign from some members of the public in Australia and abroad, including by some medical professionals, advocating for the use of ivermectin in relation to COVID-19 and against the prescribing restrictions.

The decision to remove these restrictions relates to an application by a member of the public, Dr Julian Fidge. Dr Fidge is a general practitioner who was a candidate for election to the presidency of the Royal Australian College of General Practitioners (RACGP) in 2022. Dr Fidge has been publicly advocating for the use of ivermectin in relation to COVID-19.

The interim decision, published on 3 February 2023, retained the Appendix D entry based on the ACMS advice and public submissions. The final decision sets aside the interim decision following further public consultation and reconsideration of the information and evidence that was taken into account for the interim decision.

At 30 April 2023, no formal application has been submitted to the TGA to support the use of Ivermectin for the treatment or prevention of COVID-19 as part of its inclusion on the Australian Register of Therapeutic Goods (ARTG). The TGA remains ready to discuss potential applications or data with any Sponsor considering an application to register ivermectin medicines for COVID-19-related indications.

A total of 23 submissions from individuals and organisations were received to the 2 rounds of public consultation on the applicant's proposal and the interim decision. The Australian Medical Association expressed concern that the justification for continuing to restrict the prescribing of ivermectin is weak. The Pharmacy Guild of Australia and Society of Hospital Pharmacists of Australia opposed removing restrictions on ivermectin prescribing.

OFFICIAL

Senate Committee: Community Affairs

Supplementary Budget Estimates 2021-2022

Outcome: 1 – Health Policy, Access and Support

Ivermectin – Rescheduling Decision

KEY POINTS

- Ivermectin is an anti-parasite medication that is used to treat human and animal diseases.
- Oral ivermectin (Stromectol) is approved by the TGA for the treatment of river blindness (onchocerciasis), threadworm of the intestines (intestinal strongyloidiasis) and scabies.
- Ivermectin does not have regulatory approval in Australia, or any other comparable OECD country, for the treatment or prevention of COVID-19.
- Recently there have been substantial increases in the dispensing of ivermectin, attributed to prescribing for unapproved uses, such as COVID-19.
- The TGA has placed new restrictions on the prescribing of oral ivermectin. General practitioners are now only able to prescribe ivermectin for TGA-approved conditions.
- Certain specialists are permitted to prescribe ivermectin for other unapproved indications if they believe it is appropriate for a particular patient.
- These changes have been introduced because of concerns with the prescribing of oral ivermectin for the claimed prevention or treatment of COVID-19.
- The decision was made by a senior medical officer at the TGA acting on the advice of the Advisory Committee for Medicines Scheduling (ACMS), which includes state and territory representatives.

KEY DATES

- **8 September 2021** – Advisory Committee for Medicines Scheduling (ACMS) #35 out of session meeting on ivermectin.
- **10 September 2021** – Publication of the Delegate's decision to restrict the prescribing of ivermectin by making amendments to the Poisons Standard.
- **11 September 2021** – New restrictions on ivermectin prescribing came into effect.
- (Sensitive) **13 September 2021** – Written Direction issued to wholesalers (to CSO Distributors) to allow them to constrain supply to ensure equitable distribution to community pharmacies (End Sensitive)

RESTRICTIONS ON PRESCRIBING

- General practitioners will only be able to prescribe oral ivermectin for TGA-approved conditions – scabies and certain parasite infections.
- Certain specialists including infectious disease physicians, dermatologists, gastroenterologists and hepatologists (liver disease specialists) are permitted to prescribe ivermectin for other unapproved indications if they believe it is appropriate for a particular patient.

Contact Officer:	Gillian Mitchell	Deputy Secretary Clearing Officer:	Adj Prof John Skerritt	Clearance: 11 October 2021
Mobile No:	s22 [redacted]	Mobile No:	s22 [redacted]	Updated:
Division/Agency:	|Health Products Regulation| Regulatory Practice & Support			

- The new restrictions do not prevent use of ivermectin for COVID-19 as part of a clinical trial approved by, or notified to, the Secretary of the Australian Government Department of Health under the *Therapeutic Goods Act 1989*.
- The prescribing restrictions have no impact on access to topical ivermectin for the treatment of rosacea (Soolantra and Vastreka) or veterinary products.

REASONS FOR IMMEDIATE ACTION TO RESTRICT PRESCRIBING

- There has been a 300-400 percent increase in dispensing of ivermectin prescriptions in recent months, attributed to increased prescribing for unapproved uses such as COVID-19.
- There are significant public health risks associated with taking ivermectin to treat or prevent COVID-19 infection rather than getting vaccinated.
- Individuals who believe they are protected from infection by taking ivermectin may choose not to get tested or to seek medical care if they experience symptoms. Doing so has the potential to spread the risk of COVID-19 infection throughout the community.
- Concerns that social media posts and other sources promoting ivermectin for the prevention or treatment of COVID-19 encourage doses at a significantly higher level than those approved for scabies or parasite treatment; these doses carry significant risk of adverse effects.
- The substantial increase in dispensing of ivermectin prescriptions creates a risk of ongoing national and local shortages for those who need the medicine for scabies and parasite infections. Such shortages can disproportionately impact vulnerable people, including those in Aboriginal and Torres Strait Islander communities.

CONSULTATION ON THE SCHEDULING CHANGES

- The decision to restrict prescribing of ivermectin was not open to public consultation, given the seriousness of the circumstances, the risks to the community (potential to spread the risk of COVID-19), and the urgency for action.
- The ACMS is an independent advisory committee and made up of specific scientific, medical, or clinical and pharmacist experts from across Australia, as well as representatives from the Commonwealth and each State and Territory Department of Health.
- The ACMS unanimously agreed that there was a need to urgently restrict the prescribing of oral ivermectin through amendments to the scheduling in the Poisons Standard.

PUBLIC RESPONSE TO RESTRICTIONS ON IVERMECTIN

- Since the announcement was published (10 September 2021), there has been significant public interest as well as an increase in media enquiries and FOI requests.
- The TGA has received more than 10,000 enquiries regarding the decision. Likewise, the Department's Health Contact Centre has received a significant increase in enquiries.
- The behaviour of many callers has been inappropriate. The TGA has implemented additional strategies to ensure the wellbeing of its staff, as this has been of serious concern.

INTERNATIONAL REGULATION

- Ivermectin does not have regulatory approval in any other comparable OECD country for treatment or prevention of COVID-19.
- Use of ivermectin is currently strongly discouraged by the:
  - TGA
  - National COVID-19 Clinical Evidence Taskforce (Taskforce)
  - World Health Organization (WHO)
  - US Food and Drug Administration
  - European Medicines Agency
- On 24 September 2021 the Indian Council of Medical Research (ICMR)-Covid-19 National Task Force Joint Monitoring Group dropped the usage of ivermectin from revised clinical guidelines for the management of adult Covid-19 patients. [1]

EVIDENCE OF IVERMECTIN TO TREAT COVID-19

- The Taskforce undertakes continuous evidence surveillance to identify and rapidly synthesise emerging research to provide national, evidence-based guidelines for clinical care of people with COVID-19.[2]
  - The Taskforce advises against the use of ivermectin for COVID-19 treatment outside of properly conducted clinical trials with appropriate ethical approval, and strongly discourages the use of ivermectin for the prevention or treatment of COVID-19.[3]
- **31 March 2021** – the WHO advised that current evidence on the use of ivermectin to treat COVID-19 patients is inconclusive, and until more data is available, the WHO recommends that the drug only be used within clinical trials.
- It is the consensus view of international regulators that to date there is a lack of high-quality evidence with sufficient certainty to support the safe and efficacious use of ivermectin for the prevention or treatment of COVID-19.
  - **4 February 2021** - a statement from Merck, one of the major manufacturing companies of ivermectin, has publicly confirmed that, "to date, our 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
    - a concerning lack of safety data in the majority of studies"[4].
- Whilst shown to be potentially effective in the laboratory environment, ivermectin is not recommended to be used outside clinical trials in the treatment of COVID-19.
  - **April 2020** – publication in the journal Antiviral Research, found that ivermectin could inhibit SARS-CoV-2 in cell cultures outside the body (*in vitro*).

---

[1] www.thehindu.com/news/national/icmr-stops-use-of-ivermectin-hcq-for-covid-19-treatment/article36651890.ece
[2] www.covid19evidence.net.au/faqs/#Ivermectin
[3] https://covid19evidence.net.au/faqs/#Ivermectin
[4] www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/

  - Doses used to date in laboratory studies would correspond to a much higher dosage in humans than is currently recommended and appropriate doses for use in COVID-19 are not yet determined.

- A recent analysis by the Cochrane Collaboration concluded that ivermectin could not be recommended for COVID-19 treatment or prevention.[5]
- Clinical Trials investigating ivermectin for COVID-19:
  - Evidence from large, prospective and randomised controlled studies is needed before the efficacy and safety of ivermectin for the treatment or prevention of COVID-19 can be fully understood.
  - The consensus view of international regulators and top-tier medical journals is that more evidence from large, prospective and randomised controlled trials is required.
  - There are a number of global clinical trials investigating the potential of ivermectin either alone or in combination with other medications, to treat or prevent COVID-19.[6]
  - An Egyptian ivermectin clinical trial demonstrating a dramatic treatment effect has been withdrawn from pre-print due to allegations of plagiarism, data manipulation and ethical concerns[7].

REGISTRATION OF IVERMECTIN AS A TREATMENT FOR COVID-19

- The TGA has well-established processes and data requirements for the regulatory evaluation of medicines in Australia, which are based on adopted internationally recognised guidelines.
- The TGA is regularly meeting with researchers and industry regarding concerning potential treatments for the prevention and treatment of COVID-19 in a variety of clinical settings.
- The TGA would welcome an application to register ivermectin for a new indication at any time. It is important to note, however, that the Australian Government is unable to compel pharmaceutical companies to make an application for registration. Robust clinical evidence on efficacy and safety would be required to support such an application, as well as a source of product manufactured to pharmaceutical Good Manufacturing Standards requirements.
- A medicine can only be approved by the TGA if this rigorous process is completed and the benefits are considered to be much greater than any potential risks.

RISK OF SHORTAGES

- There is no current shortage of ivermectin products in Australia.
- The previously reported shortage of Stromectol ivermectin 3mg tablet blister pack was due to unexpected increase in consumer demand. The shortage was resolved on 20 August 2021 when the sponsor received sufficient supply to meet forecasted demand.

[5] www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD015017.pub2/full
[6] www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/
[7] www.nature.com/articles/d41586-021-02081-w

- (Sensitive) To ensure equitable distribution and prevent stockpiling of available supplies, the Department has issued a Written Direction to PBS Community Service Obligation (CSO) Distributors to allow wholesalers to restrict supply to Community Pharmacies.
- The Written Direction is in effect until 31 December 2021 however it may be withdrawn earlier if the supply/demand has stabilised. (End Sensitive)

IMPORTATION

- The Personal Importation Scheme allows for the importation of a maximum of three months' supply of an unregistered product (not included in the ARTG) at the maximum dose recommended by the manufacturer.
  - If the product contains a Schedule 4 (prescription only) substance, then the importer must have a written authority issued by an authorised medical practitioner registered under a law of a state or territory (in practice, a prescription).
- Imports referred to the TGA for assessment between July 2021 and early October 2021 include a total of 73,000 tablets of ivermectin.
  - This is a significant increase in detected imports (173) compared to the previous six months (5). This trend is continuing (27 recorded imports 1-7 October 2021 compared to 120 in September 2021).
  - In most instances, the quantity being imported exceeded three months' supply.
- To date, only two valid prescriptions, or other written authorities, have been provided to support the release of products under the Personal Importation Scheme. Those were provided by GPs prior to the new prescribing restrictions.
- The imports assessed by the TGA to date were tablets for human (not animal) use that appeared to have been manufactured in India in 6mg and 12mg dosages, usually in packs of 10. Note that the ARTG registered product is available in packs of 3 x 3mg tablets.
- The importers contacted to date have confirmed that their imported ivermectin was intended for the prevention and/or treatment of COVID-19.

COVID-19 THERAPEUTIC GOODS COMPLIANCE

The TGA has undertaken the following actions in relation to advertising of ivermectin:

- **21 October 2020** – s22 [redacted] The advertising was subsequently removed, and no further action was taken.
- **5 February 2021** - s22 [redacted] The relevant advertising was removed, and the case was closed.
- **8 June 2021** - s22 [redacted] the case is closed.
- **16 August 2021** – s47G(1)(a) [redacted]

- **8 September 2021** – sent a letter to Surfers Medical Clinic requiring that they cease and desist from promoting the use of ivermectin on their website. The advertising was removed and no further action was taken.
- **9 September 2021** – sent a letter to Surecell Medical Australia requiring that they cease and desist from promoting the use of ivermectin on their website, including in a video. The advertising was removed and no further action was taken.

FACTS AND FIGURES:

As at 7 October 2021:

- 247 reports of non-compliance have been received in relation to the importation and advertising of ivermectin.

Of these reports:

- 221 were from ABF for ivermectin detected at the border.
- 75 have been closed or finalised, and 172 are subject to compliance action or are currently under investigation.

Outcomes:

- 91 contacts with entities warning them of an alleged breach of the legislation, including cease and desist letters, warning letters and education letters.
- one Directions Notice issued to s22 [redacted] for the alleged promotion of animal use ivermectin for human consumption on a Twitter account.
- 42 Section 56A Certificates (destruction of goods) issued, and
- 12,052 units destroyed.

OFFICIAL

Food Policy and Regulation and TGA
QB22-000463

ISSUE: Ivermectin

QUESTION: Restrictions to prescribing of Ivermectin in Australia

The Therapeutic Goods Administration (TGA) placed restrictions on the prescribing of Ivermectin in 2021. This occurred due to concerns about off-label prescribing of oral ivermectin for the claimed prevention or treatment of COVID-19 in the context of insufficient evidence. An application has now been submitted to overturn this ban.

Background

- On 10 September 2021, the TGA placed new restrictions on the prescribing of oral ivermectin on the advice of the Advisory Committee for Medicines Scheduling (ACMS), limiting its prescription by general practitioners.
- These changes were introduced following concerns about off-label prescribing of oral ivermectin for the claimed prevention or treatment of COVID-19 in the context of insufficient evidence.
- General Practitioners can continue to prescribe ivermectin for TGA-approved indications e.g. for parasite control. Certain specialists including infectious disease physicians, dermatologists, gastroenterologists, and hepatologists (liver disease specialists) may also prescribe ivermectin for other unapproved indications if they believe it is appropriate for a particular patient.
- The view of the TGA decision maker and of the ACMS was specialists, rather than GPs, were best positioned to prescribe ivermectin for unapproved indications. The TGA has a responsibility by law to make decisions on the general regulatory controls for the access of medicines in Australia.
- Ivermectin is not the only medicine with prescribing restrictions placed on it; there are about 30 other medicines that either cannot be prescribed by GPs, or alternatively, require individual special authorisation.
- Ivermectin has not received regulatory approval in Australia, or by other comparable international regulators, for the treatment or prevention of COVID-19. More evidence is required before they could be considered safe and effective treatment options for routine use for this indication. This is the consensus view of international regulators and top-tier medical journals.
- Supply of the registered oral ivermectin has significantly declined since the introduction of prescribing restrictions and become comparable to pre-pandemic levels.

- On 20 August 2022, the TGA received an application from Dr Julian Fidge to amend the Poisons Standard in relation to ivermectin. The application proposes to remove the prescribing restrictions on ivermectin, which would enable general practitioners to prescribe the medicine for off-label indications, including the treatment and/or prevention of COVID-19.
- The application is currently open for public consultation (closes 29 September) and will be discussed by the ACMS at their next meeting on 9 November 2022. The Delegate's interim decision is expected to be published in February 2023, and final decision later in 2023.

MEDIA COVERAGE
Publication: AUSTRALIAN DOCTOR NEWS
Publication dates: 23 August 2022
Key issues raised:

- The Royal Australian College of General Practitioners (RACGP) presidential candidate, Dr Julian Fidge (a Victorian GP), has defended his campaign for GPs to be allowed to prescribe ivermectin for COVID-19, saying doctors who believe it does not work are too "lazy" to check the evidence.
- He has described TGA's scheduling of ivermectin as "clearly irrational, irresponsible, reckless, negligent and possibly criminal"
- Dr Fidge has lodged a 33-page application to the TGA seeking removal of the ban on GPs prescribing ivermectin off label

[TOPIC]
[QB22-000XXX]

---- COVER PAGE ----

Date last updated by Dept:	7 September 2022	Cleared by Adviser/date:	
Contact Officer: Assistant Secretary	Ben Noyen	Work Phone: (02) 6289 7214	Mobile Phone: s22
Cleared by: Deputy Secretary	Adj Prof John Skerritt	Work Phone: (02) 6289 4200	Mobile Phone: s22

HCQ AND IVERMECTIN

Evidence recommending against use of ivermectin and hydroxychloroquine as COVID-19 treatments

- Ivermectin and hydroxychloroquine have not received regulatory approval in Australia, or by other comparable international regulators, for the treatment or prevention of any respiratory illness, including COVID-19.
- The consensus view of international regulators and top-tier medical journals is that more evidence is required before they could be considered safe and effective treatment options for routine use for this indication.
- The FDA and EMA released statements throughout 2021 warning consumers and health professionals to not use ivermectin for COVID-19 treatment including warning against human use of veterinary preparations. The United States Centers for Disease Control and Prevention published a warning on 26 August 2021.
- A study published in the New England Journal of Medicine (Bramante *et al*, 2022)[1] in August 2022, found that of the medications evaluated, including ivermectin, none prevented the occurrence of hypoxemia, an emergency department visit, hospitalisation, or death associated with Covid-19. In October 2022 the JAMA Network published a study (Naggie *et al*, 2022)[2] on the effectiveness of ivermectin to shorten symptom duration or prevent hospitalisation among outpatients in the US with mild to moderate symptomatic COVID-19. The study concluded that treatment with ivermectin did not significantly improve time to recovery.

Ivermectin

- With regard to ivermectin, an analysis updated in June 2022 of all published ivermectin trials by the Cochrane Collaboration concluded that there is no evidence to support the use of ivermectin for COVID-19 treatment or prevention. This review found that for inpatients, it is uncertain whether ivermectin prevents death or clinical worsening or increases serious adverse events, while there is low-certainty evidence that it has no beneficial effect regarding clinical improvement, viral clearance and adverse events. For the outpatient setting, the review found that ivermectin has no beneficial effect for people with COVID-19. This report is titled '*Ivermectin for preventing and treating COVID-19*'[3].
- Further information on ivermectin studies/ trials is available at Attachment A.

s22 [redacted]

[1] www.nejm.org/doi/full/10.1056/NEJMoa2201662?query=featured_coronavirus
2 https://jamanetwork.com/journals/jama/fullarticle/2797483
[3] https://www.cochrane.org/CD015017/INFECTN_ivermectin-preventing-and-treating-covid-19

s22 [redacted]

s22 [redacted]

Regulatory status of ivermectin and hydroxychloroquine as COVID-19 treatments

Whilst the TGA would welcome any submission from a sponsor for regulatory approval, as at 31 January 2023, no formal application has been submitted to the TGA to support the use of ivermectin or hydroxychloroquine for the treatment or prevention of COVID-19.

- On 30 August 2021 the TGA met with s22 [redacted] and associates to discuss the regulatory requirements for registering Topelia, an Ivermectin Triple Therapy (ITT): COVID-19 early treatment (ivermectin - doxycycline - zinc).
- The TGA is actively communicating and guiding Topelia and their regulatory agent via email to clarify the requirements of any application submitted to the TGA (last email from the TGA was 26 September 2022).
- The TGA have received preliminary literature-based submission search strategies to support an application from Topelia, and guidance has been

[5] The ORCHID study; www.nih.gov/news-events/news-releases/nih-halts-clinical-trial-hydroxychloroquine
[6] The RECOVERY trial: www.recoverytrial.net/files/hcq-recovery-statement-050620-final-002.pdf
[7] https://www.thelancet.com/journals/lanam/article/PIIS2667-193X(22)00060-6/fulltext
[8] www.ncbi.nlm.nih.gov/pmc/articles/PMC8273040/

provided regarding the data deficiencies associated with this preliminary submission.

- The TGA welcomes and encourages discussions with prospective sponsors at any time about the regulation process for potential COVID-19 treatments.

New restrictions on prescribing of oral ivermectin

- On 10 September 2021, the TGA placed new restrictions on the prescribing of oral ivermectin on the advice of the Advisory Committee for Medicines Scheduling (ACMS).
- These changes were introduced following concerns about off-label prescribing of oral ivermectin for the claimed prevention or treatment of COVID-19 in the context of insufficient evidence.
- General Practitioners can continue to prescribe ivermectin for TGA-approved indications. Certain specialists including infectious disease physicians, dermatologists, gastroenterologists, and hepatologists (liver disease specialists) may also prescribe ivermectin for other unapproved indications if they believe it is appropriate for a particular patient.
- On 16 November 2022, the ACMS advised the delegate on whether the prescribing restrictions remain appropriate following an application from a member of public, Dr Julian Fidge, who proposed that General Practitioners be allowed to prescribe ivermectin for unapproved indications through removal of the Appendix D entry. Public consultation on the proposal occurred from 1 to 29 September 2022, with 12 submissions received in support of the proposal to remove the restrictions and 5 submissions opposed.
- The delegate's interim decision to retain the prescribing restrictions on ivermectin, based on the ACMS advice and the information included in the public submissions, was published on 3 February 2023. The decision was primarily based on the lack of new evidence supporting the efficacy and safety of ivermectin in long-term use and in the dosage regimens for the treatment and prevention of COVID-19.
- Public consultation on the interim decision will close on 3 March 2023. The submissions will be taken into account before the delegate makes their final decision, expected to be published in April 2023.

Compliance and Enforcement information

- High volume importation of antibiotics, antivirals and antimalarials for the treatment of COVID-19 continues.
- Despite the lack of evidence to support ivermectin's efficacy against COVID-19, significant detections continue at the border. From 20 January 2020 to 31 January 2023:
  - the TGA commenced 3,668 import and 43 advertising related investigations, finalising 3,624 and 42 respectively.
  - 3,437 certificates to facilitate seizure of illegally imported products have been issued to the Australian Border Force (ABF) involving almost 1,377,860 items.

- 6 imported ivermectin products have been tested by the TGA Laboratories and found to be counterfeit.

s22 [redacted]

- The TGA has finalised an investigation into the alleged importation and subsequent sale of ivermectin and doxycycline through an encrypted website. Later consignments, addressed to an individual in Sydney, were intercepted by the ABF and did not reach the community. Two infringement notices were issued to the individual responsible and have been paid.

Division:	Medicines Regulation
Contact Officer:	Nick Henderson
Date:	8 February 2023

Attachment A

- On 21 October 2022, *Effect of Ivermectin vs Placebo on Time to Sustained Recovery in Outpatients With Mild to Moderate COVID-19* was published in JAMA (Naggie *et al*, 2022).[9] The study investigated the efficacy of ivermectin, 400 µg/kg, daily for 3 days compared with placebo for the treatment of 1,591 patients with early symptoms of mild to moderate COVID-19. The study concluded that ivermectin did not significantly improve time to recovery when compared with placebo.
- A systematic review, published in June 2022 (Shaffie *et al*, 2022)[10], included 19 randomised controlled trials and 4,328 participants and concluded that Ivermectin did not have any significant effect on outcomes for people with COVID-19.
- On 21 March 2022, *Comparison of Trials Using Ivermectin for COVID-19 Between Regions With High and Low Prevalence of Strongyloidiasis, a Meta-analysis* was published by JAMA Network Open (Bitterman *et al*, 2022)[11]. In this meta-analysis of 12 randomised clinical trials involving 3,901 patients, evidence supported that strongyloidiasis prevalence interacted with the relative risk of mortality in ivermectin trial results; and no evidence was found to suggest ivermectin has any role in preventing mortality in patients with COVID-19 in regions where strongyloidiasis is not endemic.
- In February 2022, a study published in JAMA Internal Medicine (Lim *et al* 2022)[12], reported that an open-label randomised clinical trial conducted at 20 public hospitals and a quarantine centre in Malaysia did not support the use of ivermectin for high-risk patients with mild-to-moderate COVID-19.
- A study published in May 2022 in the New England Journal of Medicine (Reis *et al* 2022)[13], reported on a double-blind, randomised, placebo-controlled, adaptive platform trial conducted on symptomatic SARS-CoV-2–positive adults in Brazil. The study found that treatment with ivermectin did not result in a lower incidence of medical admission to a hospital due to progression of COVID-19 or of prolonged emergency department observation among outpatients with an early diagnosis of COVID-19.
- In two separate studies published in December 2021 and April 2021 respectively, investigators have reported toxic reactions from using ivermectin including severe episodes of confusion, ataxia, seizures, and hypotension (Temple 2021)[14] and ivermectin associated hepatitis (Molento 2021)[15].
- In September 2021, Nature Medicine[16] reported that the results of the Elgazzar *et al* 2020 study represented more than 10% of the overall effect in at least two major meta-analyses published in 2021[17,18]. The latter meta-analysis has since been

[9] https://jamanetwork.com/journals/jama/fullarticle/2797483
[10] https://virologyj.biomedcentral.com/articles/10.1186/s12985-022-01829-8
[11] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2790173 - :~:text=No%20evidence%20was%20found%20to%20suggest%20that%20ivermectin%20has%20any,extrapolate%20to%20strongyloidiasis%2Dnonendemic%20regions
[12] jamanetwork.com/journals/jamainternalmedicine/fullarticle/2789362
[13] www.nejm.org/doi/full/10.1056/nejmoa2115869
[14] www.nejm.org/doi/full/10.1056/NEJMc2114907
[15] www.ncbi.nlm.nih gov/pmc/articles/PMC8050401/
[16] www.nature.com/articles/s41591-021-01535-y
[17] journals.lww.com/americantherapeutics/fulltext/2021/08000/ivermectin_for_prevention_and_treatment_of.7.aspx
[18] www.ncbi.nlm.nih gov/pmc/articles/PMC8420640

retracted[19] and published with a corrected version of the analysis, which demonstrated that the significant effects of ivermectin on survival initially reported were dependent on the inclusion of studies with a high risk of bias or potential medical fraud[20]. Nature Medicine also raised concerns about randomisation failure in an Iranian randomised controlled trial for ivermectin (Niaee *et al*, 2021)[21].

- On 4 February 2021, Merck, one of the major manufacturers of ivermectin, publicly confirmed that, to date, there is no scientific basis for a potential therapeutic effect against COVID-19 from pre-clinical studies, no meaningful evidence for clinical activity or clinical efficacy in patients with COVID-19 disease, and a concerning lack of safety data in the majority of studies.
- An Egyptian ivermectin study published in November 2020 (Elgazzar *et al*, 2020) which demonstrated a dramatic treatment effect has been withdrawn from pre-print due to allegations of plagiarism, data manipulation and ethical concerns. As noted above, this withdrawal was reported in Nature[22].

[19] academic.oup.com/ofid/article/8/11/ofab358/6316214
[20] academic.oup.com/ofid/article/9/2/ofab645/6509922
[21] www.apjtm.org/article.asp?issn=1995-7645;year=2021;volume=14;issue=6;spage=266;epage=273;aulast=Shakhsi
[22] https://www.nature.com/articles/d41586-021-02081-w

CURRENT RESCHEDULING PROPOSALS AND RECENT DECISIONS

Upcoming meetings: Advisory Committee on Medicines Scheduling (ACMS), Advisory Committee on Chemicals Scheduling (ACCS) and Joint ACMS-ACCS March 2023 meeting cycle

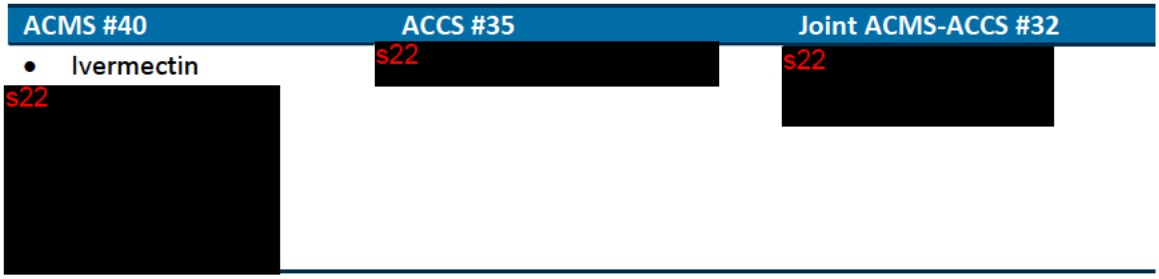
Key dates

- **Public consultations** on proposed amendments to the Poisons Standard opened from 5 January 2023 to 3 February 2023.
- **Advisory Committee meetings** will be held on 15-16 March 2023.
- **Interim decisions** for all substances are anticipated to be published in May 2023
- **Final decisions** for all substances are anticipated to be published in August 2023.

s22

[redacted]

Substances considered by ACMS/ACCS



Key substances

- **Ivermectin**
  - An applicant proposed the removal of the restriction that was implemented on 11 September 2021 on the prescribing of ivermectin by general practitioners to its approved indications (treatment of river blindness (onchocerciasis), threadworms of the intestines (intestinal strongyloidiasis) and scabies). Prescribing of ivermectin for other conditions is currently limited to appropriate specialist clinicians (such as an infectious disease specialist).
  - This change was introduced due to the significant individual and public health risks associated with taking ivermectin in an attempt to prevent COVID-19 infection rather than getting vaccinated, the unsafe dosages being promoted, and to ensure continued access for those who need the medicine for the treatment of scabies and parasitic infections.
  - 17 submissions were received as part of the public consultation inviting comment on the proposed amendment: 12 in support and 5 in opposition.
  - The interim decision is not to amend the current Poisons Standard for ivermectin, as there is insufficient new evidence for its efficacy and safety for the long-term use and dosage regimens for the treatment and prevention of COVID-19.

s22

s22

s22

s22

s22

s22

HPRG - Senate Estimates Brief

ISSUE: Current scheduling proposals and recent decisions

IF ASKED

November 2022 advisory committee meeting cycle

- Final decisions were published on 3 May 2023 regarding s22 ivermectin, s22
- The decisions followed 2 rounds of public consultation on the proposals, and interim decisions published on 3 February 2023.

s22

- Key substances:
  - **Ivermectin** (further information in back-pocket brief #11, D23-5294776)
    - The final decision was to remove the restriction on 'off-label' prescribing of oral ivermectin to certain specialist medical practitioners.
    - This final decision, which departs from the interim decision, was reached on the basis that medical practitioners are now properly informed of the risks of prescribing ivermectin for off-label indications and the clinical evidence demonstrating ivermectin provides no benefit to persons with COVID-19, and supply shortages are unlikely.

s22

HPRG - Senate Estimates Brief

s22 [redacted]

BACKGROUND & DATA

- Medicines and chemicals are classified into Schedules in the Poisons Standard according to the level of regulatory control over the availability of the medicine or chemical required to protect public health and safety.
- The Poisons Standard is implemented through state and territory legislation.
- Scheduling decisions are made by officers of the TGA acting as delegates of the Secretary of the Department of Health and Aged Care, not by the departmental Executive or ministers.
- The Delegates must make their decisions according to criteria in the *Therapeutic Goods Act 1989* (Cth) (the Act) and the Scheduling Policy Framework, the national policy for applying access restrictions on medicines and chemicals agreed to by the Commonwealth and all state and territory health ministers.
- Delegates may refer an application or proposal to amend the Poisons Standard to either or both of the Advisory Committee on Medicines Scheduling (ACMS) or Advisory Committee on Chemicals Scheduling (ACCS) for advice, as provided for by the Therapeutic Goods Regulations 1990. Alternatively, the Delegate has the power to amend the Poisons Standard on their own initiative.
- Scheduling decisions are legislative in character and cannot be appealed under the *Administrative Decisions (Judicial Review) Act 1977* in the Federal Court. Final scheduling decisions are not reviewable by the Administrative Appeals Tribunal.

RECENT SQoNs

- Nil

Division:	***Regulatory Practice and Support Division***
Cleared by:	Tracey Duffy (02) 6289 4230
Contact Officer:	Ben Noyen (02) 6289 7214
Date:	8 May 2023

TGA
QB23-000175

ISSUE: Final decision on ivermectin prescribing restrictions

QUESTION:

Ivermectin access – why has the TGA removed prescribing restrictions?

Top line response:

- Prescribing of ivermectin will no longer be restricted to certain specialists because the safety risks to individuals and public health from the use of ivermectin are now sufficiently low when prescribed 'off-label' by a general practitioner in the current health climate.
- The decision by the TGA does not mean an endorsement of off-label prescribing of ivermectin for the treatment or prevention of COVID-19. A large number of clinical studies have demonstrated that ivermectin does not improve outcomes in patients with COVID-19.
- The National Clinical Evidence Taskforce (NCET) and many similar bodies around the world, including the World Health Organization, strongly advises against the use of ivermectin for the prevention or treatment of COVID-19.
- Ivermectin has not received regulatory approval in Australia, or by other comparable international regulators, for the treatment or prevention of any respiratory illness, including COVID-19.

Prescribing restrictions on ivermectin

- Ivermectin is an anti-parasite medication that is used to treat human and animal diseases.
- Ivermectin for oral use (Stromectol) is a Prescription Only (Schedule 4) medicine in the Poisons Standard. It is only approved by the TGA for the treatment of river blindness (onchocerciasis), threadworm of the intestines (intestinal strongyloidiasis), and scabies.
- Restrictions on the prescribing of ivermectin through its scheduling in the Poisons Standard were removed from 1 June 2023. This decision was announced by the TGA on 3 May 2023.
- The restrictions were introduced in September 2021 to limit 'off-label' prescribing of oral ivermectin to certain specialists. The restrictions were introduced because of concerns that the prescribing of ivermectin for the claimed prevention or treatment of COVID-19 posed significant public health risks, and the potential for supply shortages impacting people needing treatment with ivermectin for its TGA-approved indications.
- The present decision was based on evidence and awareness of medical practitioners about the risks and benefits of ivermectin, and the low potential for any shortages of ivermectin for its approved uses. Also, given the high rates of vaccination and hybrid immunity against COVID-19 in Australia, use of ivermectin by some individuals is unlikely to now compromise public health.

- The final decision was made in accordance with the statutory process involving advice from the Advisory Committee on Medicines Scheduling (ACMS) and two rounds of public consultation.

Scheduling process

- The interim and final scheduling decisions were made by a senior medical officer of the TGA acting as a Delegate of the Secretary of the Department of Health and Aged Care. They were not decisions of the departmental executive or Government.
- In Australia, medicines and chemicals are classified into Schedules in the Poisons Standard according to the risk of harm and the level of access control required to protect public health and safety. The implementation of the Poisons Standard, as it affects access to and supply of medicines and poisons, is given legal effect through relevant state and territory drugs, poisons and controlled substances legislation.

MEDIA COVERAGE
There has been limited media coverage on the final decision from The Guardian (Josh Taylor), The Age, The Medical Republic and Pharmacy Daily.

Date last updated by Dept:	30 May 2023	Cleared by Adviser/date:	X May 2023
Contact Officer: A/g First Assistant Secretary A/g Deputy Secretary	 Chris Bedford Tracey Duffy	 Work Phone: (02) 6289 5327 Work Phone: (02) 6289 4200	 Mobile Phone: s22 [redacted] Mobile Phone s22 [redacted]

HPRG - Senate Estimates Brief

ISSUE: Hydroxychloroquine and Ivermectin

IF ASKED

Removal of restrictions on prescribing on Ivermectin

- Restrictions on the prescribing of ivermectin through its scheduling in the Poisons Standard were removed on 1 June 2023. This decision was announced by the TGA on 3 May 2023.
- The restrictions were introduced in September 2021 to limit 'off-label' prescribing of oral ivermectin to certain specialists. The restrictions were introduced because of concerns that the prescribing of ivermectin for the claimed prevention or treatment of COVID-19 posed significant public health risks.
- Oral Ivermectin is only approved by the TGA for the treatment of river blindness (onchocerciasis), threadworm of the intestines (intestinal strongyloidiasis), and scabies. The TGA has not received an application to extend the approved uses of ivermectin products to COVID-19.
- The decision to remove the restrictions is not an endorsement of the off-label prescribing of ivermectin for the treatment or prevention of COVID-19. Rather, it reflects that the safety risks to individuals and public health from its use are now sufficiently low.
- The restrictions on ivermectin prescribing were introduced on 10 September 2021 on the advice of the Advisory Committee for Medicines Scheduling (ACMS). At the time, the key public health risks of concern included:
    - people prescribed ivermectin for COVID-19 may not get vaccinated or seek medical care if they developed symptoms, and may pose a potential risk to the community through spread of the disease
    - potential adverse effects from ivermectin
    - potential for supply shortages impacting people needing treatment with ivermectin for its TGA-approved indications.
- The reasons for the decision to remove the restrictions include:
    - the abundance of clinical evidence demonstrating no benefit of ivermectin to persons with COVID-19, either for prophylaxis or treatment, such that medical professionals are properly informed of the risks of prescribing ivermectin for such an off-label indication
    - clinical studies investigating ivermectin for treatment of COVID-19 demonstrate a low-risk of adverse reactions
    - the high rate of COVID-19 vaccination in Australia, and
    - a low risk of supply shortages of ivermectin that would impact its availability for approved indications.
- The decision relates to an application by a member of the public, Dr Julian Fidge, seeking to remove the restrictions in Appendix D of the Poisons Standard. The interim decision, published on 3 February 2023, retained the Appendix D entry based on the ACMS advice and public submissions. The final decision sets aside the interim decision following further public consultation.

Efficacy of Ivermectin for COVID-19?

- Ivermectin has not received regulatory approval in Australia, or by other comparable international regulators, for the treatment or prevention of any respiratory illness, including COVID-19.

HPRG - Senate Estimates Brief

- A large number of clinical studies have demonstrated Ivermectin does not improve outcomes in patients with COVID-19. These include studies conducted in different countries and settings. See Attachment A for examples of these studies.
- These results, replicated among several independent studies, strongly supports the conclusion Ivermectin is not an effective therapy. It makes any potential bias in interpreting the overall results far less likely or plausible.
- While there is some evidence that Ivermectin is able to interfere with COVID-19 virus in vitro[1] (i.e. in the 'test-tube'), the effectiveness of a potential therapy must be proven in patients through clinical trials. An in-vitro effect does not necessarily translate into real patient benefits, or prove a therapy is safe.

s22 [redacted]

Applications to the TGA for ivermectin and hydroxychloroquine as COVID-19 treatments

- As at 30 April 2023, no formal application has been submitted to the TGA to support the use of Ivermectin or Hydroxychloroquine for the treatment or prevention of COVID-19.
- A Sponsor has had preliminary discussions with TGA regarding a potential application for Ivermectin registration and TGA has provided specific advice on the data requirements that must be submitted to support a prescription medicine application.
- TGA remains ready to discuss potential applications or data with any Sponsor considering an application to register therapeutic goods.

TGA ignored advice of its own experts and submissions when it removed restrictions on ivermectin?

- The Delegate did not ignore the advice of the ACMS, they considered all submissions (including those in the two rounds of public consultation).
- As stated in the final decision, the Delegate came to a different conclusion about the balance of the benefits and risks of removing the prescribing restrictions.
    - In particular, they gave more weight to the ability of doctors to manage the risks to individual patients under their care given the weight of evidence that is now available to them showing that ivermectin is not beneficial, but otherwise relatively safe, for the treatment or prevention of COVID-19.
    - This took into account new evidence about the safety of ivermectin that has been published since the ACMS gave their advice, and the latest COVID-19 vaccination data.
    - The Australian Medical Association (AMA) in a submission to the TGA, the justification for continuing the restriction on the prescribing of ivermectin is weak.
- The decision is consistent with the advice of the National Clinical Evidence Taskforce and international organisations including the World Health Organisation.

[1] Caly, L et al, "*The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro*", Antiviral Research 178 (2020), https://pubmed.ncbi.nlm.nih.gov/32251768/

HPRG - Senate Estimates Brief

BACKGROUND & DATA

Compliance and Enforcement information

- Importation of antibiotics, antivirals and antimalarials for the treatment of COVID-19 continues.
- In relation to Ivermectin, from 20 January 2020 to 30 April 2023:
  - the TGA commenced 3,687 import-related investigations and 45 advertising-related investigations, finalising 3,691 and 11 respectively
  - 3,531 certificates to facilitate seizure of illegally imported products have been issued to the Australian Border Force (ABF) involving 1,400,885 items.

s22 [redacted]

RECENT SQoNs

- NONE

RECENT MEDIA COVERAGE

- NONE

Division:	Regulatory Practice and Support
Cleared by:	Elspeth Kay (02) 6289 3528
Contact Officer:	s22 [redacted]
Date:	30 May 2023

Attachment A

- On 20 February 2023, *Effect of Higher-dose Ivermectin for 6 days vs Placebo on Time to Sustained Recovery in Outpatients with COVID-19: A randomised clinical trial*, was published in JAMA (Naggie et al, 2023)[2]. This examined whether 6-days treatment with Ivermectin at a maximum targeted dose of 600µg/kg would shorten symptoms or reduce hospitalisation in people with mild to moderate COVID-19. The study enrolled 1206 patients allocated to receive Ivermectin (n=602) or placebo (n=604) treatment. The study concluded that Ivermectin did not improve time to recovery or hospitalisation compared to placebo.
- On 21 October 2022, *Effect of Ivermectin vs Placebo on Time to Sustained Recovery in Outpatients With Mild to Moderate COVID-19* was published in JAMA (Naggie *et al*, 2022).[3] The study investigated the efficacy of ivermectin, 400 µg/kg, daily for 3 days compared with placebo for the treatment of 1,591 patients with early symptoms of mild to moderate COVID-19. The study concluded that ivermectin did not significantly improve time to recovery when compared with placebo.
- A systematic review, published in June 2022 (Shaffie *et al*, 2022)[4], included 19 randomised controlled trials and 4,328 participants and concluded that Ivermectin did not have any significant effect on outcomes for people with COVID-19.
- On 21 March 2022, *Comparison of Trials Using Ivermectin for COVID-19 Between Regions With High and Low Prevalence of Strongyloidiasis, a Meta-analysis* was published by JAMA Network Open (Bitterman *et al*, 2022)[5]. In this meta-analysis of 12 randomised clinical trials involving 3,901 patients, evidence supported that strongyloidiasis prevalence interacted with the relative risk of mortality in ivermectin trial results; and no evidence was found to suggest ivermectin has any role in preventing mortality in patients with COVID-19 in regions where strongyloidiasis is not endemic.
- In February 2022, a study published in JAMA Internal Medicine (Lim *et al* 2022)[6], reported that an open-label randomised clinical trial conducted at 20 public hospitals and a quarantine centre in Malaysia did not support the use of ivermectin for high-risk patients with mild-to-moderate COVID-19.
- A study published in May 2022 in the New England Journal of Medicine (Reis *et al* 2022)[7], reported on a double-blind, randomised, placebo-controlled, adaptive platform trial conducted on symptomatic SARS-CoV-2–positive adults in Brazil. The study found that treatment with ivermectin did not result in a lower incidence of medical admission to a hospital due to progression of COVID-19 or of prolonged emergency department observation among outpatients with an early diagnosis of COVID-19.
- In two separate studies published in December 2021 and April 2021 respectively, investigators have reported toxic reactions from using ivermectin including severe episodes of confusion, ataxia, seizures, and hypotension (Temple 2021)[8] and ivermectin associated hepatitis (Molento 2021)[9].

---

[2] https://jamanetwork.com/journals/jama/fullarticle/2801827

[3] https://jamanetwork.com/journals/jama/fullarticle/2797483

[4] https://virologyj.biomedcentral.com/articles/10.1186/s12985-022-01829-8

[5]https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2790173 -:~:text=No%20evidence%20was%20found%20to%20suggest%20that%20ivermectin%20has%20any,extrapolate%20to%20strongyloidiasis%2Dnonendemic%20regions

[6] jamanetwork.com/journals/jamainternalmedicine/fullarticle/2789362

[7] www.nejm.org/doi/full/10.1056/nejmoa2115869

[8] www.nejm.org/doi/full/10.1056/NEJMc2114907

[9] www.ncbi.nlm.nih.gov/pmc/articles/PMC8050401/

From: HPRG Parliamentary
To: SKERRITT, John
Cc: s22 ; s22
Subject: FOR CLEARANCE (INPUT): Due COB today, Wednesday (26/08/2020) - Ministerial Brief - ivermectin COVID-19 (MB20-002985) [SEC=OFFICIAL]
Date: Wednesday, 26 August 2020 11:04:32 AM
Attachments: image001.png
image002.png
MB20-002985 for HPRG Deputy Secretary clearance (Medicines Regulation FAS-cleared).docx
MB20-002985 for HPRG - original with QA.docx

Dear John,

OHP have requested HPRG clearance of the attached Ministerial Information Request (MIR – a Ministerial brief) that they are taking carriage of.

Dr Jane Cook has FAS-cleared the attached [**MB20-002985 for HPRG Deputy Secretary clearance (Medicines Regulation FAS-cleared)**].

*Jane and Dr Grant Pegg have essentially rewritten this Ministerial brief because Professor Borody has been endorsing the combination of ivermectin, doxycycline and zinc – and thus, the brief has been revised to cover this combination.

Please provide your Deputy Secretary clearance to HPRG Parliamentary by **COB today, Wednesday 26 August 2020**.

Please see OHP's request below, along with the original correspondence.
For your convenience, I have also attached the original response document that was drafted by OHP (pre-Jane/Grant's edits) and with a minor QA from me in track changes (MB20-002985 for HPRG - original with QA).

Regards,

s22
HPRG Regulatory Engagement Services
Reporting and Collaborative Services Section
Ministerial Correspondence | Ministerial Submissions | Ministerial Briefs | QTBs
Team leaders: s22
Regulatory Practice & Support Division | Health Products Regulation Group
Regulatory Engagement and Planning Branch
Australian Government Department of Health
T: s22 | M: s22 | E: s22 @health.gov.au
Location: Symonston, GE.32

---

s22 @health.gov.au>
Sent: Tuesday, 25 August 2020 3:00 PM
To: HPRG Parliamentary s22 @health.gov.au>
Cc: NIRDCoord s22 @health.gov.au>; Khiani, Radha s22 @health.gov.au>; Gaind, Nindiya s22 @health.gov.au>
Subject: For clearance - ivermectin / pharmaceutical question (MB20-002985) [SEC=OFFICIAL]

Hi s22 and TGA Parliamentary

I write from the Ministerial Correspondence team.

For Clearance

I am seeking your clearance of the attached Ministerial brief please regarding ivermectin, its sponsorship, why it is not listed to treat COVID-19, as well as hydroxchloroquine. Please clear the whole brief, paying particular attention to the highlighted paragraph.

Background

We are providing a Brief to an MP, who is making a representation on behalf of a constituent, asking for investigation about Professor Borody's claims.

The original correspondence is below. I have used standard words, but am seeking your clearance of the complete letter please. MB20-002985

Due date

Please clear by **COB THURSDAY (27 August)** via return email.

You are welcome to reach me on 02 6289 7119 if you have any questions.

Thank you.

s22.

s22
Assistant Director
Public Health Branch
Office of Health Protection and Response
Australian Government Department of Health

Direct line: s22
E: s22 @health.gov.au

Location: Scarborough House. 8.265
PO Box 9848, Canberra ACT 2601, Australia

From: Minister Hunt DLO <s22 @health.gov.au>
Sent: Tuesday, 25 August 2020 7:49 AM
To: MPS s22 @health.gov.au>
Cc: Minister Hunt DLO <s22 @health.gov.au>
Subject: MB20-002985 - FW: Representation, s22 , cure for Covid [SEC=OFFICIAL]

MIR – NIRD – 5 days

s22
Department Liaison Officer
Office of the Hon Greg Hunt MP
Minister for Health
T: s22 | M: s22
E: s22 @health.gov.au
Suite M1.41, PO Box 6022, Parliament House, Canberra ACT 2600, Australia

From: s22
Sent: Monday, 24 August 2020 8:43 PM
To: Minister Hunt DLO
Subject: FW: Representation, s22, cure for Covid [SEC=OFFICIAL]

MIR

From: s22 (M. Swanson, MP) s22 @aph.gov.au>
Sent: Monday, 24 August 2020 12:48 PM
To: Ask Minister Hunt <s22 @health.gov.au>
Subject: Representation, s22, cure for Covid [SEC=No Protective Marking]

Dear Minister Hunt

Please find below an email from s22 received by Meryl Swanson MP, Member for Paterson.

Your investigation of the matters raised by s22 and any advice you are able to provide would be appreciated.

Kind regards,

s22 | Community Liaison Officer
Office of Meryl Swanson MP, Federal Member for Paterson
Phone: s22 | **Email:** s22 @aph.gov.au
Electorate Office: 35 Sturgeon Street, Raymond Terrace
Parliament House: Suite R2.97 Parliament House, Canberra

www.merylswanson.com.au | facebook | instagram | twitter | youtube | email

All electoral communications authorised by Meryl Swanson Australian Labor Party Raymond Terrace NSW

From: s22 [mailto s22
Sent: Friday, 21 August 2020 6:58 PM

To: Swanson, Meryl (MP)
Subject: Covid

Hi Meryl,

I came across this article and concerned me that this Australian Professor Thomas Borody has a cure for Covid but is unable to connect with Politicians nor their Advisors simply because he is not sponsored by a big pharmaceutical company.

Please read this article and if you could forward it onto the appropriate people I am sure your constituents would be more than grateful.

Kind Regards,

s22

http://covexit.com/we-know-its-curable-its-easier-than-treating-the-flu-professor-thomas-borody/

s22 iPhone

MINISTERIAL INFORMATION REQUEST

MB20-002985
Date Sent to MO:<dd/mm/yy>

MINISTER: Greg Hunt

Issue: MIR - Article on Professor Thomas Borody on cure for COVID-19 - Meryl Swanson MP obo s22 [redacted]

Response:

- Thank you for bringing s22 [redacted] concerns to Minister Hunt's attention.
- The Australian Government is closely monitoring worldwide research into COVID-19 treatments.
- There is currently insufficient evidence to support the safe and effective use of ivermectin, doxycycline and zinc (either separately, or in combination) for the prevention or treatment of COVID-19. More robust, well-designed clinical trials are needed before they could be considered an appropriate treatment option.
- The National COVID-19 Clinical Evidence Taskforce, consisting of a large group of clinical experts, is continuously updating treatment recommendations based on the best available evidence. They have not made any recommendations for the use of ivermectin, doxycycline or zinc outside of properly conducted clinical trials with appropriate ethical approval.
- In addition, the use of hydroxychloroquine (with or without zinc) for the treatment of COVID-19 is not recommended outside of randomised trials with appropriate ethical approval. There is concern that, if used inappropriately, off-label use of medications may cause toxicity and lead to adverse patient outcomes. Hydroxychloroquine has well known risks including cardiac toxicity (potentially leading to heart attacks), irreversible eye damage and severe depletion of blood sugar levels (potentially leading to coma). These potential adverse events, as well as the serious nature of the conditions that hydroxychloroquine is registered to treat, are some of the reasons that hydroxychloroquine is regulated as a prescription-only medicine in Australia. More information is available at: www.tga.gov.au/alert/amendments-new-restrictions-prescribing-hydroxychloroquine-covid-19. Furthermore, there is insufficient data to recommend neither for nor against the use of zinc for the prevention or treatment of COVID-19.
- Although a medicine may be approved by the Therapeutic Goods Administration (TGA) to treat a particular condition, it does not automatically mean that it is safe to treat another condition 'off-label'. Doctors who prescribe medicines off-label should do so taking into account the potential risks and benefits for the patient in the setting of informed consent.
- You can be assured that the Government, along with the states and territories, are taking an evidence-based approach to COVID-19, and is committed to keep Australians safe. It is vital all Australians continue to take personal responsibility to protect themselves and others. We must all maintain physical distancing of 1.5 metres, practice good hand and cough hygiene, and stay home and get tested when unwell.

Background

- For a medicine to be registered in Australia to treat a specific condition, a sponsor (usually a pharmaceutical company) is required to submit a comprehensive developmental dossier which consists of clinical studies, non-clinical/toxicology studies, chemistry, manufacturing, risk management and other information.
- Once accepted by the TGA, a formal evaluation is carried out in multiple stages by technical experts. The process involves obtaining further information and clarification from the applicant, this may include advice from an independent committee of external experts, prior to finalisation and decision under the *Therapeutic Goods Act 1989*.
- Decisions are based on whether the overall benefit of the medicine is considered to outweigh the potential risks of its use. If a decision is made to approve the vaccine, it is included in the Australian Register of Therapeutic Goods (ARTG) and can be lawfully supplied in Australia.

Minister	**Greg Hunt**
PDR Number	**MB20-002985**
Issue	**MIR - Article on Professor Thomas Borody on cure for COVID-19 - Meryl Swanson MP obo Wayne Bertwistle**
Action Officer	s22 s22
Clearance Officer	**Graeme Barden** **02 6289 3015** s22
Division/Branch	**Office of Health Protection and Response**

Adviser/DLO Comments:

Return for Redraft ☐

MINISTERIAL INFORMATION REQUEST

MB20-002985
Date Sent to MO:<dd/mm/yy>

MINISTER: Greg Hunt

Issue: MIR - Article on Professor Thomas Borody on cure for COVID-19 - Meryl Swanson MP obo s22 [redacted]

Response:

- Thank you for bringing s22 [redacted] concerns to Minister Hunt's attention.
- The Australian Government is taking a strong and decisive approach in responding to COVID-19, informed by the latest medical advice from the Australian Health Protection Principal Committee (AHPPC).
- There is no cure or treatment to prevent COVID-19, although a number of medications can help people who are very seriously ill. Nonetheless, the Government is closely monitoring worldwide research of treatments for patients with COVID-19.
- Ivermectin is available in Australia for a range of indications, and is already sponsored by a pharmaceutical manufacturer. In order to be indicated for the treatment of COVID-19, the manufacturer must have sufficient clinical evidence to apply to the Therapeutical Goods Administration for a listing to treat COVID-19.
- There are numerous clinical trials currently being conducted around the world that are investigating the potential role of ivermectin, either alone or in combination with other medications, to prevent or treat COVID-19. However, no clinical trials have yet reported its efficacy nor safety in the context of COVID-19.
- In addition, the use of hydroxychloroquine (with or without zinc) for the treatment of COVID-19 is not recommended outside of randomised trials with appropriate ethical approval. There is concern that, if used inappropriately, off-label use of medications may cause toxicity and lead to adverse patient outcomes. Hydroxychloroquine has well known risks including cardiac toxicity (potentially leading to heart attacks), irreversible eye damage and severe depletion of blood sugar levels (potentially leading to coma). These potential adverse events, as well as the serious nature of the conditions that hydroxychloroquine is registered to treat, are some of the reasons that hydroxychloroquine is regulated as a prescription-only medicine in Australia. More information is available at: www.tga.gov.au/alert/amendments-new-restrictions-prescribing-hydroxychloroquine-covid-19. Furthermore, there is insufficient data to recommend neither for nor against the use of zinc for the prevention or treatment of COVID-19.
- You can be assured that the Government, along with the states and territories, are taking an evidence-based approach to COVID-19, and is committed to keep

Australians safe. It is vital all Australians continue to take personal responsibility to protect themselves and others. We must all maintain physical distancing of 1.5 metres, practice good hand and cough hygiene, and stay home and get tested when unwell.

Minister **Greg Hunt**

PDR Number **MB20-002985**

Issue **MIR - Article on Professor Thomas Borody on cure for COVID-19 - Meryl Swanson MP obo** s22 [redacted]

Action Officer s22 [redacted]

Clearance Officer **Graeme Barden**
02 6289 3015
s22 [redacted]

Division/Branch **Office of Health Protection and Response**

Adviser/DLO Comments:

Return for Redraft ☐

From:	SKERRITT, John
To:	s22 ; MITCHELL, Gillian; NOYEN, Benjamin; s22
Cc:	s22 ; SKERRITT, John
Subject:	RE: FOR YOUR CLEARANCE - FW: Ivermectin info brief [SEC=OFFICIAL]
Date:	Friday, 10 September 2021 11:52:05 AM
Attachments:	image001.png final media release - ivermectin 10 9 21.DOCX Ministerial Information Brief - Ivermectin - new prescribing restrictions final.DOCX
Importance:	High

Final brief and MR attached

Can the MR be posted on our website ASAP today and the brief go up to the office. I'll advise s22 now but send it up – they need to now this for Ministers weekend media.

The legislative instrument needs to be made and registered ASAP too please.

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)

PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6289 4200 Fax: (02) 6203 1265
Email: john.skerritt@health.gov.au

From: s22 @health.gov.au>
Sent: Friday, 10 September 2021 11:34 AM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: s22 @health.gov.au>
Subject: FOR YOUR CLEARANCE - FW: Ivermectin info brief [SEC=OFFICIAL]

Hi John

Gillian has just cleared the Min Info brief on Ivermectin.

Comments from the Cover page are below:

OUTLINE / COMMENTS:

Dear John

For your consideration the draft information brief for the minister regarding the ivermectin scheduling decision. Please note that some amendments are being made to the Amendment Instrument and ES to incorporate the paediatric specialities. We anticipate that the Instrument will be made today, with commencement tomorrow.

Information Brief - D21-3073095
Attachment A: media release D21-3073089

Can you please advise if the MO have requested this brief or if it will be done as a Dept Initiated Brief … noting that DIBs are not being sent to the MO unless urgent (like the Min Subs).

Thanks!

s22
Executive Office Manager to Deputy Secretary John Skerritt

Health Products Regulation
T: s22 | E: s22 @health.gov.au
Location: Symonston G.G.09a

From: MITCHELL, Gillian <Gillian.Mitchell@health.gov.au>
Sent: Friday, 10 September 2021 11:23 AM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; NOYEN, Benjamin <Benjamin.Noyen@health.gov.au>; SKERRITT, John <John.Skerritt@health.gov.au>
Subject: Ivermectin info brief [SEC=OFFICIAL]
Importance: High

s22 – I understand John is after this urgently.

The web team, through s22, is on standby re publication of the documents once they are ready. It would be good to have a sense of what John is thinking timing wise.

Thanks, Gillian

-----Original Message-----
From: HPRG TRIM Admin <TRIM_no_reply@health.gov.au>
Sent: Friday, 10 September 2021 11:02 AM
To: MITCHELL, Gillian <Gillian.Mitchell@health.gov.au>
Subject: HP TRIM Notification - Action Made Current. Clearance [SEC=OFFICIAL]

Record number: D21-3074650
Record title: Dep Sec cover sheet - RPSD - REEPB - Ministerial Information Brief - Ivermectin - new prescribing restrictions - 10 September 2021
TRIMweb: http://hpcmweb.production.tga.gov.au/HPEContentManager/?uri=187349512
Action: Clearance
Responsible location: Mitchell, Gillian
Due date: 14/09/2021 at 11:00 AM

File Notes:

This Action has been recently created and assigned to you and is due to be started on 10/09/2021 at 10:59 AM. Could you please ensure that it is completed by 14/09/2021 at 11:00 AM.

When you are ready to record in TRIM that you have completed the action, right click on the record and select Workflow > Complete Current Action.

--
This E-mail Message has been automatically generated by TRIM Content Manager.

Australian Government

Department of Health

Therapeutic Goods Administration

MEDIA RELEASE

New restrictions on prescribing ivermectin for COVID-19

Today, the TGA, acting on the advice of the Advisory Committee for Medicines Scheduling, has placed new restrictions on the prescribing of oral ivermectin. General practitioners are now only able to prescribe ivermectin for TGA-approved conditions (indications) - scabies and certain parasitic infections. Certain specialists including infectious disease physicians, dermatologists, gastroenterologists and hepatologists (liver disease specialists) will be permitted to prescribe ivermectin for other unapproved indications if they believe it is appropriate for a particular patient.

These changes have been introduced because of concerns with the prescribing of oral ivermectin for the claimed prevention or treatment of COVID-19. Ivermectin is not approved for use in COVID-19 in Australia or in other developed countries, and its use by the general public for COVID-19 is currently strongly discouraged by the National COVID Clinical Evidence Taskforce, the World Health Organisation and the US Food and Drug Administration.

Firstly, there are a number of significant public health risks associated with taking ivermectin in an attempt to prevent COVID-19 infection rather than getting vaccinated. Individuals who believe that they are protected from infection by taking ivermectin may choose not to get tested or to seek medical care if they experience symptoms. Doing so has the potential to spread the risk of COVID-19 infection throughout the community.

Secondly, the doses of ivermectin that are being advocated for use in unreliable social media posts and other sources for COVID-19 are significantly higher than those approved and found safe for scabies or parasite treatment. These higher doses can be associated with serious adverse effects, including severe nausea, vomiting, dizziness, neurological effects such as dizziness, seizures and coma.

Finally, there has been a 3-4-fold increased dispensing of ivermectin prescriptions in recent months, leading to national and local shortages for those who need the medicine for scabies and parasite infections. It is believed that this is due to recent prescribing and dispensing for unapproved uses, such as COVID-19. Such shortages can

disproportionately impact vulnerable people, including those in Aboriginal and Torres Strait Islander communities.

There is only one TGA approved oral ivermectin product, Stromectol ivermectin 3mg tablet blister pack which is indicated for the treatment of river blindness (onchocerciasis), threadworm of the intestines (intestinal strongyloidiasis) and scabies.

All medical practitioners can continue to prescribe oral ivermectin for the approved indications. However, prescribing of oral ivermectin for indications that are not approved is now limited to certain specialists.

Contact for members of the media:

- Email: news@health.gov.au
- Phone: 02 6289 7400

Australian Government
Department of Health

OFFICIAL

Information Brief

Date sent to MO:10/09/2021

To: Minister Hunt

Subject: IVERMECTIN – NEW PRESCRIBING RESTRICTIONS

Minister Hunt …… **Date: / /**			
Comments:			
Contact Officer:	*Ben Noyen*	*Assistant Secretary, Regulatory Engagement, Education and Planning Branch*	Ph: (02) 6289 7214 Mobile: s22 [redacted]
Clearance Officer:	*Adj Prof John Skerritt*	*Deputy Secretary, Health Products Regulation Group*	Ph: (02) 6289 4200 Mobile: s22 [redacted]

Key Issues:

- The TGA medicines scheduling delegate, acting on the advice of the Advisory Committee for Medicines Scheduling (ACMS) has decided to place new restrictions on the prescribing of oral ivermectin effective 11 September 2021. Our media release, which has been published on the TGA website, is at **Attachment A**.
- **Once in effect, general practitioners will only able to prescribe ivermectin for TGA-approved conditions (indications) - scabies and certain parasitic infections.**
- In addition, only certain specialists will be permitted to prescribe ivermectin for other (unapproved) indications if they believe it is appropriate for a particular patient.
- These changes are being introduced due to concerns about risks to public health and safety arising from prescribing of oral ivermectin for the prevention or treatment of COVID-19.
- There has been a 3-4 fold increase in dispensing of ivermectin prescriptions over the past 24 months (from 2,536 in August 2019 to 11,707 in July 2021) with a particularly significant increase in recent months. We are of the view that this is due to recent prescribing and dispensing for unapproved uses, such as COVID-19.

Background:

- The decision was not open to public consultation, given the seriousness of the circumstances, the risks to the community and the urgency for action. However, the ACMS (including state and territory representative members) was consulted at an out of session meeting on 8 September 2021.
- The ACMS unanimously agreed that there was a need to urgently restrict the prescribing of oral ivermectin through amendments to the scheduling in the Poisons Standard, noting the significant public health risks, including:
    - individuals who believe they are protected from COVID-19 infection by taking ivermectin rather than getting vaccinated may choose not to get tested or seek medical care if they experience symptoms. Doing so has the potential to spread the risk of COVID-19 infection throughout the community; and
    - increased dispensing of ivermectin prescriptions in recent months may lead to national and/or local shortages for those who need the medicine for scabies and parasite infections. Such shortages can disproportionately impact vulnerable people, including Aboriginal and Torres Strait Islander communities.
- On the advice of the ACMS the Delegate has imposed additional controls on the prescribing of ivermectin by including new entries for ivermectin in Appendix D of the Poisons Standard. The amendments will limit prescribing of ivermectin for unapproved indications to the following specialists:
    - dermatologist
    - adult and paediatric gastroenterologist and hepatologist
    - adult and paediatric infectious diseases physician
- There is only one TGA approved oral ivermectin product, Stromectol ivermectin 3mg tablet blister pack, which is indicated for the treatment of river blindness (onchocerciasis), threadworm of the intestines (intestinal strongyloidiasis) and scabies. All medical practitioners can continue to prescribe this product for the approved indications.
- The decision does not impact access to topical ivermectin products or veterinary products.

Attachment A: Media release

From: SKERRITT, John
To: s22
Cc: NOYEN, Benjamin; s22
Subject: RE: FOR YOUR CLEARANCE - MB21-003489 URGENT TPs - Ivermectin [SEC=OFFICIAL]
Date: Tuesday, 14 September 2021 5:38:08 PM
Attachments: image001.png
image002.png
MB21-003489 Talking points - Ivermectin - 14 Sept 2021 final.docx

Thanks – final version attached

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)

PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6289 4200 Fax: (02) 6203 1265
Email: john.skerritt@health.gov.au

From: s22 @health.gov.au>
Sent: Tuesday, 14 September 2021 4:04 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Subject: FOR YOUR CLEARANCE - MB21-003489 URGENT TPs - Ivermectin [SEC=OFFICIAL]

Hi John

Attached for your clearance is a Min Brief of urgent talking points on Ivermectin as requested by the MO yesterday.

Whilst this was initially assigned to MRD – it has been managed by RPSD with input from MRD and OHPR. (see emails below)

Response is attached.

Gillian has cleared it in the last few minutes.

It is due ASAP today.

Thanks

s22
Executive Office Manager to Deputy Secretary John Skerritt
Health Products Regulation Group
T: s22 | E: s22 @health.gov.au
Location: Symonston G.G.09a

From: Minister Hunt DLO s22 @health.gov.au>
Sent: Monday, 13 September 2021 3:49 PM
To: s22 @health.gov.au>; Minister Hunt DLO

s22 @health.gov.au>; MPS s22 @health.gov.au>; s22 @health.gov.au>; HPRG Parliamentary s22 @health.gov.au>
Subject: RE: URGENT TPs - Ivermectin [SEC=OFFICIAL]

Thanks s22, in addition to MRD, could we also seek any input OHPR might have?

I think the idea is to have an updated set of TPs on Ivermectin, which would include (but not be limited to) the recent scheduling decision.

Thanks

s22
Departmental Liaison Officer
Office of the Hon Greg Hunt MP
Minister for Health and Aged Care
T: s22 M: s22
E: s22 @health.gov.au
Suite M1.41, PO Box 6022, Parliament House, Canberra ACT 2600, Australia

---

From: s22
Sent: Monday, 13 September 2021 3:25 PM
To: Minister Hunt DLO ; MPS ; s22 ; HPRG Parliamentary
Subject: RE: URGENT TPs - Ivermectin [SEC=OFFICIAL]
Importance: High

Hi all,

I believe this is probably best assigned to RPSD and the Scheduling team, with MRD to provide input, as the majority of the recent issue is around scheduling changes enacted after last Friday's decision of the ACMS.

Cheers,

s22

s22
Executive Officer to Dr Jane Cook, First Assistant Secretary
Medicines Regulation Division | Health Products Regulation Group
(comprising the Therapeutic Goods Administration and the Office of Drug Control)
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
Location: Symonston, GG 47
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued

connection to land, sea and community. We pay our respects to all Elders past, present and emerging.

From: Minister Hunt DLO <s22 @health.gov.au>
Sent: Monday, 13 September 2021 3:22 PM
To: MPS <MPS@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; HPRG Parliamentary <s22 @health.gov.au>
Cc: Minister Hunt DLO <s22 @health.gov.au>
Subject: URGENT TPs - Ivermectin [SEC=OFFICIAL]

Hi team

Could we please request general TPs on Ivermectin, including recent events. Assign to MRD (with input from OHPR, as needed).

Due ***4pm tomorrow***.

Thanks

s22
Departmental Liaison Officer
Office of the Hon Greg Hunt MP
Minister for Health and Aged Care
T: s22 M: s22
E: s22 @health.gov.au
Suite M1.41, PO Box 6022, Parliament House, Canberra ACT 2600, Australia

Australian Government
Department of Health

Ministerial Information Request and/or Talking Points
MB21-003489
Version (1)
Date sent to MO:14/09/21

To: **Minister Hunt**

Subject: **Talking points - Ivermectin**

Response:

Approved uses in Australia

- Ivermectin is an anti-parasite medication that is used to treat human and animal diseases caused by scabies and other parasites.
- The TGA has approved one oral tablet, STROMECTOL which contains ivermectin as an active ingredient. STROMECTOL is indicated for the treatment of:
  - Onchocerciasis (river blindness caused by a filarial worm) and intestinal strongyloidiasis (anguillulosis) (parasitic disease caused by roundworms).
  - Crusted scabies in conjunction with topical therapy
  - Scabies (caused by a sarcoptic mite) when prior topical treatment has failed or is contraindicated.
  - The TGA has also approved two topical creams that contain ivermectin - VASTREKA and SOOLANTRA - indicated for the topical treatment of inflammatory lesions of rosacea (papulo-pustular) in adult patients 18 years and over.

Use of ivermectin for COVID-19

- Ivermectin has not received regulatory approval in Australia, or any other comparable OECD country, for the treatment or prevention of COVID-19.
- The use of ivermectin by the general public for COVID-19 is currently strongly discouraged by the TGA, the National COVID-19 Clinical Evidence Taskforce, the World Health Organisation and the US Food and Drug Administration and a wide range of medical authorities in North America and Europe.
- A recent analysis of published ivermectin trials by the Cochrane Collaboration, one of the main independent international bodies responsible for assessing clinical evidence for particular medical treatments and therapies, concluded that ivermectin could not be recommended for COVID-19 treatment or prevention.
- It is the consensus view of international regulators and top-tier medical journals that more evidence from large, prospective and randomised controlled studies is required before the efficacy and safety of ivermectin for COVID-19 can be ascertained.
- There are a number of global clinical trials investigating the potential role of ivermectin, either alone or in combination with other medications, to prevent or treat COVID-19.
- The TGA, has well-established processes and data requirements for the regulatory evaluation of medicines in Australia, which are based on adopted internationally recognised guidelines.
- The TGA would welcome an application to register ivermectin for a new indication at any time. It is important to note, however, that the Australian Government is unable to compel pharmaceutical companies to make an application for registration. Robust clinical evidence

on efficacy and safety would be required to support such an application, as well as a source of product manufactured to pharmaceutical Good Manufacturing Standards requirements.

Increased prescribing of ivermectin and shortages

- There has been a 300-400 per cent increase in dispensing of ivermectin prescriptions in recent months, attributed to increased prescribing for unapproved uses such as COVID-19.
- This has led to national and local shortages for those who need the medicine for scabies and parasite infections. Such shortages can disproportionately impact vulnerable people, including those in residential aged care and Aboriginal and Torres Strait Islander communities.
- There is no current national shortage of ivermectin products in Australia although there have been reports of local shortages.
- To ensure equitable distribution and prevent stockpiling of available supplies, the Department has issued a Written Direction to PBS Community Service Obligation (CSO) Distributors to allow wholesalers to restrict supply to Community Pharmacies. The Written Direction is in effect until 31 December 2021 however it may be withdrawn earlier if the supply/demand has stabilised.

New restrictions on prescribing ivermectin

- The TGA acted on the advice of the Advisory Committee for Medicines Scheduling (ACMS), which includes medical and pharmaceutical experts, consumer representatives and senior representatives of health departments of each state and territory to place new restrictions on the prescribing of oral ivermectin from 11 September 2021.
- The decision was made by a senior medical officer at the TGA and is not a decision of Government.
- The decision restricts prescribing of ivermectin for indications not approved by the TGA to certain specialists where those specialists believe it is appropriate for a particular patient (for example, dermatology, infectious diseases, gastroenterology and hepatology). All other prescribing medical practitioners, including general practitioners, can only prescribe oral ivermectin for TGA-approved indications.
- The reasons for the decision include the following:
    - significant public health risks associated with taking ivermectin in an attempt to prevent COVID-19 infection rather than getting vaccinated. Individuals who believe they are protected from infection by taking ivermectin may choose not to get tested or to seek medical care if they experience symptoms. Doing so has the potential to spread the risk of COVID-19 infection throughout the community
    - concerns that social media posts and other sources support doses of ivermectin to prevent or treat COVID-19 at a significantly higher level than the doses approved for scabies or parasite treatment; this carries significant adverse effects for patients, and
    - to ensure continued access for those who need the medicine for treatment of scabies and parasite infections.
- There are no changes to prescribing of topical ivermectin or veterinary ivermectin.
- Oral ivermectin can continue to be accessed for unapproved uses in clinical trials, and if an ivermectin product subsequently was approved by the TGA for prevention or treatment of COVID-19 it would be able to be prescribed by all registered medical practitioners.

Cover Page for Ministers' Offices

Minister	**Minister Hunt**
PDR Number	**MB21-003489**
Subject	Talking points - Ivermectin
Due Date	**14 September 2021**
Quality Assurance Check (completed by line area)	s22 [redacted] s22 [redacted]
Contact Officer	Ben Noyen (02) 6289 7214 s22 [redacted]
Clearance Officer	Adj Prof John Skerritt (02) 6289 4200 s22 [redacted]
Division/Branch	|Health Products Regulation| Regulatory Practice and Support

Adviser/DLO Comments:

Return to Dept for:

Redraft ☐

OFFICIAL

Senate Select Committee on COVID-19
December 2021

Ivermectin – Rescheduling Decision

KEY POINTS

- Ivermectin is an anti-parasite medication that is used to treat human and animal diseases.
- Oral ivermectin (Stromectol) is approved by the Therapeutic Goods Administration (TGA) for the treatment of river blindness (onchocerciasis), threadworm of the intestines (intestinal strongyloidiasis) and scabies.
- Ivermectin does not have regulatory approval in Australia, or any other comparable Organisation for Economic Co-operation and Development (OECD) country, for the treatment or prevention of COVID-19.
- Recently there have been substantial increases in the dispensing of ivermectin, attributed to prescribing for unapproved uses, such as COVID-19.
- The TGA has placed new restrictions on the prescribing of oral ivermectin.
  General practitioners are now only able to prescribe ivermectin for TGA-approved conditions.
- Certain specialists are permitted to prescribe ivermectin for other unapproved indications if they believe it is appropriate for a particular patient.
- These changes have been introduced because of concerns with the prescribing of oral ivermectin for the claimed prevention or treatment of COVID-19.
- The decision was made by a senior medical officer at the TGA acting on the advice of the Advisory Committee for Medicines Scheduling (ACMS), which includes state and territory representatives.

KEY DATES

- **8 September 2021** – Advisory Committee for Medicines Scheduling (ACMS) #35 out of session meeting on ivermectin.
- **10 September 2021** – Publication of the Delegate's decision to restrict the prescribing of ivermectin by making amendments to the Poisons Standard.
- **11 September 2021** – New restrictions on ivermectin prescribing came into effect.
- **(Sensitive) 13 September 2021** – Written Direction issued to wholesalers (to CSO Distributors) to allow them to constrain supply to ensure equitable distribution to community pharmacies. **(End Sensitive)**

RESTRICTIONS ON PRESCRIBING

- General practitioners will only be able to prescribe oral ivermectin for TGA-approved conditions – scabies and certain parasite infections.

Contact Officer:	Gillian Mitchell	Deputy Secretary Clearing Officer:	Adj Prof John Skerritt	Clearance: 01 December 2021
Mobile No:	s22 [redacted]	Mobile No:	s22 [redacted]	Updated:
Division/Agency:	|Health Products Regulation| Regulatory Practice & Support			

- Certain specialists including infectious disease physicians, dermatologists, gastroenterologists and hepatologists (liver disease specialists) are permitted to prescribe ivermectin for other unapproved indications if they believe it is appropriate for a particular patient.
- The new restrictions do not prevent use of ivermectin for COVID-19 as part of a clinical trial approved by, or notified to, the Secretary of the Australian Government Department of Health under the *Therapeutic Goods Act 1989.*
- The prescribing restrictions have no impact on access to topical ivermectin for the treatment of rosacea (Soolantra and Vastreka) or veterinary products.

REASONS FOR IMMEDIATE ACTION TO RESTRICT PRESCRIBING

- There was a 300-400 percent increase in dispensing of ivermectin prescriptions in the months prior to the new restrictions, attributed to increased prescribing for unapproved uses such as COVID-19.
- There are significant public health risks associated with taking ivermectin to treat or prevent COVID-19 infection rather than getting vaccinated.
- Individuals who believe they are protected from infection by taking ivermectin may choose not to get tested or to seek medical care if they experience symptoms. Doing so has the potential to spread the risk of COVID-19 infection throughout the community.
- Concerns that social media posts and other sources promoting ivermectin for the prevention or treatment of COVID-19 encourage doses at a significantly higher level than those approved for scabies or parasite treatment; these doses carry significant risk of adverse effects.
- The substantial increase in dispensing of ivermectin prescriptions creates a risk of ongoing national and local shortages for those who need the medicine for scabies and parasite infections. Such shortages can disproportionately impact vulnerable people, including those in Aboriginal and Torres Strait Islander communities.

CONSULTATION ON THE SCHEDULING CHANGES

- The decision to restrict prescribing of ivermectin was not open to public consultation, given the seriousness of the circumstances, the risks to the community (potential to spread the risk of COVID-19), and the urgency for action.
- The ACMS is an independent advisory committee and made up of specific scientific, medical, or clinical and pharmacist experts from across Australia, as well as representatives from the Commonwealth and each State and Territory Department of Health.
- The ACMS unanimously agreed that there was a need to urgently restrict the prescribing of oral ivermectin through amendments to the scheduling in the Poisons Standard.

PUBLIC RESPONSE TO RESTRICTIONS ON IVERMECTIN

- Since the announcement was published (10 September 2021), there has been significant public interest as well as an increase in media enquiries and FOI requests.
- The TGA has received more than 10,000 enquiries regarding the decision. Likewise, the Department's Health Contact Centre has received a significant increase in enquiries.

- The behaviour of many callers has been inappropriate. The TGA implemented additional strategies to ensure the wellbeing of its staff, as this has been of serious concern.

INTERNATIONAL REGULATION

- Ivermectin does not have regulatory approval in any other comparable OECD country for treatment or prevention of COVID-19.
- Use of ivermectin is currently strongly discouraged by the:
    - TGA.
    - National COVID-19 Clinical Evidence Taskforce (Taskforce).
    - World Health Organization (WHO).
    - US Food and Drug Administration.
    - European Medicines Agency.
- On 24 September 2021 the Indian Council of Medical Research (ICMR) - COVID-19 National Task Force Joint Monitoring Group dropped the usage of ivermectin from revised clinical guidelines for the management of adult COVID-19 patients.[1]

EVIDENCE OF IVERMECTIN TO TREAT COVID-19

- The Taskforce undertakes continuous evidence surveillance to identify and rapidly synthesise emerging research to provide national, evidence-based guidelines for clinical care of people with COVID-19.[2]
    - The Taskforce advises against the use of ivermectin for COVID-19 treatment outside of properly conducted clinical trials with appropriate ethical approval, and strongly discourages the use of ivermectin for the prevention or treatment of COVID-19.
- **31 March 2021** – the WHO advised that current evidence on the use of ivermectin to treat COVID-19 patients is inconclusive, and until more data is available, the WHO recommends that the drug only be used within clinical trials. This advice remains current.
- It is the consensus view of international regulators that to date there is a lack of high-quality evidence with sufficient certainty to support the safe and efficacious use of ivermectin for the prevention or treatment of COVID-19.
    - **4 February 2021** - a statement from Merck, one of the major manufacturing companies of ivermectin, has publicly confirmed that, “to date, our 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.
        - a concerning lack of safety data in the majority of studies”.[3]

---

[1] www.thehindu.com/news/national/icmr-stops-use-of-ivermectin-hcq-for-covid-19-treatment/article36651890.ece

[2] https://covid19evidence.net.au/faqs/#Ivermectin

[3] www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/

- Whilst shown to be potentially effective in the laboratory environment, ivermectin is not recommended to be used outside clinical trials in the treatment of COVID-19.
    - **April 2020** – publication in the journal Antiviral Research, found that ivermectin could inhibit SARS-CoV-2 in cell cultures outside the body (in vitro).
    - Doses used to date in laboratory studies would correspond to a much higher dosage in humans than is currently recommended and appropriate doses for use in COVID-19 are not yet determined.
- A recent analysis by the Cochrane Collaboration concluded that ivermectin could not be recommended for COVID-19 treatment or prevention.[4]
- Clinical Trials investigating ivermectin for COVID-19:
    - Evidence from large, prospective and randomised controlled studies is needed before the efficacy and safety of ivermectin for the treatment or prevention of COVID-19 can be fully understood.
    - The consensus view of international regulators and top-tier medical journals is that more evidence from large, prospective and randomised controlled trials is required.
    - There are a number of global clinical trials investigating the potential of ivermectin either alone or in combination with other medications, to treat or prevent COVID-19.[5]
    - An Egyptian ivermectin clinical trial demonstrating a dramatic treatment effect has been withdrawn from pre-print due to allegations of plagiarism, data manipulation and ethical concerns.[6]

REGISTRATION OF IVERMECTIN AS A TREATMENT FOR COVID-19

- The TGA has well-established processes and data requirements for the regulatory evaluation of medicines in Australia, which are based on adopted internationally recognised guidelines.
- The TGA is regularly meeting with researchers and industry regarding concerning potential treatments for the prevention and treatment of COVID-19 in a variety of clinical settings.
- The TGA would welcome an application to register ivermectin for a new indication at any time. It is important to note, however, that the Australian Government is unable to compel pharmaceutical companies to make an application for registration. Robust clinical evidence on efficacy and safety would be required to support such an application, as well as a source of product manufactured to pharmaceutical Good Manufacturing Standards requirements.
- A medicine can only be approved by the TGA if this rigorous process is completed and the benefits are considered to be much greater than any potential risks.

[4] www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD015017.pub2/full
[5] www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/
[6] www.nature.com/articles/d41586-021-02081-w

RISK OF SHORTAGES

- There is no current shortage of ivermectin products in Australia.
- The previously reported shortage of Stromectol ivermectin 3mg tablet blister pack was due to unexpected increase in consumer demand. The shortage was resolved on 20 August 2021 when the sponsor received sufficient supply to meet forecasted demand.
- **(Sensitive)** To ensure equitable distribution and prevent stockpiling of available supplies, the Department has issued a Written Direction to PBS Community Service Obligation (CSO) Distributors to allow wholesalers to restrict supply to Community Pharmacies.
- The Written Direction is in effect until 31 December 2021 however it may be withdrawn earlier if the supply/demand has stabilised. **(End Sensitive)**

IMPORTATION

- The Personal Importation Scheme allows for the importation of a maximum of three months' supply of an unregistered product (not included in the ARTG) at the maximum dose recommended by the manufacturer.
    - If the product contains a Schedule 4 (prescription only) substance, then the importer must have a written authority issued by an authorised medical practitioner registered under a law of a state or territory (in practice, a prescription).
- Imports referred to the TGA for assessment between July 2021 and 1 December 2021 include 305,770 tablets of ivermectin.
    - Increased detections commenced in September 2021.
    - In most instances, the quantity being imported has exceeded three months' supply.
- To date, only a small number of prescriptions, or other written authorities, have been provided to support the release of products under the Personal Importation Scheme. Those were provided by GPs prior to the new prescribing restrictions.
- The imports assessed to date were tablets for human (not animal) use that appeared to have been manufactured in India in 6mg and 12mg dosages, usually in packs of 10. The ARTG registered product is available in packs of 3 x 3mg tablets.
- The importers contacted to date have confirmed that their imported ivermectin was intended for the prevention and/or treatment of COVID-19.

COVID-19 THERAPEUTIC GOODS COMPLIANCE

The TGA has undertaken the following actions in relation to advertising of ivermectin:

- **21 October 2020** – sent a letter t s22 [redacted] s22 [redacted]. The advertising was subsequently removed, and no further action was taken.
- **5 February 2021** - s22 [redacted], and from making claims about therapeutic goods (including ivermectin) having any effect on COVID-19. The relevant advertising was removed, and the case was closed.

- s22 [redacted] he tweet was removed, and the case is closed.
- s47G(1)(a) [redacted] The relevant website has come into compliance, and the case is progressing to closure without further action.
- **8 September 2021** – sent a letter to Surfers Medical Clinic requiring that they cease and desist from promoting the use of ivermectin on their website. The advertising was removed and no further action was taken.
- **9 September 2021** – sent a letter to Surecell Medical Australia requiring that they cease and desist from promoting the use of ivermectin on their website, including in a video. The advertising was removed and no further action was taken.

FACTS AND FIGURES:

As at 30 November 2021:

- 1,066 reports of non-compliance have been received in relation to the importation and advertising of ivermectin.

Of these reports:

- 1,039 were from ABF for ivermectin detected at the border.
- 336 have been closed or finalised, and 730 are subject to compliance action or are currently under investigation.

Outcomes:

- 700 contacts with entities warning them of an alleged breach of the legislation, including cease and desist letters, warning letters and education letters
- A Directions Notice was issued t s22 [redacted] for the alleged promotion of animal use ivermectin for human consumption on a Twitter account
- 267 Section 56A Certificates (destruction of goods) issued, and
- 93,139 units destroyed.

From: s22
To: SKERRITT, John; BEDFORD, Chris; NOYEN, Benjamin; LANGHAM, Robyn
Cc: GILL, Tony
Subject: Interim scheduling decision submissions on ivermectin [SEC=OFFICIAL]
Date: Wednesday, 8 March 2023 1:02:48 PM
Attachments: image001.png
Ivermectin consolidated responses - Novembver 2022 interim submissions.PDF

Ivermectin submissions on Nov 22 interims for your awareness, notably from AMA:

> "The AMA is concerned that the justification for continuing the restriction on the prescribing of ivermectin is weak. While not opposing the decision, the AMA is not comfortable with the decision making process. The original decision was made in response to very significant off-label prescribing inspired by a small, vocal community. The resulting shortages were significant. The AMA does not see that this remains an issue, and the justifications provided for the decision certainly do not demonstrate that is.
> If the interim decision is carried, the AMA would like to see this discussed at the next ACMS meeting but with the intent to remove the restrictions. We would expect that strong evidence would need to be provided to justify continuing the restrictions."

s22
Director – Scheduling and Chemicals Policy Section
Regulatory Engagement Branch
Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Fairbairn (Gulgana 2.S)
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

Ivermectin

Consolidated public submissions

November 2022 interim decisions

The Pharmacy Guild of Australia

PROPOSED AMENDMENTS TO POISONS STANDARD

November 2022 Interim Decisions

Comments by The Pharmacy Guild of Australia to the Scheduling **delegate's interim decisions made under** regulation 42ZCZN on substances referred to the November 2022 ACMS and joint ACMS-ACCS meetings

1. Ivermectin

s22 [redacted]

Date 22/02/2023

National Secretariat
Level 2, 15 National Circuit, Barton ACT 2600
PO Box 310, Fyshwick ACT 2609
P: +61 2 6270 1888 • F: +61 2 6270 1800 • E: guild.nat@guild.org.au
www.guild.org.au

IVERMECTIN

Proposal

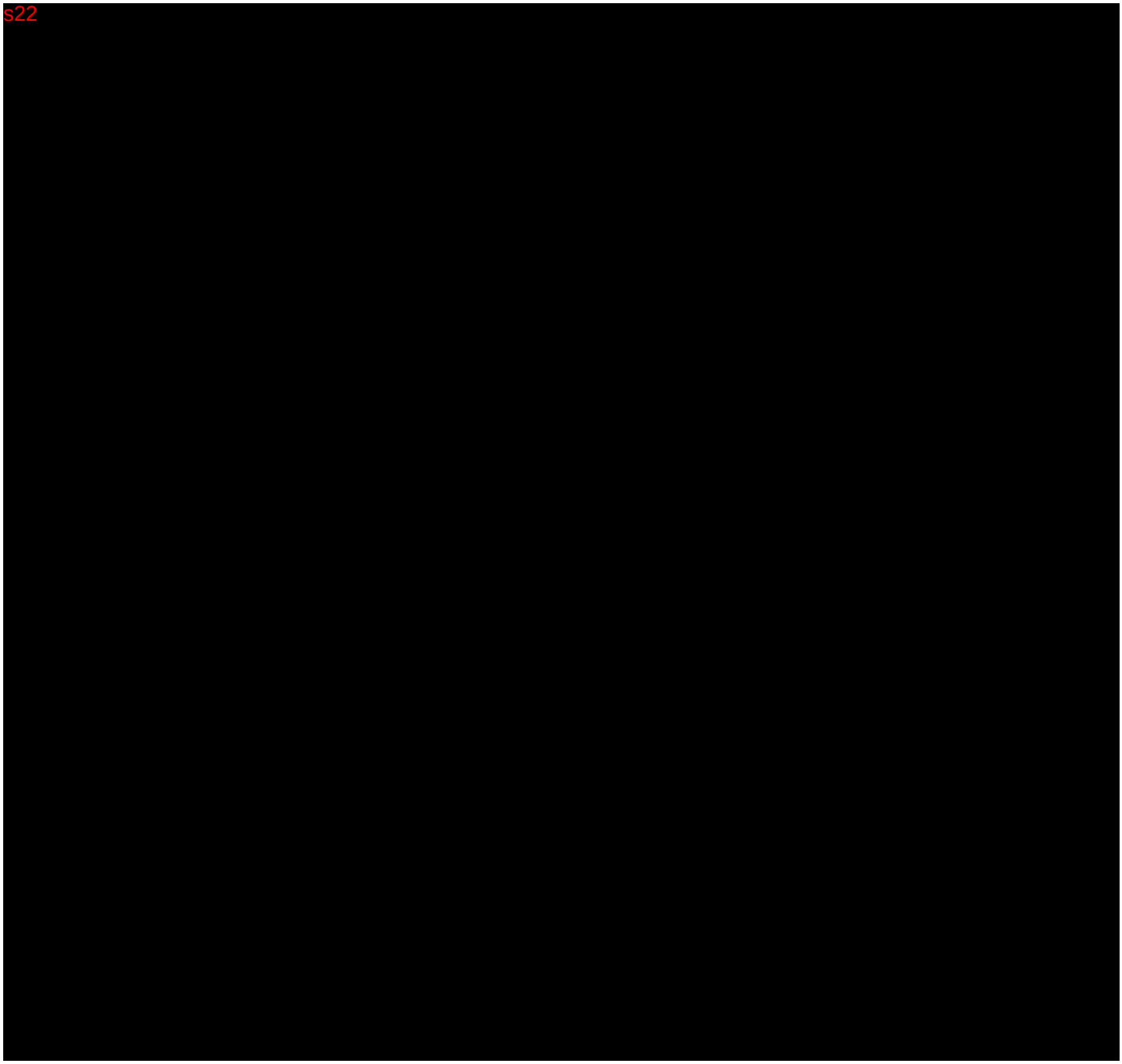
The application proposed to delete the Appendix D entry for Ivermectin. This would remove the current restrictions on the prescribing and use of ivermectin for oral administration for human use and allow prescribing without restrictions and potential for off-label use such as the treatment and prevention of COVID-19.

Interim Decision

The Scheduling Delegate has made the interim decision to not amend the Poisons Standard.

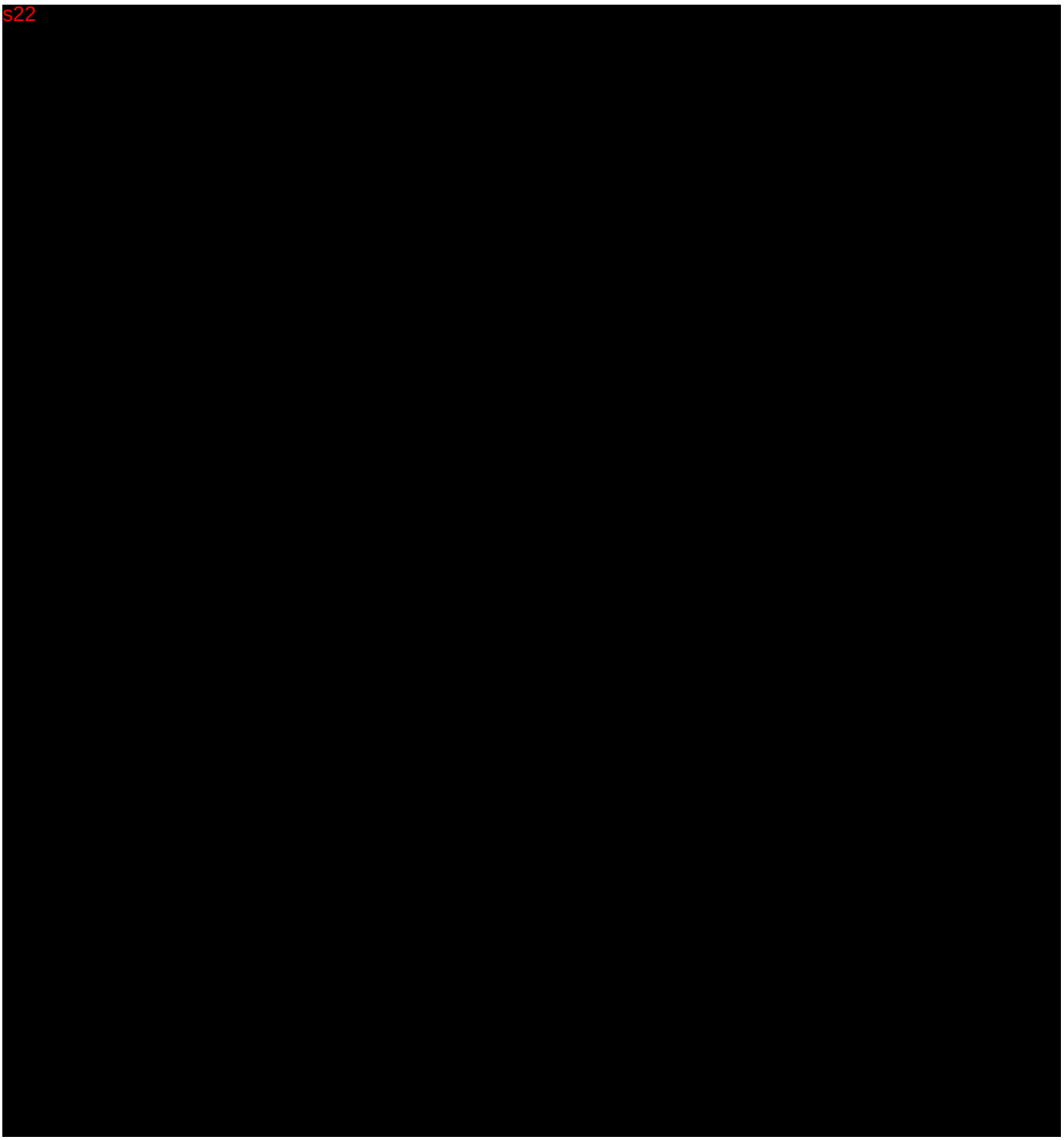
Guild Response

The Guild supports the interim decision. The Guild agrees with the Scheduling Delegate that it is important to retain the current Appendix D entry for ivermectin to ensure patients continue to utilise vaccination for the prevention of COVID-19 infection and access COVID-19 treatments that are safe and effective.


s22


s22


s22


s22

RESPONSE TO THE TGA CRITIQUE OF APPLICATION TO REVERSE IVERMECTIN CANCELLATION

PROF ROBERT CLANCY AM RS(N) BSc(Med) MB BS PhD DSc FRACP FRCP(A) FRCP(C)

I am one of the most senior physicians in Australia with strong clinical and basic research credentials in mucosal immunology. This includes drug development, and clinical trials. Years back before the TGA developed its self-contained capacity, I worked with the TGA to develop those capacities in immunology. In relation to Covid, I am the most experienced clinical mucosal immunologist in Australia, skills that are not widely shared. I was awarded recently by the University of Newcastle, their first DSc (for my work on mucosal immunity in relation to airway protection, and host-parasite relationships including viral infection, of mucosal surfaces). For many years I was the “go-to” immunologist for information on immunisation in adults.

I believe my views on the restriction of use of ivermectin are worthy of respect.

Regarding the draft opinion concluding that ivermectin restrictions should continue, I make the following comments:

1. Comments re efficacy are out of date, and with respect, unbalanced in conclusion. The politicisation, even to the extent of claims of fraudulent activity (views of others), with respect to a narrative that began with “protect the vaccine at all costs” (and inherent base to the original TGA decision), is unprecedented. An objective

progressive assessment of all medications claimed to have effect in Covid treatment including TGA-accredited anti-viral agents can be found at <ivmmeta.com> (“Ivermectin for Covid-19 Real Time Meta-analysis of 95 studies”). This would be a comprehensive document for the TGA to review, as it updates data on studies, and includes comment on some of the “holy grail” sources used in the TGA summary (eg and out-dated and severely defective Cochrane: by Popp et al; and the “Together Trial” published in the NEJM and widely used to “put IVM in a coffin”- a disgraceful study with 50 protocol concerns, including “losing half the controls”: per protocol protection by IVM was a significant 70%, yet never mentioned in the study. A letter of concern to the NEJM demanding hidden data and response to concerns, signed by senior clinicians around the world, was not printed!). You quote the infamous “Statement from Merck”: are you aware that this came with no review of data, days before a massive US Government grant, to support the development of molnupiravir? And we all know how that has gone. Merck had no interest in ivermectin, without a patent. An appalling commercial move to protect its interests.

2. Safety. It was a surprise to see the “concerning comment” about ivermectin safety. This drug is probably the safest around – claimed by others as “safer than Panadol”. Which it is. That has been covered by others. It is just not correct to state a course of 24mg per day for 5-10 days is significantly dangerous. There is No data to support that, that I have ever seen. This has been a tactic used by those promoting a tarnished

narrative, that borders on the shameful. The TGA is better than that.

3. Comparison with TGA-accredited anti-viral drugs. You are aware of the failure of molnupiravir, (the UK study of approx. 20,000 showing NO benefit) and the increasing evidence of production of viable variants capable of transmission. Paxlovid is little better, restricted re age and drug incompatibilities, rebound infection etc. The precipitous registration of both drugs (and the less than helpful, dangerous Remdesivir) stands in contrast to the TGA handling of ivermectin, a repurposed, already registered, safe, cheap (without patent or pharmaceutical friends) and effective drug for Covid-19.

These are issues others will comment on in greater detail, but you get my drift.

My major point relates to the serious impact any negative decision using contrived arguments has on the way medicine is practised in Australia, the terrible impact it will have on Australians, and the impact it will have on the credibility of an organisation I have great respect, even affection, for; the TGA.

To continue a ban on ivermectin, deprives doctors from the use of a registered drug for “off-label” use. My practise as a clinical immunologist involves use in every clinic of drugs in an “off-label” fashion. These are often far more dangerous drugs including cytotoxic medications, in conditions in particular patients for which there will never be a RCT (I do

note that only 16% of currently available drugs have ever been subjected to a RCT – not that that should ever be a final arbiter). Within the doctor-patient relationship, I make a decision that is, in my view and with the patients understanding, best for my patient. Mostly the outcome is beneficial but of course both patient and I monitor effect, changing course as appropriate. The TGA decision on an already registered drug (ivermectin) you are happy to have used in conditions for which there is far less data than available for its value in treating Covid-19, denies me the right to treat my patients with the best treatment I judge for their condition. Let me give a simple example. Chronic blepharitis caused by mites, can be a terrible condition refractory to every alternate treatment. I have had miraculous benefit in patients with this affliction, who have failed to control the condition with alternate drugs. Maintaining the TGA ban, deprives me of my right to offer the best treatment in my opinion, and the patient from receiving it. Currently the FDA is being sued by doctors over just this point – the legality of a drug registration authority , to restrict use of a registered drug for “off-label” use by doctors addressing the needs of a patient.

The concern that all physicians will have, is that this becomes the thin edge of a wedge, that can be used arbitrarily for any drug the TGA may not like, for any reason, as no medical argument in real life can be made against “off-label” use of ivermectin. I worked for 5 years with Dave Sackett (sharing admitting rosters at McMaster University, Canada), the “Father” of “Evidenced Based Medicine” (EBM). He would turn in his grave if he saw the way his fantastic contribution

to medicine had been kidnapped by those wanting to protect a narrative, regardless. His EBM combined three components: all evidence (not just RCT's), the impact of an experienced clinician, and patient expectations. By taking ivermectin out of the clinicians repertoire, one is denying the role of the doctor-patient relationship to identify the best medical option for that patient. Outside of strict classical guidelines, for a registered drug of such a reputation earned by ivermectin, and with respect, that is not a role for the TGA.

I would be pleased to discuss these issues with you, indeed work with you to get an outcome that will be best for patients, doctors and the TGA.

Responder type	Name	Text response
Australian Medical Association	s22 [redacted]	"The AMA is concerned that the justification for continuing the restriction on the prescribing of ivermectin is weak. While not opposing the decision, the AMA is not comfortable with the decision making process. The original decision was made in response to very significant off-label prescribing inspired by a small, vocal community. The resulting shortages were significant. The AMA does not see that this remains an issue, and the justifications provided for the decision certainly do not demonstrate that is. If the interim decision is carried, the AMA would like to see this discussed at the next ACMS meeting but with the intent to remove the restrictions. We would expect that strong evidence would need to be provided to justify continuing the restrictions. The AMA agrees with the interim decision against the downscheduling of modified release ibuprofen. There are significant safety concerns identified in the interim decision, such as the risk of dosing and administration errors. The risks to this change far outweigh the benefits. The priority in providing access to medicines must always be safety, not convenience."
Professional researcher	Dr. Phillip Altman	OPEN LETTER RE: NOTICE OF DECISION NOT TO AMEND THE CURRENT POISONS STANDARD FOR IVERMECTIN (APPENDIX D) – ISSUED 3 FEB. 2023 https://www.tga.gov.au/sites/default/files/2023-02/public-notice-of-interim-decisions-acms-40-accs-35-joint-acms-accs-32-november-2022.pdf On Feb. 3 2023 the TGA announced its decision (legally referred to as an "Interim Decision" prior to gazetting) to maintain the restrictive prescribing of ivermectin which effectively bans the use of ivermectin for the prevention and management of COVID-19. This was a most surprising decision as ivermectin is supported by more published safety and efficacy data than any other drug used to treat COVID-19. My detailed and extensively referenced submission, together with many other submissions, presented a compelling case for the removal of the restrictive use of ivermectin including that for the prevention and treatment of COVID-19 (see my 14 February 2023 post at phillipaltman.substack.com). In fact, the published data available (https://c19ivm.org/meta.html) comprises more than 90 clinical trials and more than 100,000 patients worldwide. Ivermectin has been shown to prevent COVID-19 and to be effective in treating mild to severe symptoms of the infection and preventing hospitalisation and death. In national treatment programmes countries such as India, Mexico and

Responder type	Name	Text response
		Peru have demonstrated, without any doubt, that ivermectin can be used safely and effectively thus saving many lives. The only problem with ivermectin was that it was inexpensive and widely available. In order to overcome vaccine hesitancy of people properly suspicious of experimental gene-based so-called COVID-19 "vaccines", it was necessary for the heavy hand of government to deny the availability of ivermectin. The Australian Therapeutic Goods Administration (TGA) have publicly admitted this was a primary reason for banning ivermectin prescribing for COVID-19. Such irresponsible action was unprecedented in drug regulatory history and this has cost thousands of lives. Remarkably, government policy was not to provide early treatment of COVID-19. At no time in history was this ever suggested for a serious infectious disease. The government chose to rely on poor quality experimental gene-based COVID-19 so-called "vaccines" which have now been reported to produce the highest incidence of death and serious adverse events of any drug in the history of the pharmaceutical industry. It is clear the TGA is covering up the death and vaccine injury toll. Only since the introduction of the so-called COVID "vaccines" the number of non-COVID related deaths have skyrocketed in Australia to over 10,000 per year. The government has failed to provide a satisfactory explanation for the alarming increase in these deaths. It is now widely recognised that these experimental products have done more harm than good and they should be withdrawn immediately. However, despite the human tragedy caused by these so-called "vaccines", the government is pushing ahead to establish pharmaceutical manufacturing plants to produce more and more of these experimental gene-based "vaccines" based on this failed technology which have never been fully approved anywhere. The TGA will undoubtedly wave through these dangerous products to an unsuspecting public on the basis of extremely limited quality, safety and efficacy data, to the delight of Big Pharma, under the recently introduced Provisional Approval system. This is the plan. The Australian TGA has clearly failed. It has turned into a parody of a drug regulator which has abandoned the precautionary principle previously and necessarily at the very heart of proper drug regulation. The TGA now performs a theatrical role in that it outwardly pretends to be diligent and conscientious but inwardly has scripted agendas written by the largest industry of all – the pharmaceutical industry. In refusing to permit off-label prescribing of ivermectin, the TGA has shown itself to be an incompetent, unprincipled and disgraceful bureaucracy devoid of integrity and humanity. The TGA has now been totally captured by commercial

Responder type	Name	Text response
		interests in "public-private-partnerships" which are not in the best interest of the Australian people. As a person who has more than 40 years of experience in working with the TGA, it is very sad to see the decent of our once proud TGA. All those responsible for the reckless behaviour of the TGA and those directing the TGA must be held to account. Until this is done.....nobody is safe. Phillip Altman BPharm(Hons, MSc, PhD Clinical Trial & Drug Regulatory Affairs Consultant Note: I consent to my name and Open Letter being made publicly available
Consumer / patient	s22 [redacted]	According to numerous RCT trials and studies Ivermectin is both an effective prophylactic and early antiviral treatment for covid19 used at 0.02, 0.04 or 0.06mg/kg, depending on the purpose and the patient's comorbidities. When used at the onset of symptoms it lowers the viral load immediately and substantially over the first 5 days, but can be continued until symptoms resolve. I have used it prophylactically for almost 3 yrs without ANY side effects and it has prevented me from contracting covid. My immediate family used it when they contracted covid and everyone recovered within a week and didn't get long covid. I nursed them all so was more than exposed to the virus! We can attest to it being an extremely safe , efficient and cheap remedy for covid 19, which is why we cannot understand why the TGA refuses to amend the poisons standard and allow GP's to prescribe it off - label for covid.
Professional researcher	Professor Robert Clancy *	I try very hard to avoid the political machinations surrounding the Covid narrative, but that does not mean I am nothing short of distressed about decisions that make no sense to me. I have tried to include the attached response to the Provisional Decision NOT to reverse the Ivermectin ban in the official format, but the technology challenge simply defeated me. I apologise, but hope you will take my contribution into account. At the end of the day, we both want the best outcome for Australians - overwhelmingly, ivermectin with respect to Covid, shares that platform. Professor Skerritt, I bring in an Australian context unique skill sets in understanding and managing airway infection in its immunological context, which I would be delighted to contribute to the TGA (a role I once had). Skill sets you do not have on your advisory committees. I wish you well in your retirement, a status I probably should also seriously consider, once we get Covid behind us.

Responder type	Name	Text response
*provided email submission with additional PDF attachment.		