Australian Government
Department of Health
Therapeutic Goods Administration

Record of the 35th meeting (out of session) of the Advisory Committee on Medicines Scheduling

08 September 2021

TRIM Reference no. D21-3074411

TGA Health Safety Regulation

Contents

1 Preliminary Matters

1.1 Opening of the Meeting

The 35th meeting of the Advisory Committee on Medicines Scheduling ([ACMS]) was held via videoconference on 08 September 2021.

The meeting was chaired by [redacted], who opened the meeting at 10:32 am and welcomed attending members and observers.

Members were informed that the discussions and recommendations of the committee are confidential until the decisions are published.

A quorum was present. Those present at the meeting were:

Minister Appointments **Jurisdictional Members**

[redacted]

Standing and invited observers:

Dr Tony GILL	Commonwealth Dept. of Health
Adj Prof John SKERRITT	Deputy Secretary, Health Products Regulation Group, Commonwealth Dept. of Health
Ms Gillian MITCHELL	First Assistant Secretary, Regulatory Practice and Support Division, Commonwealth Dept. of Health
Mr Benjamin NOYEN	Assistant Secretary, Regulatory Engagement & Planning Branch, Commonwealth Dept. of Health
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

Apologies

[redacted]

1.2 Conflict of Interest

Conflict of interest declarations were received from all members. Declared conflicts from [redacted] and [redacted] were discussed and it was agreed that they could be present and fully participate in the committee discussions.

Member	Declared conflict of interest	Comments
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

2 Proposed Changes to the Poisons Standard

2.1 Ivermectin

The TGA Delegate presented a discussion paper detailing concerns regarding increasing off-label prescribing of oral ivermectin for the prevention and treatment of COVID-19 and request for advice on the Delegate's proposal for an urgent scheduling amendment to place additional controls on supply of oral ivermectin.

The Committee noted that the TGA has observed a significant increase in the volume of supply of ivermectin tablets over the last 24 months (private and PBS prescriptions), particularly in July

and August 2021. Members were also aware of reports from pharmacies of increased prescribing ivermectin for COVID-19 and of some medical practices promoting the substance for this purpose, despite ivermectin not being approved for the prevention and treatment of COVID-19. The Committee noted that ivermectin is not currently registered or approved in any OECD countries for this purpose.

The Committee agreed that there were significant public health risks associated with the prescribing of ivermectin for COVID-19, including the likelihood that people who have been prescribed the substance for this purpose may believe themselves to be protected from the disease and not get vaccinated or tested and seek appropriate medical care if they developed symptoms. The Committee was concerned that the practice of prescribing ivermectin for COVID-19 presented a risk to the community through the spread of the disease as well as the risks to individuals using it for this purpose.

The Committee also noted that there is only one ARTG registered oral ivermectin product for human use; STROMECTOL ivermectin 3mg tablet blister pack (AUST R 181338), which has approved indications for the treatment of river blindness (onchocerciasis), threadworm involving the intestines (intestinal strongyloidiasis) and scabies. The Committee noted that the increased prescribing, if sustained, has the potential to lead to shortages, which would particularly impact Aboriginal and Torres Strait Islander communities who are at more risk of the conditions that require treatment with ivermectin. The Committee noted that there are topical ivermectin products registered on the ARTG, which are indicated for rosacea. Members noted that these products are not being used to treat COVID-19 and the proposed amendments would not impact topical ivermectin products.

The Committee unanimously agreed that there was a need to urgently restrict prescribing of oral ivermectin through amendments to the scheduling in the Poisons Standard. The Committee considered Appendix D entry proposed by the Delegate and discussed whether there were any other alternative approaches, including amending the Schedule 4 entry to restrict use, as this would allow for automatic adoption by the states and territories. One member queried whether Schedule 10 was an option. However, in response, the Committee agreed that ivermectin did not meet the Schedule 10 factors. The Committee noted that the purpose of Appendix D is to apply additional controls to Schedule 4 medicines and agreed that creating a new entry in Appendix D was the most appropriate mechanism for applying additional controls to oral ivermectin preparations. Some States and Territories noted that Appendix D is not automatically adopted and jurisdictional controls such as regulation amendment may be necessary.

The Committee noted that the Delegate's proposed scheduling amendments would not impact veterinary products. Members were aware of overseas reports of people suffering severe adverse effects after using ivermectin products intended for animals and raised the possibility of this practice increasing in Australia in the future. It was noted that placing scheduling restrictions on the supply of veterinary ivermectin would be more difficult and communication and education activities may be necessary.

Members considered the wording of the proposed Appendix D entry including whether there was merit in specifying indications that may or may not be prescribed or allowing for indications that had been registered or approved for general marketing overseas. Beyond allowing prescribing for the approved indications, the Committee agreed that it was not necessary to list specific indications and noted that it would be open to the specialists mentioned in paragraph (b) of the proposed new Appendix D entry to prescribe oral ivermectin for indications that had been registered or approved overseas, such as rosacea. The Committee noted that indications are not required to be documented on a prescription and considered the possibility of requiring the prescriber to declare on the script that it was being prescribed for an approved indication. Members noted that such an approach was outside of the scope of the Poisons Standard.

The Committee recommended the following regarding the proposed Appendix D entry:

- The entry should be limited to human therapeutic use.
- The word 'approved ARTG' indication was preferred to 'accepted' indication.
- The entry should allow for use in clinical trials that have been approved by the TGA.
- The wording should not imply any endorsement of prescribing for unapproved indications, particularly COVID-19.
- The relevant specialists listed in paragraph (b) should be confined to dermatologists, gastroenterologists, and infectious diseases specialists, as this would allow for prescribing for rare parasitic conditions that are not approved indications.
- The preamble 'an indication that is not an accepted indication' at the beginning of paragraph (b) was not entirely necessary.

The Committee requested that the Secretariat consult with relevant organisations to determine whether there is any use in other parasitic conditions that would warrant genuine off-label prescribing by GPs in Aboriginal and Torres Strait Islander communities.

The Committee also recommended that any communication about the changes be very clear about the intent of the restriction, particularly in relation to the risks of using ivermectin for the treatment and prevention of COVID-19 when it has not been registered or approved for this purpose.

3 Closure

The Chair closed the meeting at 12:32pm.

[redacted]

[redacted]

Date [08 September 2021]

Chair

35th Meeting of the Advisory Committee on Medicines Scheduling