

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Poisons Standard Amendment (Ivermectin) Instrument 2021

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act also provides a framework for the states and territories to adopt a uniform approach to control the availability and accessibility, and to ensure the safe handling, of medicines and poisons in Australia. The Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Australian Government Department of Health (“the Department”).

Part 6-3 of the Act provides the basis for a uniform system of access controls for goods containing scheduled substances. The scheduling of substances allows restrictions to be placed on the supply of those substances to the public, in the interests of public health and safety, to minimise the risks of poisoning from, and the misuse or abuse of, scheduled substances.

Subsection 52D(2) of the Act provides that the Secretary may amend the current Poisons Standard or prepare a document (“a new Poisons Standard”) in substitution for the current Poisons Standard. The current Poisons Standard classifies substances in a number of schedules, with each schedule signifying the degree of risk and the recommended controls for the availability of those substances to the public.

Section 52E of the Act specifies the matters the Secretary must take into account when exercising the power under subsection 52D(2) of the Act. In accordance with subsection 52E(1), these matters include, among other matters, the risks and benefits of the use of a substance, the purposes for which a substance is to be used and the extent of use of a substance, the toxicity of a substance, and the potential for abuse. In accordance with subsection 52E(3), the Secretary must also have regard to any recommendations of the Advisory Committee on Medicines Scheduling (“the ACMS”) and the Advisory Committee on Chemicals Scheduling (“the ACCS”), established under sections 52B and 52C of the Act respectively.

The Scheduling Policy Framework (“the SPF”) provides guidance on whether a decision concerning the scheduling of substances would benefit from the advice of the ACMS or ACCS. The SPF is available on the TGA website.

States and territories regulate the supply of medicines and poisons by incorporating the schedules contained in the current Poisons Standard in state and territory laws. This ensures there is a uniform system of restrictions in Australia relating to the supply of scheduled substances, based on the risks associated with the use of those substances and the recommended level of controls over their availability.

The purpose of the *Poisons Standard Amendment (Ivermectin) Instrument 2021* (“the Amendment Instrument”) is to amend the *Poisons Standard June 2021* (“the Principal Instrument”) in relation to the substance ivermectin in preparations for oral administration for human use. Concerns have arisen in relation to the increase in off-label prescribing of oral ivermectin as a potential therapy for the prevention or treatment of coronavirus disease (“COVID-19”).

Ivermectin is not currently registered or approved for the prevention or treatment of COVID-19 in any member country of the Organisation for Economic Co-operation and Development (“OECD”). However, there has been a noticeable increase in the prescribing of oral ivermectin

in Australia for this purpose. The Department is concerned that there are a number of significant public health risks associated with this practice including, for example, that persons taking ivermectin in an effort to prevent COVID-19 consider themselves to be protected against the disease, elect not to be vaccinated as part of the national COVID-19 vaccination program, and chose not to get tested or seek medical care if they experience symptoms. As a result, the use of oral ivermectin for the prevention or treatment of COVID-19 has the potential to spread the risk of infection throughout the community.

Oral ivermectin also has the potential to cause severe adverse events in persons, particularly when taken in high doses that have recently been described in social media and other sources for the prevention or treatment of COVID-19 infection. These include, for example, severe skin reactions accompanied by fever, chills and aching muscles, severe blisters and bleeding in the lips, eyes, mouth, nose and genitals, worsening asthma and swelling of the face, legs, ankles and feet.

While oral ivermectin is generally well-tolerated at the recommended dose for the approved indications for which it is included in the Australian Register of Therapeutic Goods (“the Register”), there is insufficient data to support any higher doses. Currently, there is only one product containing oral ivermectin included in the Register. This is the prescription medicine, Stromectol ivermectin 3mg tablet blister pack (AUST R 181338), which is indicated for the treatment of river blindness (onchocerciasis), threadworm of the intestines (intestinal strongyloidiasis) and scabies.

The TGA has observed a significant increase in sales of this product in the last 24 months that cannot be attributed to the approved indications alone. If action is not taken to address these concerns, it is possible that oral ivermectin will be in shortage in Australia for the treatment of the conditions for which it has been properly evaluated and approved in accordance with scientific data. The TGA is concerned that such shortage may disproportionately impact vulnerable communities, including Aboriginal and Torres Strait Islander communities.

The purpose of the Amendment Instrument is therefore to amend the Principal Instrument to address the safety risks outlined above, and to ensure the continued availability of oral ivermectin for its approved indications. Principally, the Amendment Instrument amends Appendix D to the Principal Instrument to impose additional controls on the possession or supply of ivermectin for human use. Specifically, this is achieved by restricting the prescribing or authorising of oral ivermectin for:

- an indication accepted by the Secretary in relation to the inclusion of ivermectin in tablet dosage form in the Register (an *approved indication*); or
- an indication that is not an approved indication, when prescribed or authorised by a medical practitioner who is a specialist in dermatology, gastroenterology and hepatology, infectious diseases, paediatric gastroenterology and hepatology, or paediatric infectious diseases; or
- use in a clinical trial that is approved by, or notified to, the Secretary under the Act.

These amendments are designed to ensure the supply of ivermectin in Australia for those patients who need the medicine for its approved indications, particularly those in vulnerable communities; and to avoid the risks to public health associated with the current patterns of off-label use by restricting prescribing and authorising practices to circumstances in which there is appropriate specialist medical expertise and oversight to consider and manage those risks.

The Amendment Instrument reflects a decision to amend the Principal Instrument (being, the current Poisons Standard) by a delegate of Secretary on their own initiative and was not open to public consultation, given the seriousness of the circumstances, the risks to the community and

the immediacy with which action needed to be taken. However, the ACMS (including state and territory representative members) was consulted by the TGA in relation to the proposal and supported the amendment. Further, it was considered necessary to make the Amendment Instrument urgently in order to support the Australian Government's response to the COVID-19 public health emergency and to support the continued availability of ivermectin for Australian patients.

The Amendment Instrument is a legislative instrument for the purposes of the *Legislation Act 2003* ("the Legislation Act"). However, section 42 of the Legislation Act relating to disallowance does not apply (subsection 52D(4A) of the Act refers). As the Amendment Instrument is not disallowable, subsection 9(1) of the *Human Rights (Parliamentary Scrutiny) Act 2011* does not require the instrument to be accompanied by a statement of compatibility with the human rights recognised under that Act.

In providing that disallowance does not apply to an instrument made under paragraphs 52D(2)(a) or (b) of the Act, subsection 52D(4A) of the Act appropriately recognises that instruments made under these paragraphs form part of an intergovernmental scheme, which should not be subject to unilateral disallowance by the Commonwealth Parliament, consistent with section 44 of the Legislation Act.

Under this scheme, the current Poisons Standard principally provides a set of recommendations to the states and territories as to the appropriate level of controls that should apply to medicines and poisons. The states and territories regulate such substances by electing to apply the current Poisons Standard as a law within their own jurisdiction. In this way, the current Poisons Standard does not have direct application in its own right.

If the current Poisons Standard was to be subject to disallowance, this would impact the current uniform system of restrictions in Australia relating to the supply of scheduled substances, based on the risk, and lead to confusion and different approaches across different states and territories with respect to their handling, storage, possession and supply.

Further, as inclusion of new medicines in the current Poisons Standard is often a consequence of the granting of marketing approval of new medicines under the Act, it is likely that disallowance would also lead to delays for Australian patients in accessing new and effective treatments.

The Amendment Instrument commences on the day after it is registered.