

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

### *Poisons Standard July 2020*

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 State and Territory governments 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.

Part 6-3 of the Act (sections 52AA to 52EC) 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 their supply to the public, in the interests of public health and safety. The scheduling of substances is aimed at minimising the risks of poisoning from, and the misuse or abuse of, scheduled substances.

Subsection 52D(2) of the Act empowers the Secretary to amend the current Poisons Standard or to prepare a document (“a new Poisons Standard”) that includes schedules containing the names or descriptions of substances, in substitution for the current Poisons Standard.

The current Poisons Standard reflects decisions of the Secretary or a delegate of the Secretary regarding the classification of medicines and poisons into the different Schedules, signifying the degree of risk and the control recommended to be exercised over their availability to the public.

The Act establishes two expert advisory committees, the Advisory Committee on Medicines Scheduling (“ACMS”) (section 52B of the Act refers) and the Advisory Committee on Chemicals Scheduling (“ACCS”) (section 52C of the Act refers), which provide advice and make recommendations to the Secretary on matters relating to medicines and chemicals scheduling decisions.

The Schedules contained in the current Poisons Standard are referred to under State and Territory legislation for regulatory purposes. This enables restrictions to be placed on the supply of scheduled substances to the public, according to the degree of risk associated with the substances and the level of control recommended over their availability, in the interest of public health and safety.

The Commonwealth takes into account the scheduling and classification of substances in the current Poisons Standard for regulatory and enforcement purposes under the Act. For example, the Act prohibits the publication or broadcasting of advertisements to consumers about prescription medicines containing substances included in Schedule 4 or Schedule 8 to the current Poisons Standard, or over-the-counter medicines containing substances included in Schedule 3 and not included in Appendix H of the current Poisons Standard. The advertising of substances included in Schedule 9 or Schedule 10 to the current Poisons Standard is also prohibited.

The Scheduling Policy Framework (“the SPF”) provides guidance on whether a decision concerning the scheduling of substances under the current Poisons Standard would benefit from being referred to ACMS or ACCS for advice. A copy of the SPF can be found at: <https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals>.

The purpose of this instrument is to make a new Poisons Standard, the *Poisons Standard July 2020*, in substitution for the previous Poisons Standard, the *Poisons Standard (No.3) June 2020*, which was registered on 17 June 2020 and commenced on 18 June 2020, and which is repealed and replaced by this instrument.

The *Poisons Standard July 2020* incorporates a small number of changes to the *Poisons Standard (No.3) June 2020*, principally, the scheduling of the new substance, remdesivir, in Schedule 4 to the current Poisons Standard, and minor amendments to the existing index entries for hydroxychloroquine, hydroxycarbamide, mitragyna speciosa and mitragynine.

Recent studies have indicated that the substance, remdesivir, may have potential in the treatment of the disease known as coronavirus disease (COVID-19). Consequently, there is a need to ensure that the substance, remdesivir, is appropriately scheduled in Australia to support controls relating to its supply. Remdesivir is included in Schedule 4 to indicate that the recommended level of control for this substance is that it may only be supplied under prescription from a practitioner permitted under state and territory legislation to prescribe.

The decision to include the substance, remdesivir, in Schedule 4 is a delegate-only decision made in accordance with the SPF and was not open to public consultation. The decision is necessary to inform the availability and supply of medicines containing remdesivir in order to support Australia’s response to the COVID-19 public health emergency.

Separately, the *Poisons Standard July 2020* also includes minor technical amendments relating to the substance, mitragyna speciosa, and its psychoactive, alkaloid mitragynine. These substances are both commonly known as kratom. For clarification, the *Poisons Standard July 2020* incorporates cross references to kratom in the index entries for mitragyna speciosa and mitragynine. The instrument also incorporates cross-references for mitragyna speciosa and mitragynine, and includes a new index entry for kratom, which cross references mitragyna speciosa and mitragynine. These technical changes are delegate-only decisions that were not open to public consultation on the basis that the changes were considered, in accordance with the SPF, to be minor in nature.

The *Poisons Standard July 2020* also includes minor editorial corrections in relation to the substance hydroxychloroquine. The entry for hydroxychloroquine in Schedule 4 is amended to include the hash symbol (#) indicating that this substance is also included in Appendix D, and the reference to hydroxychloroquine in the index is amended to include a reference to item 8 in Appendix D. The *Poisons Standard July 2020* also removes an inadvertent reference to Appendix D in the index entry for hydroxycarbamide.

The *Poisons Standard July 2020* is a legislative instrument for the purposes of the *Legislation Act 2003*. However, section 42 of the *Legislation Act 2003* relating to disallowance does not apply, in accordance with subsection 52D(4A) of the Act. As the 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. However, at the request of the Parliamentary Joint Committee on Human Rights, a statement of capability is provided as the inclusion of remdesivir in the *Poison Standard July 2020* supports the response to the COVID-19 public health emergency.

The *Poisons Standard July 2020* commences on the day after registration on the Federal Register of Legislation.

## Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

### *Poisons Standard July 2020*

The *Poisons Standard July 2020* is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

#### **Overview of legislative instrument**

The purpose of this instrument is to make a new Poisons Standard, the *Poisons Standard July 2020*, in substitution for the previous Poisons Standard, the *Poisons Standard (No.3) June 2020*, which is repealed and replaced by this instrument.

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 State and Territory governments to adopt a uniform approach to control the availability and accessibility, and to ensure the safe handling, of medicines and poisons in Australia.

Part 6-3 of the Act (sections 52AA to 52EC) 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 their supply to the public, in the interests of public health and safety. The scheduling of substances is aimed at minimising the risks of poisoning from, and the misuse or abuse of, scheduled substances.

Subsection 52D(2) of the Act empowers the Secretary to amend the current Poisons Standard or to prepare a document (“a new Poisons Standard”) that includes schedules containing the names or descriptions of substances, in substitution for the current Poisons Standard. The current Poisons Standard reflects decisions of the Secretary or a delegate of the Secretary regarding the classification of medicines and poisons into the different Schedules, signifying the degree of risk and the control recommended to be exercised over their availability to the public.

The Schedules contained in the current Poisons Standard are referred to under State and Territory legislation for regulatory purposes. This enables restrictions to be placed on the supply of scheduled substances to the public, according to the degree of risk associated with the substances and the level of control recommended over their availability, in the interest of public health and safety.

The Commonwealth takes into account the scheduling and classification of substances in the current Poisons Standard for regulatory and enforcement purposes under the Act. For example, the Act prohibits the publication or broadcasting of advertisements to consumers about prescription medicines containing substances included in Schedule 4 or Schedule 8 to the current Poisons Standard, or over-the-counter medicines containing substances included in Schedule 3 and not included in Appendix H of the current Poisons Standard. The advertising of substances included in Schedule 9 or Schedule 10 to the current Poisons Standard is also prohibited.

The *Poisons Standard July 2020* incorporates a small number of changes to the *Poisons Standard (No.3) June 2020*, principally, the scheduling of the new substance, remdesivir, in Schedule 4 to the current Poisons Standard.

Recent studies have indicated that the substance, remdesivir, may have potential in the treatment of the disease known as coronavirus disease (COVID-19). Consequently, there is a need to ensure that the substance, remdesivir, is appropriately scheduled in Australia to support the availability of supply to patients. Remdesivir is included in Schedule 4 to indicate that the recommended level of control for this substance is that it may only be supplied under prescription from a practitioner permitted under state and territory legislation to prescribe.

The *Poisons Standard July 2020* also makes minor amendments to the existing index entries for hydroxychloroquine, hydroxycarbamide, mitragyna speciosa and mitragynine. Mitragyna speciosa and its psychoactive, alkoid mitragynine are both commonly known as kratom. For clarification, the *Poisons Standard July 2020* incorporates cross references to kratom in the index entries for mitragyna speciosa and mitragynine. The instrument also incorporates cross-references for mitragyna speciosa and mitragynine, and includes a new index entry for kratom, which cross references mitragyna speciosa and mitragynine.

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### **Human rights implications**

The *Poisons Standard July 2020* engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health.

In *General Comment No.14: The Right to the Highest Attainable Standard of Health (Art.12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The *Poisons Standard July 2020* takes positive steps to support the right to health by including the new substance, remdesivir, in Schedule 4 to the current Poisons Standard. Medicines containing remdesivir may have potential in the treatment of coronavirus disease (COVID-19). The instrument ensures that remdesivir is appropriately scheduled in Australia to support controls relating to its supply.

The substance, remdesivir, is included in Schedule 4 to indicate that the recommended level of control for this substance is that it may only be supplied under prescription from a practitioner permitted under state and territory legislation to prescribe. The decision is necessary to inform the availability and supply of medicines containing remdesivir in order to support Australia’s response to the COVID-19 public health emergency.

## **Conclusion**

The *Poisons Standard July 2020* is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.