

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Poisons Standard June 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 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 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 Poisons Standard are incorporated by reference 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.

Similarly, the Commonwealth takes into account the scheduling and classification of substances in the 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 Poisons Standard, or over-the-counter medicines containing substances included in Schedule 3 and not included in Appendix H of the Poisons Standard. The advertising of substances included in Schedule 9 or Schedule 10 to the Poisons Standard is also prohibited.

The Scheduling Policy Framework (“the SPF”) provides guidance on whether a decision concerning the scheduling of substances under the 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 June 2021*, in substitution for the previous Poisons Standard, the *Poisons Standard February 2021*.

The *Poisons Standard June 2021* repeals and replaces the *Poisons Standard February 2021*, principally to incorporate a number of changes to existing entries, and to include a number of specified substances in the Poisons Standard for the first time.

A number of these changes were made following the provision of advice from the ACCS or the ACMS, in accordance with the procedures set out in Subdivision 3D.2 of Part 6 of the *Therapeutic Goods Regulations 1990* for amending the Poisons Standard when a proposed amendment is referred to an expert advisory committee.

Public comment was invited in relation to the proposed amendments that were referred to the March 2020 ACMS, November 2020 ACMS, and November 2020 Joint ACMS-ACCS meetings, as follows:

- an invitation to comment in relation to adapalene and melatonin was published on the TGA website on [20 December 2019](#), with a closing date of 10 February 2020. A further invitation to comment in relation to both proposals was published on [10 June 2020](#), with a closing date of 9 July 2020. A third invitation to comment in relation to melatonin was published on [13 August 2020](#), with a closing date of 28 August 2020; and
- an invitation to comment in relation to 2-hydroxyethyl methacrylate, bilastine, magnesium hydroxide and tetrahydrofurfuryl alcohol was published on the TGA website on [26 August 2020](#), with a closing date of 28 September 2020. A further invitation to comment in relation to these proposals was published on [3 February 2021](#), with a closing date of 4 March 2021.

The final decisions were published on the TGA website in relation to:

- adapalene, on [24 August 2020](#);
- melatonin, on [28 September 2020](#); and
- 2-hydroxyethyl methacrylate, bilastine, magnesium hydroxide and tetrahydrofurfuryl alcohol, on [22 April 2021](#).

A further, minor amendment has been incorporated in the *Poisons Standard June 2021* in relation to bilastine, to exempt bilastine from the entry for antihistamines in Appendix F. This was inadvertently omitted from the final decision on bilastine that was published on 22 April 2021.

The *Poisons Standard June 2021* also incorporates a number of new substances to the Poisons Standard for the first time, including specific entries for deutetrabenzine, lemborexant, luspatercept, risdiplam and trabectedin in Schedule 4. A number of these substances were also listed in Appendix K, including deutetrabenzine, lemborexant and trabectedin.

A small number of other, more minor, amendments were also incorporated into the *Poisons Standard June 2021*, principally to clarify the scheduling of derivatives eslicarbazepine acetate and esketamine, remove duplicatory index references and update spelling.

The decisions to make the minor correction in relation to bilastine, introduce new substances and make the above more minor amendments were delegate-only decisions that were not open

to public consultation as the changes were considered, in accordance with the SPF, to be sufficiently straightforward so as to not require consultation.

The *Poisons Standard June 2021* 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 (see subsection 52D(4A) of the Act). As a consequence, subsection 9(1) of the *Human Rights (Parliamentary Scrutiny) Act 2011* does not require that the instrument be accompanied by a statement of compatibility with the human rights recognised under that Act.

The *Poisons Standard June 2021* commences on 1 June 2021.