

EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*
Poisons Standard October 2017

The *Therapeutic Goods Act 1989* (**the TG Act**) provides for the establishment and maintenance of a system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The TG Act also provides for a framework for the 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 Therapeutic Goods Administration (**the TGA**), which is part of the Department of Health, is responsible for administering the TG Act.

Part 6-3 of the TG 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 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 TG Act (which is in Part 6-3) provides for the Secretary of the Department of Health, to amend the current Poisons Standard (known as the Standard for the Uniform Scheduling of Medicines and Poisons) 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 consists of decisions of the Secretary, regarding the classification of poisons into the different Schedules, signifying the degree of control recommended to be exercised over their availability to the public.

The TG Act establishes two expert advisory committees, the Advisory Committee on Medicines Scheduling (the ACMS) (section 52B) and the Advisory Committee on Chemicals Scheduling (the ACCS) (section 52C), 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 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 them and the degree of control over their availability, in the interest of public health and safety.

The Commonwealth also takes into account the scheduling and classification of substances in the Poisons Standard for regulatory and enforcement purposes under the TG Act.

For example, the TG Act prohibits the publication or broadcasting of advertisements to consumers about prescription medicines containing substances included in Schedule 4 or Schedule 8 of 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 of the Poisons Standard is also prohibited.

The *Scheduling Policy Framework (the SPF)* provides guidance on whether a decision concerning 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 (cited as the Poisons Standard October 2017) in substitution for the previous Poisons Standard - the Poisons Standard June 2017 (which commenced on 1 June 2017).

The Poisons Standard October 2017 incorporates a number of changes compared to the Poisons Standard June 2017. These amendments principally involve changes to existing entries, and the inclusion of 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 and/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 on those matters referred to the March 2017 ACMS, ACCS and Joint ACCS-ACMS meetings. These meetings related to proposals to amend the Poisons Standard in relation to the following substances:

Medicines

- Dihydrocodeine;
- 1,3-Dimethylbutylamine (DMBA) and other aliphatic alkylamines including 1,5-dimethylhexylamine (DMHA);
- Ibuprofen;
- Penciclovir;
- Loratadine;
- *N*-(alkylamino) cyclohexylbenzamides (opioids); and
- Tetrahydrocannabinols.

Chemicals

- Methylisothiazolinone;
- Methylchloroisothiazolinone;

- Geraniol and related compounds;
- Ethyl hexanediol;
- Isoeugenol; and
- *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941).

The invitation to comment on methylisothiazolinone and methylchloroisothiazolinone was advertised on the TGA website (<https://www.tga.gov.au/consultation-invitation/consultation-invitation-public-comment-meeting-and-joint-accsacms-meeting-july-2015>) on 27 May 2015, and closed on 25 June 2015.

The invitation to comment in relation to geraniol and related compounds was advertised on the TGA website (<https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-accs-and-joint-accsacms-july-2016>) on 26 May 2016, and closed on 24 June 2016.

The invitation to comment in relation to cannabis and tetrahydrocannabinols was advertised on the TGA website (<http://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-joint-accs-and-acms-meeting-november-2016>) on 22 September 2016, and closed on 20 October 2016.

The invitation to comment on dihydrocodeine, 1,3-dimethylbutylamine (DMBA) (and other aliphatic alkylamines including 1,5-dimethylhexylamine (DMHA)), ibuprofen, penciclovir, loratadine, *N*-(alkylamino) cyclohexylbenzamides (opioids), ethyl hexanediol, and *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) was advertised on the TGA website (<https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-accs-acms-and-joint-accsacms-meetings-march-2017>) on 22 December 2016, and closed on 10 February 2017.

The invitation to comment in relation to isoeugenol was advertised on the TGA website (<https://www.tga.gov.au/consultation-invitation/consultation-further-proposed-amendments-poisons-standard-joint-accs-and-acms-meeting-and-accs-meeting-march-2017>) on 3 February 2017, and closed on 3 March 2017.

Further public comment was subsequently invited on the delegates' interim decisions on 1 October 2015 with a closing date of 15 October 2015; on 15 September 2016 with a closing date of 29 September 2016; on 2 February 2017 with a closing date of 16 February 2017, and on 17 May 2017 with a closing date of 31 May 2017.

The delegates' final decisions in relation to these matters were published on the TGA website on 8 December 2015, 27 October 2016, 31 May 2017 and 29 June 2017 respectively, with the delegate deciding that each of these decisions should be implemented from 1 October 2017.

Other amendments set out in this instrument added a number of new chemical entities to the Poisons Standard for the first time: migalastat, fosfomycin, dupilumab, bezlotoxumab, teduglutide and guselkumab.

These decisions were delegate-only decisions that were not open to public consultation, as they were considered (in accordance with the SPF) to be sufficiently straightforward as to not require public consultation.

The Poisons Standard October 2017 also includes a number of editorial amendments, with the majority including corrections of a typographical nature to the Standard. Some examples of editorial amendments in the Poisons Standard June 2017 include:

- adding in missing Appendix E and F statements (as per final decision) for diethylene glycol monobutyl ether;
- amending typographical error in cross-referencing para-aminopropiophenone in the index entry for 4-aminopropiophenone;
- modifying index details for the strychnine entry to include an Appendix E, Part 2 listing;
- adding in a new index entry for equine anti-human thymocyte immunoglobulin, with a cross reference to immunoglobulins;
- amending the direct red 254 Schedule 5 entry to include the words ‘calculated as free acid’ after the 30 percent or less exemption cut-off;
- altering the Schedule 2 entry for loratadine, clarifying the requirement for packs containing 10 dosage units or less be labelled for adults and children 6 years and over; and
- relocating index entries for D-pulegone and D-phenothrin from ‘D’ to ‘P’.

There were also 2 editorial amendments to Parts 1-3 of the Poisons Standard, as incorrect Therapeutic Goods Order (TGO) numbers were listed. TGO 90 was corrected to TGO 91 – *Standard for labels of prescription and related medicines*, and TGO 91 was corrected to TGO 92 – *Standard for labels of non-prescription medicines*.

These decisions were also not open to public consultation as they were considered, in accordance with the SPF, to be sufficiently straightforward as to not require public consultation.

The Poisons Standard is a legislative instrument for the purposes of the Legislation Act 2003 (the LA). However, section 42 (disallowance) of the LA does not apply (refer to subsection 52D(4A) of the TG Act). Because it is not disallowable, 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 instrument commences on 1 October 2017, which means the Poisons Standard October 2017 is effective on and from that day.