# EXPLANATORY STATEMENT

*Therapeutic Goods Act 1989*

*Poisons Standard October 2019*

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 (which consists of the Standard for the Uniform Scheduling of Medicines and Poisons (section 2 of the Poisons Standard refers)) 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 ("the ACMS") (section 52B of the Act refers) and the Advisory Committee on Chemicals Scheduling ("the 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 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 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 of 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 October 2019*, in substitution for the previous Poisons Standard, the *Poisons Standard June 2019* (which commenced on 1 June 2019, and which is repealed and replaced by this new Poisons Standard).

The *Poisons Standard October 2019* incorporates a number of changes compared to the *Poisons Standard June 2019*. 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 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.

In relation to amendments made to existing entries that are reflected in the *Poisons Standard October 2019*, public comment was invited on matters referred to the July 2017 Joint ACMS-ACCS meeting, November 2017 ACMS meeting, March 2019 ACCS meeting, the March 2019 ACMS meeting and the March 2019 Joint ACMS-ACCS meeting as follows:

- the invitation to comment in relation to methylisothiazolinone was advertised on the TGA website on 17 May 2017, with a closing date of 15 June 2017;
- the invitation to comment in relation to hyaluronic acid and its polymers (referred to as hyaluronic acid) was advertised on the TGA website on 6 September 2017, with a closing date of 6 October 2017;
- the invitation to comment in relation to glyceryl trinitrate, paracetamol, cyclosilazanes, and di-me, me hydrogen, polymers with di-me, me hydrogen silazanes, reaction products with 3-(triethoxysilyl)-1-propanamine (CAS 475645-84-2) (referred to as polymer in durazane 1500), was advertised on the TGA website on 13 December 2018, with a closing date of 21 January 2019; and
- the invitation to comment in relation to MCPB was advertised on the TGA website on 10 January 2019, with a closing date of 8 February 2019.

Further public comment was subsequently invited on the delegates' interim decisions as follows:

- the invitation to comment in relation to methylisothiazolinone was advertised on the TGA website on 15 September 2017, with a closing date of 3 October 2017;

- the invitation to comment in relation to hyaluronic acid and its polymers (referred to as hyaluronic acid) was advertised on the TGA website on 5 February 2018, with a closing date of 5 March 2018; and

- the invitation to comment in relation to glyceryl trinitrate, paracetamol, cyclosilazanes, di-me, me hydrogen, polymers with di-me, me hydrogen silazanes, reaction products with 3-(triethoxysilyl)-1-propanamine (cas 475645-84-2) (referred to as polymer in durazane 1500) and MCPB, was advertised on the TGA website on 6 June 2019, with a closing date of 4 July 2019.

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

- Hyaluronic acid and its polymers (referred to as hyaluronic acid) on 10 April 2018;

- Methylisothiazolinone on 31 October 2017; and

- Glyceryl trinitrate, paracetamol, cyclosilazanes, di-me, me hydrogen, polymers with di-me, me hydrogen silazanes, reaction products with 3-(triethoxysilyl)-1-propanamine (CAS 475645-84-2) (referred to as polymer in durazane 1500) and MCPB on 22 August 2019.

In recognition of the concerns raised in the public submissions on the practicality of the implementation date proposed in the interim decision for hyaluronic acid and its polymers and methylisothiazolinone, the delegate decided to lengthen the implementation timeframe in order to allow industry sufficient time to comply with these amendments. As such these decisions have come into effect from 1 October 2019.

The *Poisons Standard October 2019* also incorporates the introduction of a number of new substances to the Poisons Standard for the first time. These include a number of specific entries for alpelisib, darolutamide, linaclotide, lorlatinib, niraparib and risankizumab in Schedule 4. A new Appendix K entry for risankizumab was also created.

A small number of minor amendments were also included in this instrument, including for example editorial amendments to the current entries for *N*,*N*-diallyldichloroacetamide, 3-iodo-2-propynyl butyl carbamate (iodocarb) and allyl esters.

The decisions to introduce the new substances and to make the above technical and minor amendments, 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 consultation.

The Poisons Standard October 2019 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 Act). As 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 Poisons Standard October 2019 commences on 1 October 2019.