

## **EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*

*Poisons Standard December 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 (“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 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 December 2019*, in substitution for the previous Poisons Standard, the *Poisons Standard October 2019* (which commenced on 1 October 2019, and which is repealed and replaced by this new Poisons Standard).

The *Poisons Standard December 2019* incorporates the introduction of a new substance to the Poisons Standard for the first time – talazoparib in Schedule 4.

A small number of minor amendments were also included in this instrument, including editorial amendments to the current entries for calcium hydroxylapatite and dextropropoxyphene and to include index entries for thymosin beta 4 (thymosin  $\beta$ 4), fibroblast growth factors and TB-500.

The decision to introduce the new substance and to make the above 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 December 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 December 2019* commences on 1 December 2019.