

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Poisons Standard (No. 3) June 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 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 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 (No. 3) June 2020*, in substitution for the previous Poisons Standard, the *Poisons Standard (No.2) June 2020*, which was registered on 29 May 2020 and commenced on 1 June 2020, and which is repealed and replaced by this new Poisons Standard.

The *Poisons Standard (No. 3) June 2020* incorporates a small number of changes to the *Poisons Standard (No.2) June 2020*, principally to correct errors made in relation to the entries of two substances by the *Poisons Standard (No.2) June 2020*. These substances, sumatriptan and zolmitriptan, were inadvertently included in Schedule 3 and Appendix H of the *Poisons Standard (No.2) June 2020*, and amendments made to the entries relating to those substances in Schedule 4 to reflect that down-scheduling.

While a delegate of the Secretary recently made a final decision under regulation 42ZCZR of the *Therapeutic Goods Regulations 1990* (“the Regulations”) to include the two substances in Schedule 3 and Appendix H (in certain oral preparations), that decision was intended to take effect by amendment to the Poisons Standard in February 2021 rather than June 2020. The delegate’s decision reflecting the date of effect as 1 February 2021 was published on the TGA website on 7 May 2020 in accordance with the requirements of regulation 42ZCZS of the Regulations.

The date of effect reflects the agreement of stakeholders, including the states and territories, for the changes to scheduling of these two substances. The *Poisons Standard (No. 3) June 2020* gives effect to the delegate’s final decision by removing the entries for sumatriptan and zolmitriptan from Schedule 3 and Appendix H and restoring those entries to Schedule 4 only.

The *Poisons Standard (No. 3) June 2020* also includes minor formatting changes and a correction to the spelling of the substance cedazuridine, which was inadvertently referred to as cezauridine in the *Poisons Standard (No.2) June 2020*.

The *Poisons Standard (No. 3) June 2020* is a legislative instrument for the purposes of the *Legislation Act 2003*. However, section 42 of that Act 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 that the instrument be accompanied by a statement of compatibility with the human rights recognised under that Act.

The *Poisons Standard (No. 3) June 2020* commences on the day after registration.