

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Poisons Standard Amendment (Vonicog Alfa) Instrument 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 (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 the *Poisons Standard Amendment (Vonicog Alfa) Instrument 2020* (“the Amendment Instrument”) is to amend the *Poisons Standard February 2020*, to remove the substance vonicog alfa from Schedule 4 of the Poisons Standard.

This is because the inclusion of vonicog alfa in Schedule 4 of the *Poisons Standard February 2020* was inadvertent. Vonicog alfa is captured by the entry of Appendix A (part iv of part c) of the *Poisons Standard February 2020* for human blood products, which allows a substance to be exempt from the Poisons Standard, and it was not intended to include this substance in Schedule 4.

Vonicog alfa is a substance that is designed to replace a protein in the human body that is needed to stop bleeding (von Willebrand factor), for a person for whom this protein is deficient in quantity or quality – that is, for a person suffering from von Willebrand disease (“VWD”). People with VWD have difficulty forming a blood clot, which is needed to stop bleeding when it occurs and may, as a result, bleed more after events such as injury, childbirth or during surgery.

The Amendment Instrument would also make a minor, consequential amendment to remove the reference to vonicog alfa in the index to the *Poisons Standard February 2020*.

The decision to make this technical amendment to correct the inadvertent inclusion of vonicog alfa in Schedule 4 was a delegate-only decision that was not open to public consultation as it was considered, in accordance with the SPF, to be sufficiently straightforward as to not require consultation.

The Amendment Instrument 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 Amendment Instrument commences on 1 February 2020, the same time that the *Poisons Standard February 2020* commences. As such, this will ensure that the inadvertent error in the *Poisons Standard February 2020* to include vonicog alfa in Schedule 4 will not take effect.