EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Amendment (2017 Measures No. 1) Instrument 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 purpose of this instrument is to amend the Poisons Standard February 2017. The effect of the amendments is to remove the following substances from Schedule 6 of the Poisons Standard (including references to the substances in other parts of the Poisons Standard):

- m-aminophenol;
- Resorcinol;
- 2-chloro-6-(ethylamino)-4-nitrophenol;

The amendments also alter the wording of the entry for 2,4-diaminophenoxyethanol in schedule 6 and in Part 3 of Appendix F of Part 5 of Schedule 1 of the Poisons Standard February 2017.

These chemicals were included in the February 2017 Poisons Standard following a delegate-only decision and consultation with the applicant. On publication of the delegate-only decisions, information was received from industry that the wording of the entries may require further amendment to account for the use of these chemicals in other industry sectors. Three chemicals have been withdrawn from the Poisons Standard, and the entry for 2,4-diaminophenoxyethanol has been amended to reflect the entry in the Poisons Standard November 2016 while these decisions are reviewed and advice is sought from the scheduling committees in accordance with the procedures set out in Subdivision 3D.2 of Part 6 of the *Therapeutic Goods Regulations 1990*.

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 February 2017, which means the amendments to the Poisons Standard February 2017 contained in this instrument are effective on and from that day.