EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Standard 2013

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 States and Territories to adopt a uniform approach to control the availability and accessibility, and to ensure the safe handling, of poisons in Australia. The Therapeutic Goods Administration (the TGA) is responsible for administering the TG Act.

Subsection 52D (2) of the TG Act authorises the Secretary to the Department of Health and Ageing, or a delegate of the Secretary, 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.

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.

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 (or a delegate of the Secretary) on matters relating to medicines and chemicals scheduling decisions.

The Poisons Standard consists of decisions of the Secretary, or a delegate of the Secretary, regarding the classification of poisons into nine different Schedules signifying the degree of control recommended to be exercised over their availability to the public.

The purpose of this instrument is to prepare a new Poisons Standard (cited as the Poisons Standard 2013) in substitution for the previous Poisons Standard. The previous Poisons Standard that is being substituted is the Poisons Standard 2012 (which was registered on the Federal Register of Legislative Instruments on 14 June 2012), together with the five subsequent amendments that have been made to the Poisons Standard 2012: Poisons Standard Amendment No. 2 of 2012, Poisons Standard Amendment No. 3 of 2012, Poisons Standard Amendment No. 4 of 2012, Poisons Standard Amendment No. 5 of 2012 and Poisons Standard Amendment No. 1 of 2013.

As such, the Poisons Standard 2013 is a consolidation of the Poisons Standard 2012 and its five amendments.

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 them and the degree of control recommended to be exercised over their availability in the interest of public health and safety.

The Commonwealth also takes into account the scheduling and classification of substances in the Poisons Standard for regulatory and enforcement purposes under the TG Act.

For example, the TG Act and Regulations prohibit the publication of advertisements to consumers about prescription medicines included in Schedule 4 or 8 of the Poisons Standard or over the counter medicines that are included in Schedule 3 and not included in Appendix H of the Poisons Standard. The advertising of substances included in Schedule 9 or Appendix C of the Poisons Standard is also prohibited.

The five amendments that have been made to the Poisons Standard 2012 included scheduling decisions that were made by a delegate of the Secretary. Some, but not all, of these amendments were delegate-initiated. In some cases, the decisions were made following referral to the relevant expert advisory committee for advice. Those five amendments also included a number of minor editorial or errata amendments.

The Poisons Standard is a legislative instrument for the purposes of the *Legislative Instruments Act 2003* (the LIA). However, section 42 (disallowance) of the LIA does not apply (refer to subsection 52D(4A) of the TG Act).

As this 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.