

EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Standard 2012

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 (section 52B) and the Advisory Committee on Chemicals Scheduling (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 and on any other matters referred to them by the Secretary.

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 Poisons Standard 2012) in substitution for the previous Poisons Standard. The previous Poisons Standard that is being substituted is the Poisons Standard 2011 (which was registered on the Federal Register of Legislative Instruments on 8 August 2011), together with the four subsequent amendments that have been made to the Poisons Standard 2011: Poisons Standard Amendment No. 3 of 2011, Poisons Standard Amendment No. 4 of 2011, Poisons Standard Amendment No. 5 of 2011 and Poisons Standard Amendment No. 1 of 2012.

As such, the Poisons Standard 2012 is principally a consolidation of the Poisons Standard 2011 and its four amendments.

However, the Poisons Standard 2012 also incorporates a small number of changes to Poisons Standard 2011 which have not previously been included in any of the amendments to the Poisons Standard 2011 mentioned above.

These amendments involve minor changes to correct a number of outdated references to relevant State and Territory government bodies, provisions of the Therapeutic Goods Regulations 1990 (the Regulations) and a number of therapeutic goods related legislative instruments and other documents such as the '*International Cosmetic Ingredient Dictionary & Handbook*'.

An example of these changes is the replacement of a reference to Therapeutic Goods Order 65 – '*Child resistant packaging for therapeutic goods*' (TGO 65) with a reference to Therapeutic Goods Order 80 – '*Child-Resistant Packaging Requirements for Medicines*' (TGO 80), to reflect that TGO 80 has replaced TGO 65 (which is no longer in operation).

The Schedules contained in the Poisons Standard are referred to under State and Territory legislation for regulatory purposes, which enables restrictions to be placed on the supply of scheduled substances to the public, according to the degree of risk 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 the Regulations prohibit the publication of advertisements to consumers about prescription medicines included in Schedules 4 or 8 of the Poisons Standard or over the counter medicines 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 four amendments that have been made to the Poisons Standard 2011 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 four 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).

In relation to compatibility with human rights, it is considered that the Poisons Standard 2012 is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*, and a Statement of Compatibility setting that out in further detail is attached.

ATTACHMENTS

1. Statement of compatibility for a legislative instrument that does not raise any human rights issues (Poisons Standard 2012).