EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Standard Amendment No. 2 *of 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 (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 amend the Poisons Standard 2012. The amendment to the Poisons Standard 2012 set out in Schedule 1 of this instrument consists of one decision made by a delegate of the Secretary. This amendment commences on 8 August 2012.

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 interests 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 Schedules 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 amendment to the Poisons Standard 2012 that is set out in this instrument consists of a single decision to include a specified substance – 1,3-dimethylamylamine (DMAA) -in the Poisons Standard for the first time.

This change was made following the provision of advice from the ACMS, and in accordance with the procedures set out in Subdivision 3D.2 of Part 6 of the Therapeutic Goods Regulations 1990 for amending the Poisons Standard when a proposed amendment is referred to an expert advisory committee. The Scheduling Policy Framework (SPF) provides guidance to assist delegates in making a decision as to whether a matter would benefit from being referred to an advisory committee for advice. A copy of the SPF is available from http://www.tga.gov.au/industry/scheduling-spf.htm.

Public comment was invited on a proposal to amend the Poisons Standard in relation to DMAA. The invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 26 April 2012, and closed on 25 May 2012. Public submissions received were taken into consideration at the June 2012 meeting of the ACMS.

Further public comment was subsequently invited on the delegate's interim decision on 20 July 2012, with a closing date of 25 July 2012. The delegate's final decision in relation to this matter was published on the TGA website on 1 August 2012. The delegate took the view that this decision should be implemented from 8 August 2012, as the scheduling of DMAA is considered to be an urgent measure necessary to protect public health in light of the potential for use of this substance to cause harm to users.

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 Poisons Standard Amendment No. 2 of 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.

ATTACHMENT

1. Statement of compatibility for a legislative instrument that does not raise any human rights issues (Poisons Standard Amendment No. 2 of 2012).