

EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Standard Amendment No.1 of 2011

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 and associated regulations under that 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 prepare a document (a new Poisons Standard) that includes schedules containing the names or descriptions of substances, in substitution for the current Poisons Standard. This authority had previously been provided to an independent statutory committee established under the TG Act, the National Drugs and Poisons Schedule Committee (NDPSC), which no longer exists due to the implementation of amendments to the TG Act that commenced on 1 July 2010.

Part 6-3 of the TG Act provides for 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 also establishes two expert advisory committees, the Advisory Committee on Medicines Scheduling (section 52B) and the Advisory Committee on Chemicals Scheduling (section 52C). These statutory committees provide advice and make recommendations to the Secretary (or a delegate of the Secretary) on matters relating to medicines and chemicals scheduling decisions and in relation to any other matters referred to them by the Secretary. Part 6-3 of the TG Act also provides for the constitution of those committees and other administrative arrangements in relation to the carrying out of their functions in accordance with the regulations.

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 2010. The amendments to the Poisons Standard 2010 set out in Schedule 1 of this instrument consist of decisions made by a delegate of the Secretary. These amendments commence on 1 June 2011.

The statutory procedures set out under the TG Act and the Therapeutic Goods Regulations 1990 (the Regulations) allow the Secretary or her delegate to consider applications under section 52EAA of the TG Act to amend the current Poisons Standard, as well as to initiate an amendment or the making of a new document to substitute the current Poisons Standard on the Secretary's or delegate's own initiative (see subsection 52D(3) of the TG Act). Regulation 42ZCZU of the Regulations allows the Secretary, or her delegate, to make a final scheduling decision in response to an application under section 52EAA to amend the current Poisons Standard, if the decision aligns with the proposal in the application and without referring the matter for consideration by an expert advisory committee.

The Schedules contained in the Poisons Standard are referred to under State and Territory legislation for regulatory purposes. 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 of the Poisons Standard is also prohibited.

The amendments to the Poisons Standard 2010 that are set out in this instrument consist of a small number of changes to existing entries and a small number of changes to include specified substances in the Poisons Standard for the first time. The changes to existing entries were two rescheduling decisions in relation to mercurochrome and diclofenac, and the deletion of the reference to pseudoephedrine from Appendix H to the Poisons Standard 2010.

These changes were made following the provision of advice from the Advisory Committee on Medicines Scheduling at its December 2010 meeting. The Scheduling Policy Framework provides guidance to assist delegates in making a decision on whether a matter would benefit from being referred to an advisory committee for advice.

Public comment on the initial proposals to amend the schedules in relation to mercurochrome, diclofenac and the Appendix H entry for pseudoephedrine was invited. This invitation to comment was advertised on the TGA website (www.tga.gov.au) from 29 September 2010, and was closed on 29 October 2010. Public submissions received were taken into consideration at the December 2010 meeting of the Advisory Committee on Medicines Scheduling. Further public comment on the delegate's interim decisions was invited on 16 February 2011, with a closing date of 2 March 2011. The delegate's final decisions in relation to these matters were published on the TGA website on 23 March 2011.

The other amendments set out in this instrument added new substances ofatumumab, rilpivirine, tolvaptan and vinflunine to the Poisons Standard for the first time. The decisions to amend the Poisons Standard to include these substances were delegate-only decisions that were not open to public consultation as the decisions related to medicines that have not previously listed in the Poisons Standard. For these

previously unscheduled medicines, consultation in relation to scheduling was undertaken with the sponsor of the medicines.

Although registered medicines containing these substances can be lawfully supplied in Australia, the States and Territories have responsibility for controls over the access to these high risk medicines. These controls include that these medicines can only be prescribed by a registered medical practitioner or other authorised prescribers when included in Schedule 4 of the Poisons Standard. It is therefore required that these new high risk medicines be included in the Poisons Standard prior to the commencement of supply.

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).