EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Standard Amendment No. 1 of 2008

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 National Drugs and Poisons Schedule Committee (the Committee) to amend the current Poisons Standard 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.

The Committee is established under Part 6-3 of the TG Act (refer to section 52B). The Committee consists of Commonwealth, State and Territory government members and other persons appointed by the Minister for Health and Ageing such as technical experts and representatives of various sectoral interests. Part 6-3 of the TG Act establishes the Committee as a statutory body, sets out its functions and activities and its responsibilities for the Poisons Standard, such as the publication of decisions by the Committee and the making of amendments.

The Poisons Standard consists of decisions of the Committee regarding classification of drugs and poisons into nine different Schedules signifying the degree of risk and 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 2007. The amendments to the Poisons Standard 2007 set out in Schedule 1 consist of decisions made by the Committee at its October 2007 meeting and confirmed at its February 2008 meeting. These amendments commence 1 May 2008.

The statutory procedures set out under the TG Act and the Therapeutic Goods Regulations 1990 (the Regulations) require that any amendments made to the Poisons Standard undergo a consultation process that involves inviting and considering public submissions (described in regulations 42ZCU and 42ZCV of the Regulations), before making a decision in relation to the scheduling of drugs and poisons. Regulations 42ZCY and 42ZCZ set out the requirements relating to the public notification of any amendment to the Poisons Standard. These requirements include inviting persons who made a valid public submission (as described in regulation 42ZCV of the Regulations) before the amendment was made to make a further submission, and a requirement that the Committee must consider any such further submissions that are in compliance with the Regulations, before determining whether to confirm, vary or set aside the amendment to the Poisons Standard.

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 52EA(2) of the TG Act).

The Schedules of poisons and drugs 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 Regulations prohibit the publication of advertisements about prescription medicines (included in Schedule 4), over the counter medicines (included in Schedule 3 and not included in Appendix H) and medicines included in Schedule 8 of the Poisons Standard in specified media such as magazines, newspapers, television, radio, cinematograph films and certain displays.

Invitations for public submissions to these amendments to the Poisons Standard were advertised in the *Gazette* on 15 August 2007. Public submissions received were taken into consideration at the October 2007 meeting. The Committee's decisions from the October meeting were published on 28 November 2007. Invitations for the second round of submissions were advertised in the *Gazette* on 28 November 2007 and taken into consideration at the February 2008 meeting. Any variations made at the February 2008 meeting to the October 2007 decisions were published on 9 April 2008. The stakeholders have been aware of the initial amendments since 28 November 2007 and any further amendments to these since 9 April 2008.

A regulatory impact statement does not accompany this instrument as the amendments to the Poisons Standard set out in this instrument are regarded as having low impact on industry in general and are considered to be necessary public health measures in order to provide appropriate and safe access to the substances contained in the amendments. The process for amending the Poisons Standard involves significant consultation with industry stakeholders and, as such, they are already aware of these amendments (as detailed above) which are to be implemented by States and Territories on 1 May 2008.