EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Standard 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 prepare a new Poisons Standard (cited as Poisons Standard 2008) in substitution for the previous Poisons Standard.

The previous Poisons Standard that is being substituted is the Poisons Standard 2007 that consists of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), No. 22 and Consolidated Amendment (the SUSDP No 22 Consolidated Amendment). The Poisons Standard 2007 was registered on FRLI on 19 December 2007.

The Poisons Standard 2008 consists of the Standard for the Uniform Scheduling of Drugs and Poisons, No. 23 (the SUSDP No 23) which was published by the Committee in June 2008. SUSDP 23 consolidates all decisions made by the Committee set out in the Poisons Standard 2007 and amendments made to that Poisons Standard that commenced 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 2008 was prepared by the Committee at its meeting in July 2008 pursuant to paragraph 52D(2)(b) of the TG Act.

The Poisons Standard 2007 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 and other Parts of the Poisons Standard are implemented in State and Territory legislation. The Commonwealth also takes into account the scheduling and classification of substances in the Poisons Standard in making regulatory and enforcement decisions under the TG Act. For example, the TG Act and Regulations prohibit 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 or newspapers for consumers, televisions, radio, cinematograph films and displays about goods.

Most of the scheduling and classification of drugs and poisons as set out in this new Poisons Standard have already been implemented and industry stakeholders are already aware of the amendments that commenced on 1 September 2007, 1 January 2008 and 1 May 2008. Therefore there should be low, or no, regulatory impact on business.

Section 1 of this instrument provides that the name of the instrument is the Poisons Standard 2008.

Section 2 of this instrument provides that the Poisons Standard prepared by the Committee consists of the Standard for the Uniform Scheduling of Drugs and Poisons No.23, published by the Committee in 2008 as set out in Schedule 1.

The Standard for the Uniform Scheduling of Drugs and Poisons No.23 is a consolidation of the amendments resulting from decisions made at meetings of the Committee up to and including the October 2007 meeting and with effective date of amendments to the current Poisons Standard of up to 1 May 2008.

Section 3 provides for the commencement dates for the Poisons Standard 2008. The Poisons Standard 2008 commences on 20 August 2008.