EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Standard 2007

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 2007) in substitution for the previous Poisons Standard. The previous Poisons Standard that is being substituted consists of the first Poisons Standard at the commencement date of Part 6-3 of the TG Act and the subsequent amendments made to it by the Committee.

The Poisons Standard 2007 consists of two parts: Part 1, being the Standard for the Uniform Scheduling of Drugs and Poisons, No. 22 (the SUSDP No 22) which was published by the Committee in 2007; and Part 2- being the Uniform Scheduling of Drugs and Poisons, No. 22, Consolidated Amendment (the SUSDP No 22 Consolidated Amendment). The Consolidated Amendment consists of decisions made by the Committee at its February, June and October 2007 meetings.

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 2007 was prepared by the Committee at its meeting in December 2007 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). The Poisons Standard falls within paragraph 44(1)(a) of the LIA, as Part 6-3 of the TG Act facilitates the operation of an intergovernmental body (the Committee) and authorises the Poisons Standard to be made and amended by the Committee for purposes of the uniform scheduling scheme. Furthermore, the States and Territories have a greater input into decisions made by the Committee to amend the Poisons Standard, and the States and Territories utilise the Poisons Standard for a range of regulatory purposes.

The Schedules of poisons and drugs contained in 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 both the amendments that commenced on 1 January 2008 and those that are yet to be implemented on 1 January 2009. 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 2007*.

Section 2 of this instrument provides that the Poisons Standard prepared by the Committee consists of the following:

(a) Part 1 – Standard for the Uniform Scheduling of Drugs and Poisons No.22, published by the Committee in 2007; and
(b) Part 2 - Standard for the Uniform Scheduling of Drugs and Poisons No.22, published by the Committee in 2007, Consolidated Amendment.

The Standard for the Uniform Scheduling of Drugs and Poisons No.22, is a consolidation of the amendments resulting from decisions made at meetings of the Committee up to and including the October 2006 meeting and with effective date of amendments to the current Poisons Standard of up to June 2007. The Standard for the Uniform Scheduling of Drugs and Poisons No.22, Consolidated Amendment is a consolidation of amendments resulting from the decisions made at meetings of the Committee in February 2007, June 2007 and October 2007.

Section 3 provides for the commencement dates for the Poisons Standard 2007. Except for Part D of Part 2 – Standard for the Uniform Scheduling of Drugs and Poisons No 22, Consolidated Amendment which commence on 1 January 2009, the Poisons Standard 2007 commences on 1 January 2008. This commencement date reflects the decision made by the Committee at its June 2007 meeting.