

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Legislation Amendment (Annual Charges) Act 2008*

#### Proclamation

Item 2 of subsection 2(1) of the *Therapeutic Goods Legislation Amendment (Annual Charges) Act 2008* (the Act) provides that Schedule 1 to the Act commences on a single day to be fixed by Proclamation. Item 2 also provides that if any of the provisions of Schedule 1 do not commence within the period of 6 months beginning on the day the Act receives Royal Assent, they commence on the first day after the end of that period. The Act received Royal Assent on 3 October 2008.

The purpose of the Proclamation is to fix 1 January 2009 as the day on which Schedule 1 to the Act commences.

Schedule 1 to the Act contains amendments to the *Therapeutic Goods Act 1989* (the TG Act) and the *Therapeutic Goods (Charges) Act 1989* (the TG Charges Act) in relation to the collection and imposition of annual charges, and the implementation of exemptions from a liability to pay annual charges because of low value turnover of therapeutic goods. In addition to other technical and consequential amendments, Schedule 1 makes it clear that annual charges can be set at nil amounts.

No consultation with industry was undertaken in relation to the measures set out in the Act in view of the low impact of the amendments on business. Some of these changes have already been implemented administratively, such as setting the date of payment of annual charges for goods already entered in the Australian Register of Therapeutic Goods as 1 October of the relevant financial year, and therefore would not affect stakeholders adversely. Stakeholder consultations held from 24 July 2008 to 6 August 2008 outlining the Government plans for reform in therapeutic goods regulations included discussions in relation to the low volume low value exemptions from the payment of annual charges as set out in the Act. The outcomes of these consultations have been published on the Therapeutic Goods Administration's website ([www.tga.gov.au](http://www.tga.gov.au)).

A notice was placed on the TGA's website on 31 October 2008 outlining the effects of the provisions in Schedule 1 of the Act, noting the Proclamation date of 1 January 2009 and explaining that while the provisions in Schedule 1 will commence on the day fixed by Proclamation, some of those provisions introduce changes that will only apply to annual charges payable for the 2009-10 financial year.

The Proclamation is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Minute recommends that the Proclamation be made in the form proposed.