EXPLANATORY STATEMENT

Subject: THERAPEUTIC GOODS ORDER NO. 69B *AMENDMENT TO THERAPEUTIC GOODS ORDER NO. 69 GENERAL REQUIREMENTS FOR LABELS FOR MEDICINES*

Therapeutic Goods Act 1989
Section 10

OUTLINE

Therapeutic Goods Order No. 69B *Amendment to Therapeutic Goods Order No. 69 General requirements for labels for medicines* (TGO 69B, this Order) is an Order made by the delegate of the Minister for Health and Ageing under section 10 of the *Therapeutic Goods Act 1989* (the Act).

This Order amends an existing Therapeutic Goods Order (Therapeutic Goods Order No.69 *General requirements for labels for medicines*) (TGO 69), gazetted on 12 September 2001, by replacing the definition of the document *'Required Advisory Statements for Medicine Labels'* in clause 2 'Interpretation' of TGO 69 with a new definition of that document. The new definition of the document *'Required Advisory Statements for Medicine Labels'* updates the version of that document from the July 2004 version to the April 2006 version.

TGO 69B commences three months after the day after it was registered on the Federal Register of Legislative Instruments (FRLI).

BACKGROUND

Section 10 of the Act provides the Minister, or the Minister's delegate, with the power to determine standards for therapeutic goods, or to amend or revoke existing standards, after consultation with a committee established by the *Therapeutic Goods Regulations 1990* (the Regulations) to advise the Minister on standards. The Therapeutic Goods Committee (TGC) is the committee established by the Regulations for this purpose, and it is established by, and its functions and composition are set out in, regulation 34 of the Regulations.

TGO 69 is a standard for medicines made under section 10 of the Act. TGO 69 defines the applicable standards in Australia for the labelling of medicines. Specifically, it requires certain information to be included on labels and specifies where and how such information is to be presented. In particular, TGO 69 requires advisory statements to be included on the labels of certain medicines. The statements that apply in this way are specified in the document *Required Advisory Statements for Medicine Labels* (RASML), which is defined in TGO 69.

At its meeting on 29 November 2007 (the TGC's 31st meeting), the TGC advised by resolution that the definition of RASML contained in TGO 69 should be amended to update the edition of RASML referred to in TGO 69. TGO 69B gives effect to this advice. TGO 69 currently defines RASML by referring to the 1 July 2004 version of that document. However, RASML has since been updated, initially in June 2005 (Update 1), then in April

2006 (Update 2) and more recently in April 2008. TGO 69B amends the definition of RASML in TGO 69 to refer to the April 2006 version of RASML, which incorporates Updates 1 and 2. The TGC has not yet considered the April 2008 update to RASML.

The effect of the amendment to the definition of RASML contained in TGO 69 is to give legislative force to those additions and other changes made to medicine advisory statements by Updates 1 and 2.

Although both Updates 1 and 2 to RASML incorporated transition periods of between 10 and 12 month for the labels of existing medicines to comply with the changes to advisory statements, TGO 69B does not commence until 3 months after registration of this Order on the FRLI. This will allow sponsors of medicines and the Therapeutic Goods Administration (TGA) time to prepare for the amended labelling requirements.

Under paragraph 6(d)(i) of the LIA, an instrument is a legislative instrument for the purposes of section 5 of the LIA if it is declared to be a disallowable instrument under legislation in force before the commencement of the LIA. This determination is a legislative instrument and it is subject to tabling and disallowance in the Parliament under sections 38 and 42 of the LIA.

CONSULTATION AND REGULATION IMPACT STATEMENT

Stakeholders were consulted on the content of Updates 1 and 2 to RASML in accordance with the consultation process outlined in RASML. In each case, the consultation process involved publication of the proposals for amendment to RASML on the website of the TGA (www.tga.gov.au) and direct contact with peak industry bodies inviting their comment. The period allowed for submission of comments was approximately 6 weeks, and comments received as a result of each invitation, in respect of each of Update 1 and Update 2, were considered by the TGA. No significant objections or issues were raised in relation to Updates 1 or 2 by stakeholders in these consultations.

A notice published on the TGA's website on 31 January 2008, following consideration of the TGC's resolution, advised stakeholders of the proposal to amend the definition of RASML contained in TGO 69 to incorporate Updates 1 and 2, and provided an opportunity for stakeholder comment on the proposal.

Only one response was received to the notice published on 31 January 2008. This was from a person acting on behalf of two companies in relation to a herbal ingredient that has been associated with liver problems in some people. Update 2 to RASML introduced a requirement for products containing this herbal ingredient to carry a specific statement advising of possible problems. The sponsors of the product do not agree that this warning statement should appear on their particular product.

This objection was not considered to constitute sufficient grounds to prevent the making of TGO 69B. No other objections or issues were raised by stakeholders.

Preliminary assessment of compliance costs associated with TGO 69B, using the Preliminary Assessment checklist of the Office of Best Practice Regulation, has been undertaken in accordance with Best Practice Regulation requirements.

This preliminary assessment led to the conclusion that this Order would have a low impact on business, and would not restrict competition. As the impact would be low, a Regulation Impact Statement has not been prepared.

In addition, the Regulations include regulatory requirements that apply or relate to the RASML as the RASML is in force from time to time. Subsection 63(4) of the Act permits the Regulations to make such provision, and regulation 2 of the Regulations defines the RASML as the document of that name published by the TGA on 1 July 2004, as in force from time to time.

As such, taken together the Act and the Regulations already apply the most current version of the RASML (being its April 2006 version, incorporating Updates 1 and 2) in relation to relevant therapeutic goods or classes of therapeutic goods.

TGO 69B is an instrument that is of a minor or machinery nature and does not substantially alter existing arrangements. It is needed in order to avoid any inconsistency between the Regulations and TGO 69 in relation to the version of the RASML referred to and applied in each.

The following documents referred to above may be viewed and obtained from the following locations:

1. the Act and Regulations may be viewed and downloaded from the website ComLaw (www.comlaw.gov.au), a link to which is on the TGA's website (www.tga.gov.au);
2. TGO 69 and TGO 69A may be viewed and downloaded from ComLaw and the TGA's website;
3. RASML (version April 2006), Updates 1 and 2 and archived versions of RASML June 2005 and July 2004 may be viewed and downloaded from the TGA's website;
4. the meeting report and resolution of the TGC's 31st meeting may be viewed and downloaded from the TGA's website.