EXPLANATORY STATEMENT

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

Therapeutic Goods Act 1989
Section 10

OUTLINE

Therapeutic Goods Order No. 69C *Amendment to Therapeutic Goods Order No. 69 General requirements for labels for medicines* (TGO 69C, 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 updates the version of the document from the April 2006 version to the September 2008 version; and
- making a consequential amendment to how the content of Vitamin A is to be expressed on labels of medicines in order to achieve consistency with the wording of advisory statements relating to Vitamin A intake and the expression of Nutrient Reference Values for Vitamin A as determined by the National Health and Medical Research Council.

TGO 69C commences on the later date of the day after it is registered on the Federal Register of Legislative Instruments or 23 April 2009, this being the final date specified in the document *Required Advisory Statements for Medicine Labels* (RASML) for implementation of the amended advisory statements relating to Vitamin A intake.

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.

Among other things, TGO 69 requires that the names and the quantity or proportion of all active ingredients be shown on the labels of medicines and specifies how this information must be expressed. TGO 69 also requires that advisory statements 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 held on 15-16 October 2008 (the TGC's 33rd meeting), the TGC advised by resolution that the definition of RASML contained in TGO 69 should be amended to reflect the most recent version of RASML and a consequential amendment be made to the method of expression of Vitamin A content on labels of medicines. TGO 69C gives effect to this advice.

TGO 69 currently defines RASML by referring to the April 2006 version of that document. However RASML is a dynamic document and is regularly updated. The April 2006 version has been superseded twice – in April 2008 (Update 3.1) and in September 2008 (Update 4). TGO 69C will therefore amend the definition of RASML contained in TGO 69 so that it refers to the September 2008 version, which incorporates Updates 3.1 and 4.

The effect of the amendment to the definition of RASML contained in TGO 69 will be to give legislative force to those additions and other changes made to medicine advisory statements by Updates 3.1 and 4.

Clause 4 of TGO 69 specifies how the quantity or proportion of an active ingredient must be expressed on the label of a medicine. Subclause 4(13) currently specifies that, for preparations containing Vitamin A, the quantity or proportion of Vitamin A must be expressed in terms of International Units (IU). The amendment made by TGO 69C to subclause 4(13) will remove reference to International Units and require the content of Vitamin A present as an active ingredient in a medicine to be quantified in retinol equivalents.

This change is consequential to changes to the wording of advisory statements for medicines containing Vitamin A included in the April 2008 update of RASML and will ensure consistency between the units of measurement used for the declaration of content of Vitamin A and the limits used in advisory statements relating to Vitamin A that are required by RASML.

TGO 69 has been amended twice previously – initially in July 2004 (through Therapeutic Goods Order No. 69A) to include the definition of RASML and secondly in September 2008 (through Therapeutic Goods Order No. 69B) to update the version of RASML to include Updates 1 and 2.

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. TGO 69C 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 previously consulted on the proposed additions and changes to RASML which were included in Update 3.1 and Update 4, in accordance with the process outlined in RASML (Appendix 1 - Procedural Matters).

In each case, the consultation process involved publication of the proposals for amendment to RASML on the website of the Therapeutic Goods Administration (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 3.1 and Update 4, were considered by the TGA.

Matters raised by stakeholders were generally minor and related to proposed advisory statements for individual substances. These matters were resolved by the TGA before finalisation of the updates to RASML. No significant objections to updating RASML were raised by stakeholders in these consultations. Records of Decisions and Reasons are available on the TGA internet site for both Update 3.1 and Update 4.

A notice published on the TGA's website on 10 December 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 3.1 and 4 and to amend the manner in which the content of Vitamin A is expressed on labels. This provided a further opportunity for stakeholder comment. Responses were received from two industry associations – both associations supported the proposed amendments to TGO 69.

TGO 69C is an instrument that is of a minor or machinery nature and does not substantially alter existing arrangements.

In addition, the Regulations include regulatory requirements that apply or relate to the RASML as 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 September 2008 version) in relation to relevant therapeutic goods or classes of therapeutic goods.

TGO 69C 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.

Preliminary assessment of compliance costs associated with TGO 69C, 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.

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 (including previous amendments made through TGO 69A and TGO 69B) and TGO 69C may be viewed and downloaded from ComLaw and the TGA's website;
3. RASML (version September 2008), Updates 3.1 and 4, and archived earlier versions of RASML may be viewed and downloaded from the TGA's website;
4. the meeting report and resolution of the TGC's 33rd meeting may be viewed and downloaded from the TGA's website.