

## **EXPLANATORY STATEMENT**

### **Therapeutic Goods Act 1989**

#### **Therapeutic Goods Order No. 91A – Therapeutic Goods Order No. 91 (Standard for labels of prescription and related medicines) Amendment Order 2017**

#### **OUTLINE**

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in or exported from Australia. The Therapeutic Goods Administration (TGA), which is part of the Department of Health, is responsible for administering the Act.

Under powers of the Act, the TGA is responsible for establishing and enforcing requirements for the way medicines are labelled for commercial supply in Australia. Under section 10 of the Act, the Minister may, by way of a legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods.

For this purpose, *Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines* (the original Order, TGO 91), was made on 2 August 2016 (Register ID: F2016L01285) by the delegate of the then Minister for Health and Aged Care under section 10 of the Act. TGO 91 commenced on 31 August 2016.

*Therapeutic Goods Order No. 91A – Therapeutic Goods Order No. 91 (Standard for labels of prescription and related medicines) Amendment Order 2017* (this Order) amends the original Order.

The amendments are minor but were necessary to:

- correctly reference the recently re-made *Therapeutic Goods Order No. 69 - General Requirements for Labels for Medicines* (TGO 69) by its new name, *Therapeutic Goods Order No. 69 - General Requirements for Labels for Medicines 2017* (TGO 69 (2017)), which commenced on 1 July 2017;
- remove from the scope of the original Order medicines that are not required to be entered in the Australian Register of Therapeutic Goods (the Register) because they are authorised for supply by way of health practitioner notifications under subsection 19(7A) of the Act (introduced recently by the *Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017*); and
- make minor editorial changes to Schedule 1 to the original Order, to clarify or correct a small number of matters.

This Order commenced on the day after registration in the Federal Register of Legislation.

Similar amendments have concurrently been made to *Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines* (TGO 92), made on 2 August 2016, by the

*Therapeutic Goods Order No. 92A- Therapeutic Goods Order No. 92 (Standard for labels of non-prescription medicines) Amendment Order 2017.*

The new labelling Orders, TGO 91 and TGO 92, are intended to replace TGO 69/now TGO 69 (2017) at the end of the transition period (1 September 2020) that was provided for when those new instruments commenced. During the transition period, sponsors can choose between complying with either the requirements of TGO69/now TGO 69 (2017), or TGOs 91 or 92, as relevant to their medicine.

## **BACKGROUND**

Standards made under section 10 of the Act may relate to any matter relevant to the quality, safety or efficacy of a medicine, and generally, a medicine must not be imported, exported or supplied if it does not conform to an applicable standard. Paragraph (c) of subsection 10(2) of the Act states that an Order establishing a standard for therapeutic goods may require that therapeutic goods, or a class of therapeutic goods identified in the Order, be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the Order.

TGO 91 mandates information that must be on labels of prescription and related medicines and the format and placement in which it must be presented, to contribute to the quality use of medicines by Australian consumers and healthcare professionals. Examples of information required by TGO 91 include the name of the medicine, the name of the active ingredient and its strength or quantity, storage requirements, expiry date and the declaration of certain inert or inactive substances in the medicine.

The changes made to TGO 91 by this Order:

- correctly reflect the name of the re-made TGO 69 (2017), which replaces the previous TGO 69, as well as including necessary consequential amendments;
- provide that medicines not required to be included in the Register before their lawful supply under the health practitioner notification arrangement under subsection 19(7A) of the Act (introduced recently by the *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017*) are not required to comply with this Order;
- provide a note in Schedule 1 to the Order to exclude glycerol from the entry for sugar alcohols;
- amend the entry for ‘sorbates’ in Schedule 1 to the Order to clarify its intent;
- correctly state the entries for sodium and potassium in Schedule 1 to the Order, ensuring that they align with relevant entries in Schedule 1 to TGO 92; and
- clarify the introductory text in Schedule 1 to the Order to confirm that multiple substance declarations can be made within the same sentence, aligning with similar provisions in the Poisons Standard.

## **CONSULTATION**

The Therapeutic Goods Committee (TGC) has been consulted in regard to proposed changes to Schedule 1 to the Order, under the provisions of subsection 10(4) of the Act. The TGC was established under regulation 34 of the Therapeutic Goods Regulations 1990 to provide advice and to make recommendations to the Minister on matters such as the adoption of standards for therapeutic goods and matters relating to the requirements for labelling and packaging of therapeutic goods. This committee has now been disbanded.

In June 2017, targeted consultation was undertaken with the major industry sponsors that would supply unapproved therapeutic goods authorised for supply by health practitioner notification under subsection 19(7A) of the Act. In that consultation, in which the top 20 manufacturers and suppliers of unapproved goods via the Special Access Scheme and the relevant peak industry bodies were consulted, sponsors were made aware that Therapeutic Goods Orders Nos. 69, 91 and 92 will be amended to exempt goods supplied under subsection 19(7A) of the Act (the new Category C pathway) from the labelling requirements.

## **REGULATION IMPACT**

These amendments to TGO 91 and 92 are part of the implementation of TGO 91 and TGO 92 and are covered in the regulation impact statement (RIS): General requirements for labels for medicines (OBPR ID: 20860). The RIS was assessed by Office of Best Practice Regulation (OBPR) as compliant with the Government's RIS requirements and the RIS is consistent with best practice. Given the expected magnitude of the impacts of the proposal, the OBPR considered the level of analysis in the RIS is consistent with best practice. The average annual regulatory cost associated with the RIS is \$1.1 million. The OBPR agreed to the regulatory cost and offset estimates.

This Order is a legislative instrument for the purposes of the *Legislation Act 2003*.

In relation to compatibility with human rights, it is considered that this Order is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*, and a Statement of Compatibility setting that out in further detail is below.

## **SUPPLEMENTARY MATERIAL - STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS FOR A LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES**

### **Statement of Compatibility with Human Rights**

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

### **Therapeutic Goods Order No. 91A – Therapeutic Goods Order No. 91 (Standard for labels of prescription and related medicines) Amendment Order 2017**

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

### **Overview of the Legislative Instrument**

*Therapeutic Goods Order No. 91A – Therapeutic Goods Order No. 91 (Standard for labels of prescription and related medicines -Amendment Order 2017* (this Order) amends *Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines* (the original Order). The original Order was made on 2 August 2016 (Register ID: F2016L01285) by the delegate of the then Minister for Health and Aged Care under section 10 of the *Therapeutic Goods Act 1989* (the Act). The original Order commenced on 31 August 2016.

The amendments to the original Order are minor but are necessary to:

- correctly reference the recently re-made *Therapeutic Goods Order No. 69 - General Requirements for Labels for Medicines* by its new name, *Therapeutic Goods Order No.69- General Requirements for Labels for Medicines 2017*, and include appropriate consequential amendments;
- remove from the scope of the original Order medicines that are not required to be entered in the Australian Register of Therapeutic Goods because they are authorised for supply by way of health practitioner notifications under subsection 19(7A) of the Act (introduced recently by the *Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017*);
- provide a note in Schedule 1 to the Order to exclude glycerol from the entry for sugar alcohols;
- amend the entry for ‘sorbates’ in Schedule 1 to the Order to clarify its intent;
- correctly state the entries for sodium and potassium in Schedule 1 to the Order, ensuring that they align with relevant entries in Schedule 1 to TGO 92; and
- clarify the introductory text in Schedule 1 to the Order to confirm that multiple substance declarations can be made within the same sentence, aligning with similar provisions in the Poisons Standard.

This Order commenced on the day after registration in the Federal Register of Legislation.

**Human rights implications**

This legislative instrument does not engage any of the applicable rights or freedoms.

**Conclusion**

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

**Jane Cook, delegate of the Minister for Health**