

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Order No. 91B - Therapeutic Goods Order No. 91 (Standard for labels of prescription and related medicines) Amendment Order 2018

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 subsection 10(1) 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. Under subsection 10(2), an order establishing a standard for therapeutic goods may require, *inter alia*, that therapeutic goods or a class of therapeutic goods identified in the order be labelled or packaged in a manner specified in the order. Subsection 10(3A) of the Act makes it clear that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1).

Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines (TGO 91), which commenced on 31 August 2016, sets out a range of requirements relating to the kinds of information to be included on the labels and packaging of mostly prescription medicines, in order to support the quality use of medicines in relation to enabling health practitioners and patients to select health management options wisely, be aware of key information about medicines such as their contents, potency and storage requirements, and to be in a position to use such medicines safely and effectively.

Therapeutic Goods Order No. 91B - Therapeutic Goods Order No. 91 (Standard for labels of prescription and related medicines) Amendment Order 2018 (this Order) amends TGO 91, principally to:

- introduce new mandatory warning statements on the labels of medicines that contain neuromuscular blocking agents; and
- make minor editorial amendments, including corrections to requirements for composite packs in subsection 9(8) of TGO 91.

This Order commenced on 2 July 2018.

TGO 91 is intended to replace *Therapeutic Goods Order No. 69 – General Requirements for Labels for Medicines 2017* (TGO 69, Register ID: F2017L00865) at the end of the transition period (1 September 2020) that was provided when TGO 91 commenced. During the transition period, sponsors of medicines to which these two instruments apply are able to elect to choose between complying with the requirements of either TGO 69 or TGO 91. This

Order only amends TGO 91, not TGO 69, therefore providing a 26 month transition period for these new requirements relating to medicines containing neuromuscular blocking agents.

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.

AMENDMENTS

The changes made to TGO 91 by this Order:

- introduce a definition of ‘neuromuscular blocking agent’ in section 6 of TGO 91;
- introduce requirements for neuromuscular blocking agent-containing medicines to include the warning statement ‘Warning: Paralysing agent’ on the labels of the medicine container and primary pack;
- introduce specific requirements for very small containers and small plastic ampoules which may include a shortened warning statement on the container label due to space limitations;
- introduce specific colours for the warning statement. The specified colours are consistent with the colours for neuromuscular blocking agents in the National Standard for User-Applied Labelling of Injectable Medicines, Fluids and Lines (www.safetyandquality.gov.au/publications/national-standard-for-user-applied-labelling/) published by the Australian Commission on Safety and Quality in Health Care. The specific colour identifiers are available free of charge, in the referenced document and on the TGA website (www.tga.gov.au). Plastic ampoule labels do not require specific colours for the warning statement due to manufacturing limitations;
- introduce Schedule 3 to identify ingredients that are neuromuscular blocking agents. This list is based on the classification of ingredients as ‘muscle relaxants, peripherally acting agents’ in the World Health Organization Anatomical Therapeutic Chemical classification system (www.whocc.no/atc_ddd_index), except that botulinum toxin is not considered a neuromuscular blocking agent for the purposes of this Order; and
- make minor editorial amendments, including amendment to subsection 9(8) of TGO 91 to correct typographical errors and to align with the requirements for similar medicines subject to *Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines* (Register ID: F2017C00744).

Neuromuscular blocking agents are used to cause paralysis during anaesthesia. Medicine administration errors involving neuromuscular blocking agents present significant risk to patient safety due to potential for unintended paralysis, respiratory arrest, severe permanent harm (including physical and psychological harm) or even death. Most reported administration errors involving neuromuscular blocking agents in Australia are caused by look-alike selection errors, i.e. where two medicines are similar in appearance resulting in the wrong medicine being chosen and administered.

The new requirements will help reduce administration errors by introducing a visually distinct warning statement on the labels of neuromuscular blocking agent-containing medicines. These measures will improve patient safety.

The modified requirements for neuromuscular blocking agents in very small containers and small plastic ampoules were introduced due to label space or manufacturing limitations which may prevent current medicine sponsors from complying with the new requirements. Unduly onerous labelling requirements may threaten supply of these essential medications to the Australian market.

CONSULTATION

The TGA has collaborated with anaesthetists, healthcare groups (including the Australian and New Zealand College of Anaesthetists (ANZCA), Victorian and New South Wales Therapeutic Advisory Groups (VicTAG, NSWTAG), the Australian Commission on Safety and Quality in Health Care (ACSQHC) and the Society of Hospital Pharmacists Australia (SHPA)) and medicine sponsors to investigate possible strategies to minimise administration errors of neuromuscular blocking agent-containing medicines. This included a round table meeting, targeted consultation with all parties and a targeted costings survey of medicine sponsors on the proposed changes. This consultation occurred between November 2017 and May 2018.

Consumer groups have not been consulted because these medicines are generally not visible to consumers, but are only available in hospitals for administration by medical professionals.

The two year transition period for these changes has begun and will end on 1 September 2020. After this time, all neuromuscular blocking agent-containing medicine labels must include the new requirements. Medicine sponsors are aware of this transition period.

REGULATION IMPACT

A Regulation Impact Statement is not required for these new requirements (OBPR reference 23719).

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.

Statement of Compatibility with Human Rights

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

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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. 91 - Standard for labels of prescription and related medicines (TGO 91, Register ID: F2017C00743) commenced on 31 August 2016. It was made by the delegate of the then Minister for Health under section 10 of the Act. *Therapeutic Goods Order No. 91B - Therapeutic Goods Order No. 91 (Standard for labels of prescription and related medicines) Amendment Order 2018* (this Order) amends TGO 91.

Changes made by this Order:

- introduce a definition of ‘neuromuscular blocking agent’ in section 6 of TGO 91;
- introduce requirements for neuromuscular blocking agent-containing medicines to include the warning statement ‘Warning: Paralysing agent’ on the labels of the medicine container and primary pack;
- introduce specific requirements for very small containers and small plastic ampoules which may include a shortened warning statement on the container label due to space limitations;
- introduce specific colours for the warning statement. Plastic ampoule labels do not require specific colours for the warning statement due to manufacturing limitations;
- introduce Schedule 3 to identify ingredients that are neuromuscular blocking agents. This list is, generally, based on the classification of ingredients as ‘muscle relaxants, peripherally acting agents’ in the World Health Organization Anatomical Therapeutic Chemical (www.whocc.no/atc_ddd_index) classification system; and
- make minor editorial amendments.

Neuromuscular blocking agents are medicines used to cause paralysis during anaesthesia. Medicine administration errors involving neuromuscular blocking agents present significant risk to patient safety due to potential for unintended paralysis, respiratory arrest, severe permanent harm (including physical and psychological harm) or even death. Most reported administration errors involving neuromuscular blocking agents in Australia are caused by look-alike selection errors, i.e. where two medicines are similar in appearance resulting in the wrong medicine being chosen and administered.

The new requirements will help reduce administration errors by introducing a visually distinct warning statement on the labels of neuromuscular blocking agent-containing medicines. These measures will improve patient safety.

This Order commenced on 2 July 2018.

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.

Larry Kelly, delegate of the Minister for Health