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| **Therapeutic Goods Order No. 70C (TGO70C) – Standards for Export Only Medicine** **Stakeholder consultation for sunsetting instrument**  |
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## Summary

Part 4 of Chapter 3 of the *Legislation Act 2003* (<https://www.legislation.gov.au/C2004A01224/latest/text>) sets out the sunsetting regime for legislative instruments. Generally, legislative instruments sunset (that is, automatically repeal), 10 years after they are registered on the Federal Register of Legislation. Sunsetting provides a unique opportunity for the Government to reduce red tape, deliver clearer laws and align existing legislation with current government policy. Its purpose is to ensure that legislative instruments are kept up-to-date and only remain in force for as long as they are needed.

Therapeutic Goods Order No. TGO 70C (TGO 70C) – Standards for Export Only Medicine (<https://www.legislation.gov.au/F2014L00683/asmade/text>) is a relevant standard for therapeutic goods which are listed for export only in the Australian Register of Therapeutic Goods (ARTG). TGO 70C is due to sunset on 1 October 2024. The Therapeutic Goods Administration (TGA) Export Unit as part of the Prescription Medicines Authorisation Branch (PMAB) is reviewing the sunsetting TGO with the intention to replace this with a new instrument (i.e. a new TGO) with a number of minor amendments/changes which aim to expand options and increase flexibility for industry whilst safeguarding product safety and quality prior to export.

**The TGA proposes to replace the sunsetting TGO with a new instrument that will contain the following minor amendments:**

* **Reference to current standards (pharmacopoeia);**
* **Minor formatting and clarification of existing requirements.**

It is expected that the impact of replacing the current TGO with a new instrument that is current and clearly sets out the requirements for export only medicines, will be positive and welcomed by sponsors and industry. The likely impacts include: a clearer understanding for sponsors of the standards that can be used to facilitate the listing of an export only medicine in the ARTG; in addition to a more fit-for-purpose TGO which keeps pace with medical advancements and drug discovery, whilst ensuring product quality and safety is balanced with minimally required regulatory burden.

### Background

**Regulation of export only medicines**

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods for use in humans. Therapeutic goods imported into, supplied in or exported from Australia must comply with applicable standards. Section 10 of the Act authorises the Minister, or the Minister’s delegate, to determine standards for therapeutic goods, or to amend or revoke existing standards.

The TGA’s role in regulating export only medicines is designed to ensure that medicines exported from Australia meet appropriate safety and quality standards in order to support global health. Simultaneously, the regulation encourages the application of flexibility to export only medicines in meeting alternate standards via the provision of TGO 70C, TGO 70C is specifically designed to ensure that appropriate benchmarks apply to export only medicines. This is complemented by provisions in other TGA standards to expressly carve out export only medicines from their scope.

**History of the standards for export only medicines**

Export only medicines are listed in the ARTG, and are not permitted for supply in Australia. TGO 70B, which was revoked and replaced by TGO 70C, specified that specific editions of international pharmacopoeia, being the British Pharmacopoeia (BP), the United States Pharmacopoeia (USP), the European Pharmacopoeia (EP) and the Japanese Pharmacopoeia (JP) constitute alternative standards for export only medicines.

A pharmacopoeia is a comprehensive compilation of information regarding the preparation of medicines and characterisation of their ingredients by suitable monographs. A monograph contained in a pharmacopoeia may be adopted as a standard by a health authority. Pharmacopoeias are published by the authority of a government or a medical/pharmaceutical society.

At the time of the making of TGO 70B in February 2007, the BP was the only pharmacopoeia recognised in the Act as being the standard to which therapeutic goods for use in humans were required to conform if there was no Order in place under section 10. The definition of the BP included in the Act at that time only included updates to that pharmacopoeia that were specified by the Minister in an order published in the *Gazette*.

In 2009, a number of amendments were made to the Act by the *Therapeutic Goods* *(Medical Devices and Other Measures) Act 2009* in relation to standards, with the effect being that the USP and the EP were added as additional ‘default standards’. Definitions for each of these pharmacopoeia were introduced to the Act, and a new definition for the BP was also added (subsection 3(1) of the Act refers). These new definitions included any additions and amendments made to the pharmacopoeia by the bodies responsible for their publication, from the effective date of such changes (i.e. without the need for the Minister to gazette updates).

To reflect these developments, updates in 2009 to TG0 70C principally replaced the references to specific editions of each of the BP, EP and USP in TGO 70B with references to those pharmacopoeia as they are defined in subsection 3(1) of the Act. TGO 70C also updated the reference to the edition of the JP mentioned in TGO 70B, from the 14th edition to the 16th edition, to reflect updates to that document since 2007 and because the Japanese Pharmacopoeia has not been added to the Act as a default standard.

The existing TGO 70C references the current versions of the BP, USP and EP (as each are defined in subsection 3(1) of the Act) and JP (16th edition including English language translation of Supplement 1 of April 2013 and partial revision of Supplement 1 of May 2013).

#### Proposed changes

**Reference to current standards (pharmacopoeia)**

The proposed remake of the TGO will not include references to specific editions of the standards (pharmacopoeia). The new TGO will instead refer to current editions of standards that are applied within industry internationally.

By including current standards in the new TGO, sponsors will be able to use global product specifications for applications for export only listings, which is likely to reduce regulatory burden and improve alignment with requirements of international regulators. These changes also ensure that products exported from Australia are compliant with current internationally accepted quality and safety requirements.

Referencing current standards will also ensure that the TGA will align with comparable international jurisdictions and regulators, which is consistent with the TGA’s strategic policy aim of harmonisation of regulatory requirements.

**Formatting changes**

The TGA will make formatting changes to the TGO which will not affect the meaning, requirements, or operation of the current TGO. Proposed formatting changes will clarify that sponsors must comply with both the relevant current pharmacopeia ***and*** any requirements of the importing country.

#### Stakeholder impact, discussion and feedback

Export only medicines cover a wide range of medicines such as prescription medicines, complementary medicines, medicinal cannabis, over-the-counter medicines, and cosmetic type medicines such as sunscreens. Consequently, exporters of medicines from Australia range from small start-up companies to large multinational pharmaceutical companies. It is anticipated that businesses (as a whole or in part) that focus on exporting medicines from Australia will be impacted by the proposed minor amendments within the new TGO. The new TGO will affect all sponsors of new (and existing should the sponsor wish to make manufacturing/formulation/product specification changes) export only medicine as well as numerous industry peak body organisations, which include but are not limited to: Complementary Medicines Australia (CMA), Consumer Healthcare Products Association (CHPA), Medicines Australia (MA), Generic and Biosimilar Medicines Association (GBMA), Accord, Medicinal Cannabis Industry Association (MCIA) and manufacturers.

The TGA Export Unit seeks to understand the nature of the impact of the proposed changes to TGO70C on industry, specifically:

* ***Do you agree that the references to specific editions of a standard or pharmacopoeia should be removed? YES/NO/COMMENTS OR N/A***
* ***Do you agree with formatting changes in order to provide clarity on the requirements of the TGO? YES/NO/COMMENTS OR N/A***
* ***If there are any further proposed changes that should be considered for implementation into the new TGO70C? YES/NO/COMMENTS OR N/A***

The TGA Export Unit welcomes any type of feedback from all impacted stakeholders including but not limited to sponsors, manufacturers and peak industry organisations. Please provide all feedback to tga.exports@health.gov.au.

Version history

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| Version | Description of change | Author | Effective date |
| V1.0 | Original publication | Application Entry Support and Export Section | May 2024 |

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