Therapeutic Goods (Standard for Export Only Medicines) (TGO 114) Order 2024

I, Nicholas Henderson, as delegate of the Minister for Health and Aged Care, make the following order.

Dated 25 September 2024

Nicholas Henderson
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

Authorised Version F2024L01211 registered 25/09/2024

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1 Name

(1) This instrument is the *Therapeutic Goods (Standard for Export Only Medicines) (TGO 114) Order 2024*.

(2) This instrument may also be cited as TGO 114.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	30 September 2024.	30 September 2024

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 10 of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) British Pharmacopoeia;
(b) European Pharmacopoeia;
(c) export only medicine;
(d) standard;
(e) United States Pharmacopoeia-National Formulary.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

Japanese Pharmacopoeia means the English edition of the publication of that name, published by the Japanese Pharmaceuticals and Medical Devices Agency or any replacement body, as in force or existing from time to time.

5 Standard

The matters specified in this instrument constitute a standard for export only medicines.

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6 Application

(1) This instrument applies to export only medicines.

(2) For the avoidance of doubt, and subject to section 13 of the Act, this instrument applies in addition to any other instruments made under section 10 of the Act that apply to export only medicines.

7 Requirements

An export only medicine must:

(a) comply with the requirements specified in the applicable individual, specific and general monographs in at least one of the following pharmacopoeia, as interpreted in accordance with the General Notices section of the relevant pharmacopoeia:

(i) the British Pharmacopoeia;

(ii) the European Pharmacopoeia;

(iii) the Japanese Pharmacopoeia;

(iv) the United States Pharmacopoeia-National Formulary; and

(b) where the export only medicine is not regulated as a medicine in the country to which it is to be exported—meet the regulatory requirements of the country to which it is to be exported.

8 Repeals

Each instrument that is specified in Schedule 1 is repealed as set out in the applicable items in that Schedule.

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Schedule 1—Repeals

Therapeutic Goods Order No. 70C – Standards for Export Only Medicine

1 The whole of the instrument

Repeal the instrument.

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