EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

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

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act is administered by the Therapeutic Goods Administration ("the TGA") within the Australian Government Department of Health and Aged Care.

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Subsection 10(2) provides that an order establishing a standard for therapeutic goods may be specified by reference to the quality of the goods, or the procedures to be carried out in the manufacture of the good, among other things. Relevantly subparagraphs 10(2)(a)(iv) and (v) provide that an order establishing a standard for therapeutic goods may be specified by reference to a monograph in the British Pharmacopoeia, the European Pharmacopoeia, or the United States Pharmacopoeia-National Formulary, or a monograph in another publication approved by the Minister for the purposes of subsection 10(2). Under subsection 10(3A) of the Act, the Minister may vary or revoke an order made under subsection 10(1) by legislative instrument.

Importantly, a person who imports, exports or supplies therapeutic goods that do not conform to an applicable standard may be subject to offence and civil penalty provisions in sections 14 and 14A of the Act. The Secretary may, however, give consent in writing in relation to the importation, exportation or supply of therapeutic goods that do not conform to an applicable standard, in accordance with those sections.

The *Therapeutic Goods (Standard for Export Only Medicines) (TGO 114) Order 2024* ("the Order") is made under section 10 of the Act for the purpose of establishing a ministerial standard for export only medicine. In particular, the Order specifies requirements by reference to the individual, specific and general monographs applicable to the export only medicine in the British Pharmacopoeia, the European Pharmacopoeia, the Japanese Pharmacopoeia, or the United States Pharmacopoeia-National Formulary. The Order repeals and replaces the *Therapeutic Goods Order No. 70C – Standard for Export Only Medicine* ("the former Order"), which would otherwise sunset on 1 October 2024.

Background

The Australian Government is responsible for regulating the quality, safety and efficacy or performance of therapeutic goods. This is achieved in part by specifying ministerial standards under section 10 of the Act by reference to a range of matters, including the manufacture of therapeutic goods, and by otherwise applying default standards that are constituted by statements in international pharmacopoeias defined in subsection 3(1) of the Act, being the British Pharmacopoeia, European Pharmacopoeia and United States Pharmacopeia-National Formulary.

The former Order is made under section 10 of the Act and specifies minimum requirements that export only medicines must comply with. Export only medicines are medicines that are imported into, or manufactured in, Australia solely for export.

The former Order provides that export only medicines must comply with any of the British Pharmacopoeia, European Pharmacopoeia, United-States Pharmacopoeia ("the default standards"), or the 16th edition of the Japanese Pharmacopoeia. Additionally, the Former Order specifies that where a

medicine is regulated other than as a medicine in the country to which it is to be exported, it must also meet the regulatory requirements of that country for such products. Also, specifically in relation to compliance with the Japanese Pharmacopoeia, the exporter of an export only medicine that is regulated as a medicine in the country to which it is to be exported must also hold evidence that a relevant authority of the country to which the medicine is to be exported has confirmed its willingness to accept medicine which complies with the former Order or confirmed that it would have no objection to accepting such medicine.

Purpose

The former Order is due to sunset on 1 October 2024. The Order replaces the former Order and makes a number of changes to update the instrument, however without substantively changing the effect of the instrument. The purpose of the Order is to establish a standard for export only medicines to support the continued application of appropriate standards to such medicines, given the former Order is due to sunset.

The Order provides that an export only medicine must comply with the requirements specified in the applicable individual, specific and general monographs in at least one of the British Pharmacopoeia, European Pharmacopoeia, United-States Pharmacopoeia, or Japanese Pharmacopoeia, as interpreted in accordance with the General Notices section of the relevant pharmacopoeia. This provides an option for an export only medicine to comply with the current Japanese Pharmacopoeia instead of one of the default standards. This requirement to comply with either the default standards or the Japanese Pharmacopoeia, being inconsistent with the requirement in the Act for compliance with the default standards, applies to the exclusion of the requirement in the Act to comply with the default standards (section 13(2) of the Act refers). Therefore, if an export only medicine complies with the Japanese Pharmacopoeia, it does not also need to comply with the default standards under the Act.

The former Order incorporated the Japanese Pharmacopoeia by reference to the 16th edition of the pharmacopoeia, which has since been updated. The Order, however, incorporates the Japanese Pharmacopoeia as in force from time to time, in accordance with section 10(4) of the Act, so the Order remains up-to-date and does not require industry to comply with outdated requirements.

The Order also contains a specific requirement for export only medicines that are not regulated as a medicine in the country to which the medicine is to be exported. Such export only medicines must meet the regulatory requirements of the country to which they are to be exported. This is the same requirement that is in the former Order.

The Order does not include the requirement that the exporter hold evidence that a relevant authority of the country to which the medicine is to be exported has confirmed its willingness to accept medicine which complies with the former Order or confirmed that it would have no objection to accepting such medicine, as this requirement is a duplicate of a similar requirement in section 26 of the Act under which export only medicines are listed in the Australia Register of Therapeutic Goods.

Incorporation by reference

Subsection 10(4) of the Act relevantly provides that, despite subsection 14(2) of the *Legislation Act 2003* ("the Legislation Act"), an order (or a variation of an order) under this provision may make provision in relation to a matter by applying, adopting or incorporation, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

The Order incorporates by reference the British Pharmacopoeia, the European Pharmacopoeia, the Japanese Pharmacopoeia, and the United States Pharmacopoeia-National Formulary.

The British Pharmacopoeia, the European Pharmacopoeia and the United States Pharmacopoeia-National Formulary are default standards for the purpose of the Act. The note in section 4 of the Order

makes it clear that each pharmacopoeia is incorporated as defined in subsection 3(1) of the Act, which is effectively as in force or existing from time to time. The definition of Japanese Pharmacopoeia in section 4 of the Order makes it clear that it is also incorporated as in force from time to time.

These pharmacopoeias may be accessed from www.pharmacopoeia.com/, pheur.edqm.eu/home, www.pmda.go.jp/english/ and www.uspnf.com/.

The Japanese Pharmacopoeia is available for free. While unfortunately the British Pharmacopoeia, European Pharmacopoeia and United States Pharmacopoeia-National Formulary are not available for free, it is anticipated that the persons most affected by their adoption in this Order (sponsors of export only medicines), would be in possession of these documents in order to manufacture the medicine or ingredients. As important international benchmarks for the safety and quality of export only medicines, it would be infeasible from a regulatory perspective to not adopt such benchmarks on the basis that the publications are not available for free.

However, by prior written arrangement with the TGA, members of the public may request to view the pharmacopoeias without charge at the TGA office in Fairbairn, ACT.

It should also be noted that the National Library's Trove online system (www.trove.nla.gov.au) allows users to identify libraries in Australia that are open to the public where editions (in most cases, earlier editions) of the pharmacopoeias may be viewed (for example, the University of Tasmania or the University of Western Australia in relation to the British Pharmacopoeia). Members of the public may also approach any library that participates in inter-library loans with those university libraries to request an inter-library loan, or to obtain a photocopy of a particular part of a monograph for personal study or research (but not for commercial purposes). Fees apply in relation to the making of such a request. Enquiries should be made with local libraries, state libraries or the National Library.

Consultation

The Office of Information Analysis advised that the TGA is able to self-assess and certify that the former Order is operating efficiently and effectively with minor amendment in lieu of an Impact Analysis (OIA24-07033). The certification letter will be published on the Office of Impact Analysis website.

Between 15 July and 26 August 2024, the TGA undertook a public consultation on the proposal to replace the sunsetting Former Order. The TGA only received 4 responses (three from peak bodies, and one from a manufacturer), all of which stated their support for the making of the Order in the same terms as the former Order.

Details of the Order are set out in **Attachment A**.

The Order is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Order is a disallowable legislative instrument for the purposes of the Legislation Act and commences on 30 September 2024.

Attachment A

Details of the *Therapeutic Goods (Standard for Export Only Medicines) (TGO 114) Order 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Standard for Export Only Medicines) (TGO 114) Order 2024* ("the Order"), and that the Order may also be cited as TGO 114.

Section 2 – Commencement

This section provides that the Order commences on 30 September 2024.

Section 3 – Authority

This section provides that the legislative authority for making the Order is section 10 of the *Therapeutic Goods Act 1989* ("the Act").

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Under subsection 10(3A) of the Act, the Minister may vary or revoke an order made under subsection 10(1) by legislative instrument.

Section 4 – Definitions

This section provides the definitions of key terms used in the Order, being 'Act' and 'Japanese Pharmacopoeia'. This section also notes that some expressions used in the Order, including 'British Pharmacopoeia', 'European Pharmacopoeia', 'export only medicine', 'standard' and 'United States Pharmacopoeia-National Formulary', have the same meaning as in the Act.

Section 5 – Standard

This section provides that matters specified in the Order constitute a standard for export only medicines.

Section 6 – Application

This section provides that the Order applies to export only medicines. This section also confirms that the Order applies in addition to any other instrument made under section 10 of the Act that applies to export only medicines.

Section 7 – Requirements

This section provides that the requirements for an export only medicine are:

(a) the requirements that are specified in individual, specific and general monographs applicable to the export only medicine, in at least one of either the British Pharmacopoeia, the European Pharmacopoeia, the Japanese Pharmacopoeia, or the United States Pharmacopoeia-National Formulary, as interpreted in accordance with the General Notices section of the relevant pharmacopoeia; and

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

The first requirement gives sponsors the option to comply with either one of the default standards or the Japanese Pharmacopoeia. Export only medicines must comply with all the monographs that are applicable to the goods, whether they are individual, specific or general monographs. However, the goods only need to comply with the applicable monographs in one of the pharmacopoeia, not all of the pharmacopoeia.

The second requirement, where the goods are not a medicine in the country to which it is to be exported ("the receiving country"), is that the goods must meet the regulatory requirements of the receiving country. For example, if the goods are considered a food in the receiving country, not a medicine, the goods must meet the applicable requirements for the regulation of food in that country. In addition, if import requirements apply to the goods, the goods must meet those requirements.

Section 8 – Repeals

This section provides that each instrument in Schedule 1 to the Order is repealed as set out in the applicable items in that Schedule.

Schedule 1 – Repeals

This Schedule provides that the *Therapeutic Goods Order No. 70C Standards for Export Only Medicine* is repealed. This instrument was, otherwise, due to sunset on 1 October 2024.

Attachment B

Statement of Compatibility with Human Rights

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

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

This disallowable 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 legislative instrument

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Subsection 10(2) provides that an order establishing a standard for therapeutic goods may be specified by reference to the quality of the goods, or the procedures to be carried out in the manufacture of the good, among other things. Relevantly subparagraphs 10(2)(a)(iv) and (v) provide that an order establishing a standard for therapeutic goods may be specified by reference to a monograph in the British Pharmacopoeia, the European Pharmacopoeia, or the United States Pharmacopoeia-National Formulary, or a monograph in another publication approved by the Minister for the purposes of subsection 10(2). Under subsection 10(3A) of the Act, the Minister may vary or revoke an order made under subsection 10(1) by legislative instrument.

Importantly, a person who imports, exports or supplies therapeutic goods that do not conform to an applicable standard may be subject to offence and civil penalty provisions in sections 14 and 14A of the Act. The Secretary may, however, give consent in writing in relation to the importation, exportation or supply of therapeutic goods that do not conform to an applicable standard, in accordance with those sections.

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Background

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Purpose

The former Order is due to sunset on 1 October 2024. The Order replaces the former Order and makes a number of changes to update the instrument, however without substantively changing the effect of the instrument. The purpose of the Order is to establish a standard for export only medicines to support the continued application of minimum standards to such medicines, given the former Order is due to sunset.

The Order provide that an export only medicine must comply with the requirements specified in the applicable individual, specific and general monographs in at least one of the British Pharmacopoeia, European Pharmacopoeia, United-States Pharmacopoeia, or Japanese Pharmacopoeia, as interpreted in accordance with the General Notices section of the relevant pharmacopoeia. This effectively provides an option for an export only medicine to comply with the Japanese Pharmacopoeia instead of one of the default standards. This requirement to comply with either the default standards or the Japanese Pharmacopoeia, being inconsistent with the requirement in the Act for compliance with the default standards, applies to the exclusion of the requirement in the Act to comply with the default standards (section 13(2) of the Act refers). Therefore, if an export only medicine complies with the Japanese Pharmacopoeia, it does not also need to comply with the default standards under the Act.

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The Order also contains a specific requirement for export only medicines that are not regulated as a medicine in the country to which the medicine is to be exported. Such export only medicines must meet the regulatory requirements of the country to which they are to be exported. This is the same requirement that is in the former Order.

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Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights ("the ICESCR"). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health.

In *General Comment No.14: The Right to the Highest Attainable Standard of Health (Art.12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a

‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The instrument takes positive steps to promote the right to health by ensuring the safety, quality and efficacy of export only medicines. The Order does this by continuing to require that these medicines meet the requirements in one of the specified pharmacopoeia, being the British Pharmacopoeia, the European Pharmacopoeia, the Japanese Pharmacopoeia, or the United States Pharmacopoeia-National Formulary. These documents are comprehensive compilations of information about the preparation of medicines and characterisation of their ingredients.

The application of a minimum standard for export only medicines is important to ensure that export only medicines meet minimum benchmarks, particularly as such medicines are listed in the Australian Register of Therapeutic Goods and do not undergo a full pre-market assessment for quality, safety and efficacy.

Conclusion

The order is compatible with human rights because it maintains and supports the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.