

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Foreign Countries) Determination 2016

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 Act is administered by the Therapeutic Goods Administration (the TGA) within the Department of Health.

Subsection 19A(1) of the Act relevantly provides that the Secretary may, in circumstances described in the subsection, approve the importation or supply of therapeutic goods that are not on the Australian Register of Therapeutic Goods (ARTG) for a specified period if the approval is necessary in the interests of public health.

The circumstances include the requirement that the Secretary must be satisfied that registered therapeutic goods, which could act as substitutes for the specified therapeutic goods, are unavailable or are in short supply. The Secretary must also be satisfied that the specified therapeutic goods are registered or approved for general marketing in at least one foreign country specified by the Secretary in a determination under subsection 19A(3), or are the subject of an application for registration on the ARTG under section 23 of the Act.

In addition, the Secretary must be satisfied that the specified therapeutic goods are of a kind that are included in Schedule 10 to the *Therapeutic Goods Regulations 1989* (which includes prescription medicines) or are specified in a determination under subsection 19A(4) of the Act.

The *Therapeutic Goods (Foreign Countries) Determination 2016* (the Determination) is made under subsection 19A(3) of the Act. The Determination specifies the foreign countries in which registration or approval for general marketing of the specified therapeutic goods is required for the purposes of subparagraph 19A(1)(b)(i). This measure is intended to support continuity of access to therapeutic goods critical for patient care and well-being when there is a shortage of registered therapeutic goods in Australia.

The Determination is a disallowable legislative instrument and commences on the day after it is registered on the Federal Register of Legislation. It repeals two former subsection 19A(3) determinations identified in Schedule 1 to the Determination. These determinations are dated 26 August 1997 (the first determination) and 5 May 2004 (the second determination). Both determinations were due to have been automatically repealed, in accordance with the sunset provisions of the *Legislation Act 2003*, on 1 October 2017.

The second determination has been remade in this Determination without any material change to its content. The nine countries specified in the second determination continue to be specified under this Determination. These are Canada, France, Germany, New Zealand, Sweden, Switzerland, The Netherlands, United Kingdom and United States of America.

The first determination is repealed on the basis that the country specified in that determination, France, is also specified in this Determination and thus has no need to be remade. Its repeal does not alter government policy or have any regulatory impact on business. There is no reason for it to be allowed to remain in force until 1 October 2017.

Any approval extant at the time the former determinations are repealed, and given under subsection 19A(1) on the basis that the specified therapeutic goods are registered or approved for general marketing in one of those nine countries, will continue to have effect in accordance with its terms provided those goods continue to be registered or approved for general marketing in at least one of the countries specified in the Determination.

BACKGROUND

Under the Act, it is an offence for therapeutic goods be imported into, exported from, manufactured in, or supplied in Australia, unless the goods are included in the ARTG, exempt from inclusion in the ARTG, or otherwise subject to an approval or authority by the Secretary.

Subsection 19A(1) of the Act provides a mechanism to approve the importation or supply of unregistered therapeutic goods, if all comparable registered goods which could act as substitutes are unavailable or are in short supply and the approval is necessary in the interests of public health. If the specified therapeutic goods are not the subject of an application for registration under section 23 of the Act, the goods must be registered or approved for general marketing in at least one of the foreign countries specified by the Secretary in a determination under subsection 19A(3).

The foreign countries specified in the Determination are those that the Secretary has historically regarded, and continues to regard, as demonstrating comparable regulatory standards of assessment for quality, safety and efficacy of therapeutic goods (medicines, in particular). These countries maintain reliable regulatory systems, within which the registration or approval of specified therapeutic goods is considered to be comparable to the registration of therapeutic goods in Australia.

Therapeutic goods in relation to which an approval is granted under subsection 19A(1) of the Act are exempt from inclusion in the ARTG, and can therefore be imported, supplied and used for treatment in Australia, in accordance with any conditions specified in the relevant notice. Approvals may be granted by the Secretary for such period as is specified in the notice, consistent with the period of time necessary to cover the unavailability or shortage of the registered therapeutic goods. The lapsing of an approval on the expiry of a specified period does not prevent the Secretary from granting another approval in relation to the same goods before the lapsing of the first-mentioned approval. The subsequent approval may take effect on the expiry of the earlier period.

CONSULTATION

This Determination remakes the second determination without any material change to its substance or effect. It does not alter existing arrangements under subsection 19A(3) of the Act with respect to specified foreign countries.

The Office of Best Practice Regulation (OBPR) was consulted regarding the proposal to remake the second determination. OBPR advised that a Regulation Impact Statement was not required to remake the regulatory instrument (reference number 20273). However, the performance of the instrument would need to be reviewed to assess whether it continues to achieve its objectives efficiently and effectively.

Prior to making this Determination, the TGA assessed the regulatory performance of the second determination to consider its overall effectiveness and efficiency, and whether it remained fit-for-purpose, necessary and relevant. As part of this process, the TGA conducted targeted consultation with twenty-two affected stakeholders, being those companies who submitted applications under subsection 19A(1) of the Act in the 2014 and 2015 calendar years.

The consultation was conducted to confirm whether, in the view of those stakeholders, the current process for specifying foreign countries under subsection 19A(3) supported the objectives of subsection 19A(1) to ensure that specified therapeutic goods, which are registered or approved for general marketing in a country with a comparable regulatory system, can be made readily available, in the event of unavailability or shortage of supply in Australia of registered therapeutic goods, in particular, prescription medicines.

The TGA received submissions from stakeholders accounting for 91% of applications made in the relevant period. The feedback confirmed the need to continue the regulatory instrument in this form. The stakeholders generally endorsed the second determination as being fit-for-purpose, and operating effectively and efficiently to support the objectives of subsection 19A(1) of the Act.

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

This statement is prepared in accordance with subsection 9(1) of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Therapeutic Goods (Foreign Countries) Determination 2016

The *Therapeutic Goods (Foreign Countries) Determination 2016* 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

This instrument is made under subsection 19A(3) of the *Therapeutic Goods Act 1989* (the Act) by a delegate of the Secretary of the Department of Health. It repeals two earlier determinations made under that subsection in 1997 and 2004 and remakes the substance of the latter determination without material change. The former determination is now redundant.

This instrument specifies nine foreign countries, registration or approval for general marketing in at least one of which is a prerequisite for approving an application under subsection 19A(1) of the Act to import into, or supply in, Australia specified therapeutic goods, if comparable registered therapeutic goods are unavailable or are in short supply, and approval is necessary in the interests of the public health.

Human rights implications

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

Conclusion

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

Anthony Gill, delegate of the Secretary of the Department of Health