

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Guidelines for Multi-Site Licences) Instrument 2020

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.

Section 38A of the Act provides that the Secretary must, by legislative instrument, make guidelines setting out the circumstances in which a licence, issued under Part 3-3 of the Act to manufacture therapeutic goods to which that Part applies, may cover two or more manufacturing sites.

Relevantly, subsection 38(2A) of the Act provides that the Secretary must have regard to the guidelines under section 38A in granting a licence to a person who applies to carry out steps in the manufacture of therapeutic goods under section 38.

The *Therapeutic Goods (Guidelines for Multi-Site Licences) Instrument 2020* (“the Instrument”) is an instrument made by a delegate of the Secretary under section 38A of the Act for the purpose of setting out the circumstances in which a manufacturing licence may cover two or more manufacturing sites.

The Instrument also repeals and replaces the Therapeutic Goods (Multi-Site Manufacturing Licences) Guidelines of 2010 (“the former Guidelines”), which was due to sunset on 1 April 2020 under Part 4 of the *Legislation Act 2003*.

Background

Part 3-3 of the Act sets out requirements relating to the manufacture of therapeutic goods other than medical devices, Class 1 biologicals or goods or persons that are exempt from the operation of Part 3-3 by regulations made for the purposes of section 34 of the Act.

Part 3-3 contains criminal offences and civil penalty provisions that apply where a person carries out, at premises in Australia, a step in the manufacture of therapeutic goods and the person does not have a licence issued under Part 3-3 or the person, or the goods involved, are not exempt from the operation of that Part under section 34 of the Act.

Section 37 of the Act sets out requirements for an application for a licence, including that the application be in accordance with the form approved for that purpose by the Secretary and that the application identify the therapeutic goods or classes of therapeutic goods proposed to be manufactured.

Section 38 of the Act provides that where a person has made such an application, paid the prescribed application and inspection fees, and complied with any requirements imposed by the Secretary under subsection 37(2) of the Act, the Secretary must grant the applicant a licence covering one or more manufacturing sites unless the Secretary is satisfied of a matter listed in paragraphs 38(1)(e) to (h) of the Act.

These matters include, for example, that the applicant will be unable to comply with the manufacturing principles (made by the Minister under section 36 of the Act) or that the applicant has, within the 10 years before the application, been convicted of an offence against the Act or a

corresponding State law, or a Commonwealth or State or Territory offence involving fraud or dishonesty.

In considering the matters listed in paragraphs 38(1)(e) to (h) of the Act, subsection 38(2A) of the Act provides that the Secretary must have regard to the guidelines under section 38A of the Act in granting licences under section 38. The effect of these provisions, taken together, is that a manufacturing licence will, in most instances, cover one manufacturing site, except as provided for in the guidelines made under section 38A of the Act.

The Instrument repeals and replaces the former Guidelines, with minor changes to improve clarity and consistency. The Instrument does not introduce any new or substantive changes to the circumstances set out in the former Guidelines in which it is considered appropriate for a licence to cover more than one manufacturing site.

In that regard, the Instrument provides that, the circumstances in which a licence to manufacture therapeutic goods other than blood, blood components, haematopoietic progenitor cells or human tissue may cover two or more manufacturing sites are where:

- steps in the manufacture of the therapeutic goods are to be carried out at one fixed site, and any additional site or sites are to be used for the secondary packaging of the finished product, or the storage or release for supply of the packaging materials, starting materials, in-process materials, or the finished product; and
- all of the steps in the manufacture of the goods are to be covered by a single quality system; and
- all sites are capable of being inspected within the relevant period; and
- all sites are located with sufficient proximity such that the total travel time between the sites under inspection does not exceed 60 minutes.

The Instrument specifies similar circumstances in which a licence may cover two or more manufacturing sites in relation to a licence to manufacture therapeutic goods that are blood, blood components, haematopoietic progenitor cells or human tissue. In particular, those circumstances make provision in relation to mobile (non-fixed) sites for the collection of blood or blood components.

Consultation

The TGA conducted a targeted consultation with industry representative bodies in January and February 2020 in relation to the continued suitability and relevance of the former Guidelines, and the continuation of the substantive effect of the former Guidelines in the proposed making of the Instrument.

Feedback was received from industry representative bodies for the pharmaceutical manufacturing sector as well as the blood and biological manufacturing sectors. The responses supported the making of the Instrument in accordance with the former Guidelines without change, thereby representing a continuation of existing regulation with no increase in regulatory burden.

The Office of Best Practice Regulation advised that a regulation impact statement was not required in relation to the Instrument (Office of Best Practice Regulation reference ID 24085).

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

The Instrument 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 Instrument is a disallowable legislative instrument, and commences on the day following its registration on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Guidelines for Multi-Site Licences) Instrument 2020*

Section 1 Name

This section provides that the name of the instrument is the *Therapeutic Goods (Guidelines for Multi-Site Licences) Instrument 2020* (“the Instrument”).

Section 2 Commencement

This section provides that the Instrument commences on the day following its registration on the Federal Register of Legislation.

Section 3 Authority

This section provides that the legislative authority for making the Instrument is section 38A of the *Therapeutic Goods Act 1989*.

Section 4 Definitions

This section provides the definitions of certain terms used in the Instrument. The section notes that a number of terms have the meaning given in section 3 of the Act, including ‘licence’, ‘manufacture’, and ‘supply’. Other terms have been defined for the purposes of the Instrument, including ‘blood’, ‘in-process material’ and ‘starting material’.

Section 5 Circumstances for multi-site licence—manufacture of therapeutic goods other than blood, blood components, haematopoietic progenitor cells or human tissue

This section sets out the circumstances in which a licence may cover more than one manufacturing site for the manufacture of therapeutic goods other than blood, blood components, haematopoietic progenitor cells or human tissue.

Section 6 Circumstances for multi-site licence—manufacture of therapeutic goods that are blood, blood components, haematopoietic progenitor cells or human tissue

This section sets out the circumstances in which a licence may cover more than one manufacturing site for the manufacture of therapeutic goods that are blood, blood components, haematopoietic progenitor cells or human tissue.

Section 7 Repeals

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

Schedule 1 – Repeals

This Schedule repeals the *Therapeutic Goods (Multi-Site Manufacturing Licences) Guidelines of 2010*.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Guidelines for Multi-Site Licences) Instrument 2020

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 the Legislative Instrument

The *Therapeutic Goods (Guidelines for Multi-Site Licences) Instrument 2020* (“the instrument”) is made under section 38A of the *Therapeutic Goods Act 1989* (“the Act”).

Section 38A provides that the Secretary must, by legislative instrument, make guidelines setting out the circumstances in which a licence may cover two or more manufacturing sites.

The purpose of the instrument is to set out such guidelines, in relation to when it may be appropriate for a manufacturing licence to cover two or more manufacturing sites.

Relevantly, subsection 38(2A) of the Act provides that the Secretary must have regard to the guidelines under section 38A in granting a licence to a person who applies to carry out steps in the manufacture of therapeutic goods under section 38.

The instrument also repeals and replaces the Therapeutic Goods (Multi-Site Manufacturing Licences) Guidelines of 2010 (“the former instrument”), which was due to sunset on 1 April 2020 under Part 4 of the *Legislation Act 2003*.

The instrument repeals and replaces the former instrument, with minor changes to improve clarity and consistency. The instrument does not introduce any new or substantive changes to the circumstances set out in the former instrument in which it is considered appropriate for a licence to cover more than one manufacturing site.

In that regard, the instrument provides that, the circumstances in which a licence to manufacture therapeutic goods other than blood, blood components, haematopoietic progenitor cells or human tissue may cover two or more manufacturing sites are where:

- steps in the manufacture of the therapeutic goods are to be carried out at one fixed site, and any additional site or sites are to be used for the secondary packaging of the finished product, or the storage or release for supply of the packaging materials, starting materials, in-process materials, or the finished product; and
- all of the steps in the manufacture of the goods are to be covered by a single quality system; and
- all sites are capable of being inspected within the relevant period; and
- all sites are located with sufficient proximity such that the total travel time between the sites under inspection does not exceed 60 minutes.

The instrument specifies similar circumstances in which a licence may cover two or more manufacturing sites in relation to a licence to manufacture therapeutic goods that are blood, blood components, haematopoietic progenitor cells or human tissue. In particular, those circumstances make provision in relation to mobile (non-fixed) sites for the collection of blood or blood components.

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 standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

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 to 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 that licences issued under Part 3-3 of the Act only cover more than one manufacturing site in circumstances where the safety and integrity of the steps in the manufacture of therapeutic goods performed at those sites can be adequately and appropriately assessed and verified.

Such measures will assist to protect the safety of consumers who use therapeutic goods that are manufactured under licence in Australia.

Conclusion

This instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR as outlined above, and otherwise does not raise any human rights issues.

Tracey Duffy, delegate of the Minister for Health