

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Manufacturing Principles) Amendment Determination 2022

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 Australian Government Department of Health.

Subsection 36(1) of the Act provides that the Minister may, from time to time, determine written principles to be observed in the manufacture of therapeutic goods for use in humans. Subsection 36(4) of the Act provides that such manufacturing principles are legislative instruments.

Under subsection 36(2) of the Act, manufacturing principles may relate to any of the matters specified in paragraphs 36(2)(a) to (e), including the standards to be maintained and the equipment to be used at manufacturing premises, procedures for quality assurance and quality control and the manufacturing practices to be employed in the manufacturing of therapeutic goods.

The *Therapeutic Goods (Manufacturing Principles) Determination 2020* (“the Principal Determination”) is an instrument made by a delegate of the Minister under subsection 36(1) of the Act for the purpose of determining written principles to be observed in the manufacture of therapeutic goods.

The *Therapeutic Goods (Manufacturing Principles) Amendment Determination 2022* (“the Amendment Determination”) amends the Principal Determination to incorporate an updated version of the *Guide to Good Manufacturing Practice for Medicinal Products* (“the PIC/S Guide to GMP”), which was published by the Pharmaceutical Inspection Co-operation Scheme (“PIC/S”) in May 2021.

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 exempt from the operation of that Part by regulations made for the purposes of section 34 of the Act.

Part 3-3 contains criminal offences and civil penalty provisions that may 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).

It is a condition of each manufacturing licence that a manufacturer of therapeutic goods complies with the manufacturing principles (subparagraph 40(4)(a)(ii) of the Act refers). If the holder of a manufacturing licence breaches this or any other condition of the licence, the Secretary may suspend or revoke the licence (subparagraph 41(1)(a)(viii) of the Act refers). The Secretary can also refuse to grant a manufacturing licence if satisfied that the applicant for the licence will be unable to comply with the manufacturing principles (paragraph 38(1)(e) of the Act refers).

The manufacturing principles set out the minimum requirements that are to be observed in the manufacture of therapeutic goods (other than medical devices), to ensure that therapeutic goods are produced to a high quality, and consistent with their specifications. The Principal Determination separately specifies the principles to be observed in relation to the manufacture of the following therapeutic goods:

- registered and listed therapeutic goods (principally, these are medicines, active pharmaceutical ingredients and sunscreens), and biologicals that comprise or contain live animal cells, tissues or organs; and
- blood, blood components, haematopoietic progenitor cells and biologicals (other than biologicals that comprise or contain live animal cells, tissues or organs).

The TGA uses internationally harmonised manufacturing standards to allow manufacturers to operate in an international environment. The TGA maintains Good Manufacturing Practice (“GMP”) requirements in line with updates issued through PIC/S. Updates are necessary in order to maintain mutual confidence with regulators overseas, and to promote quality assurance of inspections and the harmonisation of technical standards and procedures with international inspection standards for the production and testing of medicinal products.

PIC/S is a non-binding, informal co-operative arrangement between regulatory authorities in the field of GMP of medicinal products for human or veterinary use. PIC/S leads the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates. The PIC/S Guide to GMP (PE 009-15), published on 1 May 2021 includes minor changes as compared to the version published on 1 July 2018 (PE009-14), including in particular:

- guidance for the manufacture of Advanced Therapy Medicinal Products, (“ATMPs”) for biologicals that comprise or contain live animal cells, tissues or organs (Annex 2A); and
- reorganisation of existing guidance in relation to the manufacture of biological medicinal substances and products for human use, with the exception of ATMPs (Annex 2B).

The amendment of the Principal Determination to incorporate the updated version of the PIC/S Guide to GMP ensures consistency with best international practice, and that an appropriate level of GMP will be required to be applied to the manufacture of therapeutic goods for use by patients in Australia. The amendments also reduce the risk and burden for sponsors and manufacturers of therapeutic goods associated with having to comply with requirements in Australia that are inconsistent with those in place in major international markets such as Europe and the United States, providing confidence for sponsors and manufacturers to bring their products to market in Australia and reducing delays for Australian patients in accessing new therapeutic goods. The specific changes resulting from the adoption of the updated version of the PIC/S Guide in comparison to the previous edition reflect the need to provide guidance on the management of new and novel technologies and to ensure continuous improvements in the way such goods are manufactured.

Australian manufacturers will also benefit from reduced regulatory burden where the TGA is able to adopt harmonised international standards and establish mutual recognition agreements and cooperation arrangements with comparable overseas regulatory authorities.

Incorporation by reference

The Amendment Determination incorporates by reference the *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009-15, 1 May 2021), which was published by the Pharmaceutical Inspection Co-operation Scheme (PIC/S). This document sets out standards that apply to the manufacture of medicines and similar products intended for human use, and is available for free on the TGA website (www.tga.gov.au). This document is incorporated as in force or existing at 1 July 2022, i.e., the time that the Amendment Determination commences, in accordance with paragraph 14(1)(b) of the *Legislation Act 2003* (“the Legislation Act”). The effect of incorporating this document is to update the PIC/S Guide to GMP specified in the Principal Determination from the 2018 version to the version published in 2021.

Consultation

The TGA undertook targeted consultation in relation to the incorporation of the updated version of the PIC/S Guide to GMP. A gap-analysis of the differences between the two versions of the PIC/S

Guide to GMP published in 2018 and 2021 (as adopted by the Principal Determination and the Amendment Determination respectively) was made available by the TGA for consultation with the Technical Industry Working Group on GMP (“TIWGG”) in September 2021.

The TIWGG is a stakeholder representational group comprising members nominated by key peak industry associations Accord Australasia, the Active Pharmaceutical Ingredients Manufacturers’ Association of Australia, the Association of Therapeutic Goods Consultants, the Australia New Zealand Industrial Gas Association, Australia and New Zealand Region of International Society of Cell and Gene Therapy, Australian Red Cross Lifeblood, Biotherapeutics Association of Australasia, Complementary Medicines Australia, Consumer Healthcare Products Australia and the Generic and Biosimilar Medicines Association, Medicinal Cannabis Industry Association and Medicines Australia. Feedback from the key industry associations regarding the gap analysis was positive and the associations supported the adoption of the updated version of the PIC/S Guide to GMP.

The Office of Best Practice Regulation advised that a Regulation Impact Statement was not required in relation to the making of the Amendment Determination as the proposed amendments are unlikely to have a more than minor regulatory impact (OBPR22-02040).

Details of the Amendment Determination are set out in **Attachment A**.

The Amendment Determination 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 Amendment Determination is a disallowable legislative instrument for the purposes of the Legislation Act, and commences on 1 July 2022.

Details of the *Therapeutic Goods (Manufacturing Principles) Amendment Determination 2022*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Manufacturing Principles) Amendment Determination 2022* (“the Amendment Determination”).

Section 2 – Commencement

This section provides that the Amendment Determination commences on 1 July 2022.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Determination is section 36 of the *Therapeutic Goods Act 1989* (“the Act”).

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. The Amendment Determination is made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Determination is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Determination has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Manufacturing Principles) Determination 2020* (“the Principal Determination”).

Item 1 repeals and substitutes the definition of ‘PIC/S Guide to GMP’ in section 4 of the Principal Determination to reflect that ‘PIC/S Guide to GMP’ means the updated version of the *PIC/S Guide to Good Manufacturing Practice for Medicinal Products*, being PE 009-15, as published on 1 May 2021.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Manufacturing Principles) Amendment Determination 2022

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 36(1) of the Act provides that the Minister may, from time to time, determine written principles to be observed in the manufacture of therapeutic goods for use in humans. These manufacturing principles set out the minimum requirements that are to be observed in the manufacture of therapeutic goods (other than medical devices), to ensure that therapeutic goods are produced to a high quality.

The *Therapeutic Goods (Manufacturing Principles) Determination 2020* (“the principal instrument”) is made by the Minister under subsection 36(1) of the *Therapeutic Goods Act 1989* (“the Act”) to determine such principles.

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 exempt from the operation of that Part by regulations made for the purposes of section 34 of the Act. That Part contains criminal offences and civil penalty provisions that may 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.

It is a condition of each manufacturing licence that a manufacturer of therapeutic goods complies with the manufacturing principles (subparagraph 40(4)(a)(ii) of the Act refers). If the holder of a manufacturing licence breaches this (or any other) condition of the licence, the Secretary may suspend or revoke the licence (subparagraph 41(1)(a)(viii) of the Act refers). The Secretary can also refuse to grant a manufacturing licence if satisfied that the applicant for the licence will be unable to comply with the manufacturing principles (paragraph 38(1)(e) of the Act refers).

The *Therapeutic Goods (Manufacturing Principles) Amendment Determination 2022* (“the amendment instrument”) is made under section 36 of the Act and amends the principal instrument, principally to incorporate the updated version of the *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009-15) (“PIC/S Guide to Good Manufacturing Practice”) published by the Pharmaceutical Inspection Co-operation Scheme (“PIC/S”) in May 2021.

The incorporation of the updated version of the PIC/S Guide to Good Manufacturing Practice in the principal instrument ensures that an appropriate level of Good Manufacturing Practice (“GMP”) applies to the manufacture of therapeutic goods manufactured or supplied in Australia. The updated version includes minor changes as compared to the version published in July 2018 (PE009-14), including in particular:

- guidance for the manufacture of Advanced Therapy Medicinal Products, (“ATMPs”) for biologicals that comprise or contain live animal cells, tissues or organs (Annex 2A); and
- reorganisation of existing guidance in relation to the manufacture of biological medicinal substances and products for human use, with the exception of ATMPs (Annex 2B).

These specific changes reflect the need to provide guidance on the management of new and novel technologies and to ensure continuous improvements in the way goods are manufactured.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (“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 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 therapeutic goods manufactured in Australia continue to be subject to an appropriate level of GMP, and are of a high quality.

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

Conclusion

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and does not raise any other human rights issues.