

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Manufacturing Principles) Amendment (PIC/S Guide) Determination 2025

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, Disability and Ageing.

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 made 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 (PIC/S Guide) Determination 2025* (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), published by the Pharmaceutical Inspection Co-operation Scheme (PIC/S), effective 25 August 2023.

The Amendment Determination also replaces Part 3 of the Principal Determination, which contains application provisions that are no longer required, to introduce application provisions which provide that version PE 009-17 of the PIC/S Guide to GMP applies to the manufacture of therapeutic goods that occurs on or after 1 September 2025, with the exception of clauses 2.1, 2.3, 7.14 and 9.31 of Annex 1 which applies to the manufacture of therapeutic goods that are sterile medicines or sterile active pharmaceutical ingredients that occurs on or after 1 March 2026.

Background

Manufacturing 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.

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 and sunscreens), active pharmaceutical ingredients, 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).

PIC/S Guide to GMP

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 version PE 009-17, which came into effect on 25 August 2023, includes revisions limited to Annex 1 (Manufacture of sterile medicinal products) to the guide. The revised Annex 1 introduces a number of changes that largely clarify existing GMP requirements, provide guidance for the adoption of new manufacturing technologies, support the application of Quality Risk Management to manufacturing operations and contamination control, and offer additional direction on environmental classification, qualification, and monitoring expectations.

Purpose

The Amendment Determination amends the Principal Determination to replace the definition of ‘PIC/S Guide to GMP’ with a reference to the updated version of the *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009-17, 25 August 2023) published by PIC/S.

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. This provides confidence for sponsors and manufacturers to bring their products to market in Australia and reduces delays for Australian patients in accessing new therapeutic goods.

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.

In addition to updating the reference to the PIC/S Guide to GMP, the Amendment Determination also replaces Part 3 of the Principal Determination, as the application provisions provided by that Part are no longer required. The Amendment Determination replaces Part 3 with new application provisions which provide that version PE 009-17 of the PIC/S Guide to GMP applies to the manufacture of therapeutic goods that occurs on or after 1 September 2025, with the exception of clauses 2.1, 2.3, 7.14 and 9.31 of Annex 1 which applies to the manufacture of therapeutic goods that are sterile medicines or sterile active pharmaceutical ingredients that occurs on or after 1 March 2026.

Incorporation by reference

The Amendment Determination incorporates by reference the *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009-17, 25 August 2023), which was published by 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 PIC/S's website (<https://picscheme.org>).

This document is incorporated as in force or existing at 1 September 2025, being the time that the Amendment Determination commences, in accordance with paragraph 14(1)(b) of the *Legislation Act 2003* (the Legislation Act).

Consultation

Between March and July 2025, the TGA undertook targeted consultation in relation to the incorporation of version PE 009-17 of the PIC/S Guide to GMP. Stakeholders consulted included members of the TGA Industry Working Group on GMP and industry associations, including the Australasian College of Physical Scientists and Engineers in Medicine, Active Pharmaceutical Ingredient Manufacturers' Association of Australia, Generic and Biosimilar Medicines Association, Association of Therapeutic Goods Consultants Inc, Medicines Australia, TGA-Licensed Chemotherapy Compounders of Australia, and Standards Australia.

The TGA provided stakeholders with a detailed gap analysis of the differences between versions PE 009-16 and PE 009-17 of the PIC/S Guide to GMP. Feedback from the key industry associations was generally positive, and the associations encouraged and supported the adoption of version PE 009-17, recognising the importance of international equivalence and reputation for Australian manufacturers. In response to consultation feedback from manufacturers of sterile medicines and active pharmaceutical ingredients, the Amendment Determination provides for a delayed application of 6 months for clauses 2.1, 2.3, 7.14 and 9.31 of Annex 1 to version PE 009-17, for the manufacture of therapeutic goods that are sterile medicines or active pharmaceutical ingredients, to allow industry sufficient time to ensure that their manufacturing practices comply with the updated requirements in those clauses.

Other details

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 September 2025.

Details of the *Therapeutic Goods (Manufacturing Principles) Amendment (PIC/S Guide) Determination 2025*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Manufacturing Principles) Amendment (PIC/S Guide) Determination 2025* (the Amendment Determination).

Section 2 – Commencement

This section provides that the Amendment Determination commences on 1 September 2025.

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 – Section 4 (definition of *PIC/S Guide to GMP*)

Item 1 replaces 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 *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009-17, 25 August 2023) (the PIC/S Guide to GMP) as in force or existing at 1 September 2025.

The note to the definition of ‘PIC/S Guide to GMP’ makes it clear that the PIC/S Guide to GMP could, in 2025, be viewed on the PIC/S’s website at <https://picscheme.org>.

Item 2 – Part 3

Item 2 repeals Part 3 of the Principal Determination, which provides for application provisions relating to amendments made by a former instrument, and replaces with a new Part 3 to provide for the application of amendments made by the Amendment Determination.

Subsection 8(1) introduces definitions of ‘amending determination’ and ‘sterile therapeutic goods’ for the purposes of section 8.

Subsection 8(2) provides that the amendments made to the Principal Determination by item 1 in Schedule 1 to the amending determination apply to the manufacture of therapeutic goods that occurs on or after 1 September 2025.

Subsection 8(3) provides that despite subsection 8(2), the amendments made to the Principal Determination by item 1 in Schedule 1 to the amending determination, only to the extent that the amendment has the effect of incorporating clauses 2.1, 2.3, 7.14 and 9.31 of Annex 1 to the PIC/S Guide to GMP, applies to the manufacture of sterile therapeutic goods that occurs on or after 1 March 2026. The delayed application of 6 months for clauses 2.1, 2.3, 7.14 and 9.31 of Annex 1 for the manufacture of sterile therapeutic goods is intended to provide industry with sufficient time to ensure that their manufacturing practices comply with the updated requirements in those clauses.

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 (PIC/S Guide) Determination 2025

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 *Therapeutic Goods Act 1989* (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.

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Human rights implications

The Amendment Determination 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, 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 Amendment Determination 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 Good Manufacturing Practice (GMP), and are of a high quality. The Amendment Determination ensures consistency with best international practice for the manufacture of therapeutic goods (other than medical devices), 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. Accordingly, these measures will assist to protect the safety of consumers who use therapeutic goods that are manufactured under licence in Australia.

In ensuring consistency with best international practice, the Amendment Determination also reduces 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. This provides confidence for sponsors and manufacturers to bring their products to market in Australia and reduces delays for Australian patients in accessing new therapeutic goods.

Conclusion

The Amendment Determination 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.