EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Exempt Monographs) Amendment 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 ("the Department").

Subsection 3(1) of the Act defines a 'standard' in relation to therapeutic goods as a standard that is constituted by the matters specified in an order under section 10 of the Act that is applicable to the goods, any monographs to which the goods are subject in the British Pharmacopoeia ("the BP"), the European Pharmacopoeia ("the EP") or the United States Pharmacopeia-National Formulary ("the USP") (each defined as a 'default standard'), and homeopathic and anthroposophic standards.

Section 3C of the Act provides that the Minister may, by legislative instrument, determine that specified monographs, or specified statements in specified monographs in the BP, the EP or the USP are exempt for the purposes of paragraphs (b), (c) or (d), respectively, of the definition of 'standard' in subsection 3(1) of the Act. The effect of this is that any such specified exempt monograph or statement will not be part of the default standards that would otherwise apply to the specified therapeutic goods.

The *Therapeutic Goods (Exempt Monographs) Determination 2021* ("the Principal Determination") is made under section 3C of the Act and determines, for subsection 3C(1), that the monographs specified in the table in Schedule 1 are exempt for the purposes of paragraph (b), (c) or (d) of the definition of 'standard' in subsection 3(1) of the Act, in relation to therapeutic goods.

The *Therapeutic Goods (Exempt Monographs) Amendment Determination 2025* ("the Amendment Determination") is made under section 3C of the Act and amends the Principal Determination to provide for the exemption of specified statements in specified monographs in the BP, the EP or the USP, in relation to specified therapeutic goods in accordance with subsection 3C(2) of the Act. The Amendment Determination exempts the specified statement in monograph for Live Biotherapeutic Products for Human Use (monograph 3053) of each of the BP and EP that the label state the name of any stabilisers and other excipients, in relation to listed medicines and medicines eligible for listing (other than export only medicines) that contain certain whole live microorganisms as an active ingredient. The effect of this amendment is that the specified statement in monograph 3053 of the BP and EP is exempt for the purposes of paragraph (b) or (c) of the definition of 'standard' in subsection 3(1) of the Act, and therefore does not form part of the default standards that apply to such listed medicines or medicines that are eligible for listing.

Background

The TGA 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 quality of therapeutic goods or procedures to be carried out in their manufacture, and by otherwise applying default standards that are constituted by statements in three international pharmacopoeias defined in the Act - the BP, the EP and the USP.

However, the definition of 'standard' in section 3(1) of the Act excludes from the definition any monograph exempted under subsection 3C(1) of the Act and any statement in a monograph exempted under subsection 3C(2) of the Act. The effect of this is that such exempt monographs or exempt statements in monographs are not covered by the meaning of a standard and do not need to be

complied with as an applicable standard for the therapeutic goods in relation to which those monographs or statements are exempted.

Subsection 3C(1) of the Act provides that the Minister may, by legislative instrument, determine that specified monographs in the BP, the EP or the USP are exempt for the purposes of paragraphs (b), (c) or (d), respectively, of the definition of 'standard' in subsection 3(1) of the Act.

Similarly, subsection 3C(2) provides that the Minister may, by legislative instrument, determine that specified statements in monographs in the BP, the EP or the USP are exempt for the purposes of paragraphs (b), (c) or (d), respectively, of the definition of 'standard' in subsection 3(1) of the Act.

The Principal Determination is made under section 3C of the Act and determines that the monographs specified in the table in Schedule 1 are exempt for the purposes of paragraph (b), (c) or (d) of the definition of 'standard' in subsection 3(1) of the Act, in relation to therapeutic goods. The Principal Determination does not currently exempt any specific statements in monographs.

Purpose

Monograph 3053 of the BP and monograph 3053 of the EP – in each case, being a monograph for Live Biotherapeutic Products for Human Use - requires that labels for such products state the name of any stabilisers and other excipients. However, this is inconsistent with general labelling practices of these goods which do not include this information on the labels of these medicines. Although it may be possible to comply with both the Australian requirements and the labelling requirements in monograph 3053, this would result in inconsistent labelling between different types of medicines and possible confusion for consumers.

The Amendment Determination amends the Principal Determination to exempt the statement in monograph 3053 of the BP and EP that labels of such medicines include the name of any stabilisers and other excipients. This would only apply to medicines that are listed goods or are eligible for listing, other than export only medicines, and that contain a whole live microorganism (other than other than *arthrospira maxima* or *arthrospira platensis*) as an active ingredient ("the specified class of therapeutic goods"). The statement would be exempt for the purpose of paragraph (b) and (c) of the definition of 'standard' in subsection 3(1) of the Act and would not be considered a part of the default standards that must be complied with, in relation to the specified class of therapeutic goods.

The reason for the exemption of this labelling requirement in monograph 3053 of the BP and EP is to maintain consistency with general Australian labelling practices for the specified class of therapeutic goods.

Incorporation by reference

The Amendment Determination amends the Principal Determination to determine that parts of monograph 3053 in the BP and EP are exempt for the purposes of paragraph (b) or (c) of the definition of 'standard' in the Act, in relation to the specified class of therapeutic goods.

The Amendment Determination references monograph 3053 and the BP and EP, and the note in section 4 of the Amendment Determination makes it clear that each is defined in subsection 3(1) of the Act.

The definitions of the pharmacopoeia in subsection 3(1) of the Act refer to the publications of each as in force from time to time. The intention in the Amendment Determination is therefore to adopt the defined meaning of the pharmacopoeia as set out in subsection 3(1) of the Act (an approach permitted by subsection 3C(3) of the Act). These pharmacopoeia are incorporated in the Determination as in force or existing from time to time, in accordance with these provisions, and may be accessed from www.pharmacopoeia.com/, pheur.edqm.eu/home and www.uspnf.com/.

However, these documents are not publicly available for free. Rather, where possible, by prior written agreement and without charge, the pharmacopoeia may be viewed by members of the public at the TGA office in Fairbairn, ACT. It is not anticipated that the persons to whom the Principal Determination applies would need to obtain copies of the specified exempt parts of the monograph to the extent that the exemption made under section 3C(2) of the Act expressly excuses those persons from conforming to the specified statement in the specified monograph. In any case, as important benchmarks for the safety of therapeutic goods and other consumer goods, it would be infeasible from a regulatory perspective to not adopt such benchmarks on the basis that the publications are not available for free.

It should also be noted, in relation to the pharmacopoeia, 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 pharmacopoeia 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 or 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 and the National Library.

Consultation

Between 10 February and 13 March 2025, the TGA undertook targeted consultation with peak industry stakeholders and some of the sponsors that would be directly impacted by the Amendment Determination, through the Complementary and Over the Counter Medicines Regulatory and Technical Consultative Forum (ComTech). ComTech is a forum that facilitates consultation between the TGA and representatives from the complementary and over the counter medicines industries, including Accord Australasia, the Association of Therapeutic Goods Consultants, Complementary Medicines Australia and Consumer Healthcare Products Australia. The feedback received broadly indicated support for the proposal to exempt the part of monograph 3053 that requires the stabilisers and excipients to be stated on the label of the good.

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 2003,* and commences on the day after it is registered on the Federal Register of Legislation.

Attachment A

Details of the *Therapeutic Goods (Exempt Monographs) Amendment Determination 2025*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Exempt Monographs) Amendment Determination 2025* ("the Amendment Determination").

Section 2 – Commencement

This section provides that the Amendment Determination commences on the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Determination is section 3C 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 as set out in the applicable items in the Schedule concerned, and 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 (Exempt Monographs) Determination 2021* ("the Principal Determination").

Item 1 – Section 4 (note)

This item repeals and replaces the original note in section 4, to update the list of terms used in the Principal Determination that are defined in the Act.

Item 2 – Section 5 (at the end of the heading)

This item amends the heading of section 5 to add 'of entire monographs' at the end of the heading, to read as 'Exemption of entire monographs'. This item has the effect of distinguishing between exempting entire monographs under subsection 3C(1) of the Act and exempting parts of monographs under subsection 3C(2) of the Act.

Item 3 – After section 5

This item introduces new section 6 to the Principal Determination which provides that, for the purpose of subsection 3C(2) of the Act, the statements in monographs specified in column 2 of the table in Schedule 2 to the Principal Determination, in the pharmacopoeia specified in column 3, are exempt for the purposes of paragraph (b), (c) or (d) of the definition of 'standard' in subsection 3(1) of the Act, in relation to therapeutic goods specified in column 4. The effect of this amendment is that

the specified statements in monographs will not be part of the default standards that apply to the specified therapeutic goods.

Item 4 – After Schedule 1

Item 4 introduces Schedule 2 to the Principal Determination, which includes a table that lists the statements in monographs of pharmacopoeia that are exempt from paragraph (b), (c) or (d) of the definition of 'standard' in subsection 3(1) of the Act, for a particular specified class of therapeutic good.

Item 1 of the table in Schedule 2 has the effect of exempting the statement in monograph 3053 of the British Pharmacopoeia, and monograph 3053 of the European Pharmacopoeia, that the label state the name of any stabilisers and other excipients for the purposes of paragraphs (b) and (c) of the definition of 'standard' in subsection 3(1) of the Act. The specified class of therapeutic goods to which this applies is medicines that:

(a) are listed goods or eligible for listing, other than export only medicines; and
(b) contain a whole live microorganism, other than *arthrospira maxima* or *arthrospira platensis*, as an active ingredient.

This has the effect that labels for this specified class of therapeutic goods do not need to include the name of any stabilisers or other excipients, aligning the requirements of these goods with current general labelling practices.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Exempt Monographs) Amendment 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 the legislative instruments

Subsection 3(1) of the Act defines a 'standard' in relation to therapeutic goods as a standard that is constituted by the matters specified in an order under section 10 of the Act that is applicable to the goods, any monographs to which the goods are subject in the British Pharmacopoeia ("the BP"), the European Pharmacopoeia ("the EP") or the United States Pharmacopeia-National Formulary ("the USP") (each defined as a 'default standard'), and homeopathic and anthroposophic standards.

Section 3C of the Act provides that the Minister may, by legislative instrument, determine that specified monographs, or specified statements in specified monographs in the BP, the EP or the USP are exempt for the purposes of paragraphs (b), (c) or (d), respectively, of the definition of 'standard' in subsection 3(1) of the Act. The effect of this is that any such specified exempt monograph or statement will not be part of the default standards that would otherwise apply to the specified therapeutic goods.

The *Therapeutic Goods (Exempt Monographs) Determination 2021* ("the Principal Determination") is made under section 3C of the Act and determines, for subsection 3C(1), that the monographs specified in the table in Schedule 1 are exempt for the purposes of paragraph (b), (c) or (d) of the definition of 'standard' in subsection 3(1) of the Act, in relation to therapeutic goods.

The *Therapeutic Goods (Exempt Monographs) Amendment Determination 2025* ("the Amendment Determination") is made under section 3C of the Act and amends the Principal Determination to provide for the exemption of specified statements in specified monographs in the BP, the EP or the USP, in relation to specified therapeutic goods in accordance with subsection 3C(2) of the Act. The Amendment Determination exempts the specified statement in monograph for Live Biotherapeutic Products for Human Use (monograph 3053) of each of the BP and EP that the label state the name of any stabilisers and other excipients, in relation to listed medicines and medicines eligible for listing (other than export only medicines) that contain certain whole live microorganisms as an active ingredient. The effect of this amendment is that the specified statement in monograph 3053 of the BP and EP is exempt for the purposes of paragraph (b) or (c) of the definition of 'standard' in subsection 3(1) of the Act, and therefore does not form part of the default standards that apply to such listed medicines or medicines that are eligible for listing.

Background

The TGA 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 quality of therapeutic goods or procedures to be carried out in their manufacture, and by otherwise applying default standards that are constituted by statements in three international pharmacopoeias defined in the Act - the BP, the EP and the USP.

However, the definition of 'standard' in section 3(1) of the Act excludes from the definition any monograph exempted under subsection 3C(1) of the Act and any statement in a monograph exempted under subsection 3C(2) of the Act. The effect of this is that such exempt monographs or exempt statements in monographs are not covered by the meaning of a standard and do not need to be complied with as an applicable standard for the therapeutic goods in relation to which those monographs or statements are exempted.

Subsection 3C(1) of the Act provides that the Minister may, by legislative instrument, determine that specified monographs in the BP, the EP or the USP are exempt for the purposes of paragraphs (b), (c) or (d), respectively, of the definition of 'standard' in subsection 3(1) of the Act.

Similarly, subsection 3C(2) provides that the Minister may, by legislative instrument, determine that specified statements in monographs in the BP, the EP or the USP are exempt for the purposes of paragraphs (b), (c) or (d), respectively, of the definition of 'standard' in subsection 3(1) of the Act.

The Principal Determination is made under section 3C of the Act and determines that the monographs specified in the table in Schedule 1 are exempt for the purposes of paragraph (b), (c) or (d) of the definition of 'standard' in subsection 3(1) of the Act, in relation to therapeutic goods. The Principal Determination does not currently exempt any specific statements in monographs.

Purpose

Monograph 3053 of the BP and monograph 3053 of the EP – in each case, being a monograph for Live Biotherapeutic Products for Human Use - requires that labels for such products state the name of any stabilisers and other excipients. However, this is inconsistent with general labelling practices of these goods which do not include this information on the labels of these medicines. Although it may be possible to comply with both the Australian requirements and the labelling requirements in monograph 3053, this would result in inconsistent labelling between different types of medicines and possible confusion for consumers.

The Amendment Determination amends the Principal Determination to exempt the statement in monograph 3053 of the BP and EP that labels of such medicines include the name of any stabilisers and other excipients. This would only apply to medicines that are listed goods or are eligible for listing, other than export only medicines, and that contain a whole live microorganism (other than other than *arthrospira maxima* or *arthrospira platensis*) as an active ingredient ("the specified class of therapeutic goods"). The statement would be exempt for the purpose of paragraph (b) and (c) of the definition of 'standard' in subsection 3(1) of the Act and would not be considered a part of the default standards that must be complied with, in relation to the specified class of therapeutic goods.

The reason for the exemption of this labelling requirement in monograph 3053 of the BP and EP is to maintain consistency with general Australian labelling practices for the specified class of therapeutic goods.

Human rights implications

The amendment 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 amendment instrument supports the right to health by reducing regulatory burden for sponsors of listed medicines that contain a whole live microorganism (other than *arthrospira maxima* or *arthrospira platensis*) as an active ingredient, ensuring consistency of regulatory requirements for the labelling of such medicines and in so doing reducing the risk of confusion and inadvertent non-compliance in relation to medicine labelling. The amendment instrument will also support the right to health through helping support the continued supply of such therapeutic goods in Australia.

Conclusion

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