EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Exempt Monographs) 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 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 ("BP"), the European Pharmacopoeia ("Ph. Eur.") or the United States Pharmacopeia-National Formulary ("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 in the BP, the Ph. Eur. 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 *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 certain nicotine vaping products.

The Therapeutic Goods (Exempting monographs of pharmacopoeias) Determination No. 1 of 2011 ("the Former Determination") is also made under section 3C of the Act and determines that specified monographs in the USP are exempt for the purposes of paragraph (d) of the definition of 'standard' in subsection 3(1) of the Act.

Most of the monographs mentioned in the Former Determination are no longer official (i.e. do not form part of the USP) and, as such, are no longer required to be exempted. A small number of the monographs mentioned in the Former Determination still form part of the USP and there is a need to ensure that these continue to be exempted under section 3C of the Act.

The *Therapeutic Goods (Exempt Monographs) Amendment Determination 2022* ("the Amendment Determination") is made under section 3C of the Act and amends the Principal Determination to include the monographs of the USP mentioned in the Former Determination for which there is still a need to exempt from paragraph (d) of the definition of 'standard' in subsection 3(1) of the Act.

The Amendment Determination also repeals the Former Determination, which would otherwise sunset on 1 April 2022.

Background

The Australian Government is responsible for regulating the quality, safety and efficacy 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 manufacture of therapeutic goods, and by otherwise applying default standards that are constituted by statements in three international pharmacopoeias defined in the Act, being the BP, Ph. Eur. and USP.

The Former Determination specified a number of monographs of the USP as being exempt for the purpose of paragraph (d) of the definition of 'standard' in subsection 3(1) of the Act. However, since the commencement of the Former Determination in 2011, changes have occurred to the USP with the

effect that many of the monographs specified in the Former Determination are no longer official (i.e. do not form part of the USP) – for instance Anthrax Vaccine Adsorbed, Mumps Virus Vaccine Live and Rabies Vaccine.

A small number of the USP monographs mentioned in the Former Determination remain part of the USP. The Amendment Determination amends the Principal Determination to include these monographs:

- antithrombin III human;
- factor IX complex;
- pancreatin;
- pancrelipase;
- plasma protein fraction.

The continued exemption of each of these monographs from the definition of 'standard' in the Act is necessary for one or more of the following reasons:

- expressions of potency in the monograph are in a form that are not comparable to units used in the BP or the Ph. Eur. with established use in Australia, with the potential for product labelling in the USP units to be confusing to users;
- the monograph refers to, or relies on, Unites States of America legislation or decisions of the United States Food and Drug Administration, and so is not self-contained;
- the monograph lacks a requirement for mandatory Nucleic Acid Amplification Testing of starting plasma, which could present an increased risk of infectious disease.

Amending the Principal Determination to exempt these monographs reflects that, with the repeal of the Former Determination (which would otherwise sunset on 1 April 2022) the Principal Determination will provide a single, consolidated instrument highlighting all of the monographs that have been determined by the Minister under section 3C of the Act to be exempt for the purposes of paragraph (b), (c) or (d) of the definition of 'standard' in subsection 3(1) of the Act.

Incorporation by reference

The Amendment Determination amends the Principal Determination to determine that the monographs for antithrombin III human, factor IX complex, pancreatin, pancrealipase and plasma protein factor in the USP are exempt for the purposes of paragraph (d) of the definition of 'standard' in the Act.

These monographs are incorporated by reference in the Amendment Determination, notwithstanding any additions or amendments to those monographs. This is consistent with the definition of the 'United States Pharmacopeia-National Formulary' in subsection 3(1) of the Act, noting that expressions used in instruments made under an Act have the same meaning as in the Act (section 13 of the *Legislation Act 2003* refers). Consequently, the exempt monographs are identified with reference to the USP, irrespective of any new editions of that pharmacopeia.

The exempt monographs in the USP may be obtained from www.uspnf.com. Unfortunately, these publications are not available without charge, and varying prices apply depending on whether a person wishes to subscribe to the pharmacopoeia or purchase a particular edition.

It is not anticipated that the persons to whom the Principal Determination applies would need to obtain copies of the specified exempt monographs to the extent that the exemption made under section 3C of the Act expressly excuses those persons from conforming to the monographs.

In any case, the TGA may facilitate access to view the pharmacopeia without charge by prior written arrangement with the TGA at the TGA office in Symonston, ACT. It should also be noted that the

National Library's Trove online system (wwww.trove.nla.gov.au) allows users to identify libraries in Australia that are open to the public where (in most cases, earlier) editions of these pharmacopoeias may be viewed.

Members of the public may also approach libraries that participate in inter-library loans to request an inter-library loan with libraries holding the pharmacopoeia to obtain a photocopy of a particular monograph for personal study or research. Fees apply in relation to the making of such a request. Enquiries should be made directly with local libraries, state libraries or the National Library.

Consultation

The Office of Best Practice Regulation advised that a Regulation Impact Statement was not required in relation to the making of the instrument as repealing the Former Determination and including the relevant monographs of the USP in the Principal Determination is unlikely to have more than a minor regulatory impact (OBPR21-01205).

Between 22 October and 19 November 2021, the TGA undertook targeted consultation with peak industry stakeholders and selected medicine sponsors that would be directly impacted by the Amendment Determination. The TGA only received 2 responses (1 from a peak body, the other from an industry sponsor), both of which stated their support for the continued exclusion of the monographs for antithrombin III human, factor IX complex, pancreatin, pancrelipase and plasma protein fraction of the USP and the proposed removal of the unofficial monographs.

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 2002* and commences on 31 March 2022.

Attachment A

Details of the *Therapeutic Goods (Exempt Monographs) Amendment Determination 2022.*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Exempt Monographs) Amendment Determination 2022* ("the Amendment Determination").

Section 2 – Commencement

This section provides that the Amendment Determination commences on 31 March 2022.

Section 3 – Authority

This section provides that the legislative authority for making the Order 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 or repealed 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 adds the following monographs in the United States Pharmacopeia-National Formulary to the table in Schedule 1 to the Principal Determination:

- antithrombin III human;
- factor IX complex;
- pancreatin;
- pancrealipase;
- plasma protein factor.

The effect of this amendment is to specify that these monographs are exempt for the purposes of paragraph (d) of the definition of 'standard' in subsection 3(1) of the Act for all applicable therapeutic goods.

Schedule 2—Repeals

This Schedule provides for the repeal of the Therapeutic Goods (Exempting monographs of pharmacopoeias) Determination No. 1 of 2011, which would otherwise sunset on 1 April 2022.

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 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 the legislative instruments

Subsection 3(1) of the *Therapeutic Goods Act 1989* ("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 ("BP"), the European Pharmacopoeia ("Ph. Eur.") or the United States Pharmacopeia-National Formulary ("USP") (each defined as a 'default standard') and homeopathic and anthroposophic standards.

The *Therapeutic Goods (Exempt Monographs) Determination 2021* ("the principal instrument") 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.

The *Therapeutic Goods (Exempt Monographs) Amendment Determination 2022* ("the amendment instrument") is made under section 3C of the Act, for the purpose of specifying certain monographs of the United States Pharmacopeia-National Formulary as being exempt for the purpose of paragraph (d) of the definition of 'standard' in subsection 3(1) of the Act.

Specifically, the amendment instrument has the effect of repealing and replacing the Therapeutic Goods (Exempting monographs of pharmacopoeias) Determination No. 1 of 2011 ("the former instrument") by specifying that the monographs for antithrombin III human, factor IX complex, pancreatin, pancrealipase and plasma protein factor in the USP are exempt for the purposes of paragraph (d) of the definition of 'standard' in the Act. The former instrument would otherwise sunset on 1 April 2022.

The continued exemption of these monographs for the purposes of paragraph (d) of the definition of 'standard' in the Act is necessary for one or more of the following reasons:

- expressions of potency in the monograph are in a form that are not comparable to units used in BP or the Ph. Eur. with established use in Australia, with the potential for product labelling in the USP units to be confusing to users;
- the monograph refers to, or relies on, Unites States of America legislation or decisions of the United States Food and Drug Administration, and so is not self-contained;
- the monograph lacks a requirement for mandatory Nucleic Acid Amplification Testing of starting plasma, which could present an increased risk of infectious disease.

Amending the principal instrument to exempt these monographs has the effect of consolidating, into a single instrument, all of the monographs that have been determined by the Minister under section 3C of the Act to be exempt for the purposes of paragraph (b), (c) or (d) of the definition of 'standard' in subsection 3(1) of the Act.

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 takes positive steps to promote the right to health by helping to ensure the safety, quality and efficacy of therapeutic goods, by exempting the monographs for antithrombin III human, factor IX complex, pancreatin, pancrealipase and plasma protein factor in the USP for the purposes of paragraph (d) of the definition of 'standard' in the Act. The exemption of such monographs is critical to ensure the safety of therapeutic goods, the use of which may otherwise be compromised due to inadequate product characterisation or lack of required mandatory testing.

Conclusion

The amendment 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 other human rights issues.