EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Listed Medicines—Conditions of Listing) 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 Department of Health and Aged Care.

Subsection 28(1) of the Act provides that the registration or listing of therapeutic goods is subject to the conditions set out in a determination under subsection (2). Subsection 28(2) relevantly provides that the Minister may, by legislative instrument, make a determination setting conditions that relate to specified matters, including for instance the manufacture of the goods, or the custody, use, supply, disposal or destruction of the goods.

The *Therapeutic Goods (Listed Medicines—Conditions of Listing) Determination 2022* ("the Determination") is made under subsection 28(2) of the Act, and has the effect of specifying, for the purposes of subsection 28(1) of the Act, standard conditions that will automatically apply to the listing of certain medicines that are listed in the Australian Register of Therapeutic Goods ("the Register") under section 26A or 26AE of the Act.

Background

Medicines that are listed in the Register under 26A of the Act are considered to be low risk and are not individually evaluated before those medicines are listed. Medicines that are listed in the Register under section 26AE of the Act are also considered to be low risk, but are evaluated in relation to whether the efficacy of the medicine for the purpose for which it is to be used has been satisfactorily established (these purposes are specific efficacy claims for which the sponsor of the medicine holds supporting evidence). When listed under section 26AE, these listed medicines are commonly referred to as 'assessed listed medicines'.

As the safety and quality of medicines listed under section 26A and 26AE are not evaluated by the TGA before being given marketing approval, the Act contains mechanisms to help ensure that those medicines are of appropriate quality and able to be used safely by consumers. In particular, medicines listed under section 26A and 26AE may only contain ingredients from an approved list of ingredients that have been evaluated in relation to their quality, safety and suitability for use in such medicines (currently set out in the *Therapeutic Goods (Permissible Ingredients) Determination (No. 5) 2022*). Further, sponsors of such medicines may only use indications (statements of therapeutic use) from a list of pre-approved low-level indications (currently set out in the *Therapeutic Goods (Permissible Indications) Determination (No.1) 2021*) to ensure that these products do not overstate their therapeutic benefits.

Part 3-2 of the Act sets out requirements relating to the listing of therapeutic goods on the Register. Relevantly, section 28 of the Act provides a mechanism for imposing conditions of listing or registration that are to be applied to medicines entered in the Register. There are three kinds of conditions that may apply to listed medicines:

- conditions that automatically apply to all medicines (i.e. listed medicines and registered medicines) from the date of inclusion of the medicine in the Register;
- additional automatic conditions that only apply to listed medicines from the time of listing in the Register; and
- discretionary conditions that the Secretary may apply to a medicine at any time after the medicine is listed (or registered) in the Register.

A refusal or failure to comply with any condition to which the listing (or registration) of a therapeutic good in the Register is subject may result in the cancellation of the medicine from the Register (paragraph 30(2)(c) of the Act refers).

There are currently a number of "standard" conditions that are imposed on all, or all relevant, listed medicines by the Secretary at the time of listing. These include conditions relating to the keeping of records, notifying the TGA about the details of product recalls or regulatory action taken in relation to the medicine outside of Australia, holding and providing testing data in relation to claims about sunscreen protection factor, broad spectrum and water resistance for listed medicines that are sunscreens, and in relation to confirming the absence of aristolochic acid in listed medicines that contain certain herbal substances.

The purpose of the Determination is to provide greater transparency and awareness for sponsors of listed medicines about these conditions and the medicines to which they apply, by providing a single and public record of the conditions on the Federal Register of Legislation. This is also designed to ensure that sponsors who are considering applying to list their products in the Register are able to be aware beforehand of the conditions to which their products will be subject if they proceed.

Consultation

The TGA conducted targeted consultation on the proposed codification of conditions with the Complementary and Over the Counter Medicines Regulatory and Technical Forum (ComTech) at ComTech meetings in October 2021, January 2022 and October 2022.

ComTech consists of industry representatives from:

- Complementary Medicines Australia;
- Consumer Health Products Australia;
- ACCORD (representation the hygiene, cosmetic and specialty products industry; and
- the Association of Therapeutic Goods Consultants.

In general, ComTech members were supportive of the transparency that the proposed instrument would provide for industry in relation to conditions that are applies at the time they list their medicine. However, ComTech made their position clear that any additional conditions added to the instrument should be subjected to industry consultation, particularly given that sponsors would not be able to seek an exemption from conditions included in the legislative instrument. Reflecting this feedback, the Determination does not introduce any new conditions of listing, and the TGA has committed to ensuring that any future additions of new conditions to the Determination would be subject to consultation.

The Office of Impact Analysis has advised that the making of the Determination is unlikely to have more than a minor regulatory impact, and therefore an Impact Analysis is not required (OBPR22-03745).

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

The 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 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 (Listed Medicines—Conditions of Listing) Determination 2022*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Listed Medicines—Conditions of Listing) Determination 2022* ("the Determination").

Section 2 – Commencement

This section provides that the 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 Determination is subsection 28(2) of the *Therapeutic Goods Act 1989* ("the Act").

Section 4 – Definitions

This section provides the definitions of key terms used in the Determination, including 'relevant person' and 'specified listed medicines'. The section also notes that some expressions used in the Determination, including 'batch', 'export only medicine', 'manufacture', 'medicine', 'Register' and 'supply', have the same meaning as in the Act.

Section 5 – Listing of Medicines

Subsection 5(1) provides that for subsection 28(2) of the Act, the matters specified in column 2 of the table in Part 1 of Schedule 1, are determined to be conditions to which the listing of specified listed medicines in the Register is subject.

Subsection 5(2) provides that for subsection 28(2) of the Act, the matters specified in column 2 of the table in Part 2 of Schedule 1, are determined to be conditions to which the listing of specified medicines that are sunscreen preparations in the Register is subject.

Subsection 5(3) provides that for subsection 28(2) of the Act, the matters specified in column 2 of the table in Part 3 of Schedule 1, are determined to be conditions to which the listing of specified medicines that may contain aristolochic acids in the Register is subject.

Schedule 1— Conditions for listing

Part 1 of Schedule 1 determines the conditions applicable to specified listed medicines including, that the relevant person must:

- keep records relating to the medicine that are necessary to expedite the recall (if necessary) of a batch of the medicine and to identify the manufacturer of each batch;
- retain records of the distribution of the of the medicine for a period of five years and provide copies of such records to the TGA upon request;
- notify the TGA of any product recall or regulatory action taken in relation to the medicine outside Australia, which is relevant to the quality, safety or efficacy of the medicine distributed in Australia; and
- hold copies of Good Manufacturing Practice agreements in relation to the manufacture, where a step in the manufacture is sub-contracted to a third party.

Part 2 of Schedule 1 determines that where the testing of specified listed medicines that are sunscreens is conducted by AMA Laboratories Inc., the relevant person must hold either, adequate

supplementary in-vitro testing data, relevant testing data on a comparable formula from an independent testing laboratory, or other acceptable justification, to scientifically justify the validity and accuracy of the SPF, broad spectrum and water resistance claims for the medicine. The relevant person must provide such information to the TGA within 10 days, or within such longer period as agreed with the TGA.

Part 3 of Schedule 1 determines the conditions applicable to specified listed medicines that may contain aristolochic acid, including that the relevant person must:

- confirm the absence of aristolochic acids in each batch of the medicine using Liquid Chromatography Mass Spectrometry;
- provide confirmatory evidence to the TGA; and
- not supply a batch of the medicine in Australia until confirmatory evidence is approved in writing by the TGA.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Listed Medicines—Conditions of Listing) 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

Medicines that are listed in the Australian Register of Therapeutic Goods ("the Register") under 26A of the Act are considered to be low risk and are not individually evaluated before those medicines are listed. Medicines that are listed in the Register under section 26AE of the Act are also considered to be low risk, but are evaluated in relation to whether the efficacy of the medicine for the purpose for which it is to be used has been satisfactorily established (these purposes are specific efficacy claims for which the sponsor of the medicine holds supporting evidence). When listed under section 26AE, these listed medicines are commonly referred to as 'assessed listed medicines'.

As the safety and quality of medicines listed under section 26A and 26AE are not evaluated by the TGA before being given marketing approval, the Act contains mechanisms to help ensure that those medicines are of appropriate quality and able to be used safely by consumers. In particular, medicines listed under section 26A and 26AE may only contain ingredients from an approved list of ingredients that have been evaluated in relation to their quality, safety and suitability for use in such medicines (currently set out in the *Therapeutic Goods (Permissible Ingredients) Determination (No. 5) 2022*). Further, sponsors of such medicines may only use indications (statements of therapeutic use) from a list of pre-approved low-level indications (currently set out in the *Therapeutic Goods (Permissible Indications) Determination (No.1) 2021*) to ensure that these products do not overstate their therapeutic benefits.

Part 3-2 of the Act sets out requirements relating to the listing of therapeutic goods on the Register. Relevantly, section 28 of the Act provides a mechanism for imposing conditions of listing or registration that are to be applied to medicines entered in the Register. There are three kinds of conditions that may apply to listed medicines:

- conditions that automatically apply to all medicines (i.e., listed medicines and registered medicines) from the date of inclusion of the medicine in the Register;
- additional automatic conditions that only apply to listed medicines from the time of listing in the Register; and
- discretionary conditions that the Secretary may apply to a medicine at any time after the medicine is listed (or registered) in the Register.

A refusal or failure to comply with any condition to which the listing (or registration) of a therapeutic good in the Register is subject may result in the cancellation of the medicine from the Register (paragraph 30(2)(c) of the Act refers).

Subsection 28(1) of the Act provides that the registration or listing of therapeutic goods is subject to the conditions set out in a determination under subsection (2). Subsection 28(2) relevantly provides that the Minister may, by legislative instrument make a determination setting conditions that relate to:

- the manufacture of the goods; or
- the custody, use, supply, disposal or destruction of the goods; or
- the keeping of records relating to the goods; or

- matters dealt with in, or matters additional to matters dealt with in, standards applicable to the goods; or
- such other matters relating to the goods as the Minister thinks appropriate.

The *Therapeutic Goods (Listed Medicines—Conditions of Listing) Determination 2022* ("the determination") is made under subsection 28(2) of the Act, and has the effect of specifying, for the purposes of subsection 28(1) of the Act, standard conditions that will automatically apply to the listing of certain medicines that are listed in the Register under section 26A or 26AE of the Act.

Human rights implications

The determination 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 determination takes positive steps to promote the right to health by ensuring the safety and quality of therapeutic goods that are listed medicines through specifying, in a clear and transparent manner, important safety-related conditions to which the listing in the Register of listed medicines is subject. These include, for instance, a condition requiring that the details of any product recall or regulatory action that is taken in relation to a listed medicine outside Australia, and that is relevant to the medicine's quality, safety or efficacy, must be notified to the TGA. Such conditions are particularly important to ensure the safety listed medicines, as these goods are usually available for self-selection by consumers without a requirement to first obtain a prescription, or to seek advice from a registered health professional.

Conclusion

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