**EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*

*Therapeutic Goods (Prescription Medicines⎯Transparency Measures) Specification 2020*

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.

Section 61 of the Act relevantly provides that the Secretary may release specified therapeutic goods information to the public, and certain organisations, bodies or authorities. Subsection 61(1) of the Act provides that therapeutic goods information means, for the purposes of the section, information relating to therapeutic goods, which is held by the Department and relates to the performance of the Department’s functions.

Under subsection 61(5C) of the Act, the Secretary may release to the public kinds of therapeutic goods information specified under subsection 61(5D) of the Act. Subsection 61(5D) provides that the Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purposes of subsection 61(5C) of the Act.

The *Therapeutic Goods (Prescription Medicines⎯Transparency Measures) Specification 2020* (“the Specification”) is made under subsection 61(5D) of the Act to specify kinds of therapeutic goods information that the Secretary may release to the public under subsection 61(5C) of the Act. The purpose of the Specification is to facilitate the publication of certain therapeutic goods information relating to applications for the registration of prescription medicines in the Australian Register of Therapeutic Goods (“the Register”).

**Background**

Prescription medicines are registered in the Register under section 25AB of the Act, following evaluation by the Secretary in relation to a number of matters specified in section 25 of the Act, particularly in relation to quality, safety and efficacy.

The Specification is intended to address concerns from patients, carers and health professionals regarding a lack of information about the potential availability of new prescription medicines in Australia. To their frustration, information relating to the market authorisation of a prescription medicine only becomes publicly available when the medicine is registered. The TGA can “neither confirm nor deny” receipt of an application for registration of a medicine for commercial-in-confidence reasons.

The purpose of the Specification is to enable the Secretary to release specified information in relation to applications for the registration of certain new prescription medicines. This will increase transparency in relation to such applications that are being evaluated in a way that better informs patients, carers and health professionals with certain information that may inform potential new treatment options.

The Specification enables earlier publication of certain information about significant, innovative new medicines that have passed preliminary assessment and are being evaluated for their suitability for registration in the Register. Specifically, the Specification authorises the publication of information relating to two categories of medicines of greatest interest to patients, carers and health professionals:

* a new prescription medicine, which is defined in regulation 2 of the *Therapeutic Goods Regulations 1990* (“the Regulations”) as a prescription medicine that contains a chemical, biological or radiopharmaceutical active ingredient that has not previously been included in an entry in the Register, or a fixed combination of chemical, biological or radiopharmaceutical active ingredients at least one of which has not previously been included in an entry in the Register;
* a new indications medicine, which is defined in regulation 2 of the Regulations as a medicine that has the same chemical, biological or radiopharmaceutical active ingredient (or fixed combination of such ingredients) as another prescription medicine included in the Register and does not have the same indications as that other medicine.

However, the Specification does not authorise the publication of information in relation to a medicine that is a biosimilar in relation to a registered medicine.

The Specification supports the approach of greater transparency in relation to applications for marketing approval of these medicines by enabling the Secretary to publish the following kinds of therapeutic goods information:

* the name of the medicine;
* the applicant for the registration of the medicine;
* the active ingredients of the medicine;
* a summary of indications for the medicine (being, the therapeutic uses of the medicine); and
* the application type—whether the medicine contains or is a new chemical entity (type A), a new combination of chemical, biological or radiopharmaceutical active ingredients (type B) or an extension of indications (where a medicine is the same as an existing medicine in the Register but has different indications) (type C).

**Consultation**

A regulation impact statement was not required in relation to the development of the Specification, as the measure is unlikely to have more than a minor regulatory impact (OBPR ID 42952).

On 15 February 2019, the TGA released a public consultation paper on the proposal to publish information regarding a prescription medicine that is under evaluation, including the types of prescription medicine applications that should be covered. The consultation closed on 29 March 2019 and a total of 39 submissions were received from industry, health professionals, consumer representative groups, regulatory consultants and government.

The submissions generally supported the proposal for more information about major innovator prescription medicines under evaluation. In response, the Australian Government provided approval to implement this measure to make a new specification to enable early publication of information relating to major innovator medicine applications. Further targeted consultation with industry stakeholders was conducted to refine the implementation options between 27 March and 9 June 2020.

The generic and biosimilar sector did not raise any objections about this measure, consistently with its responses to the 2019 consultation. The innovator sector continued to be supportive, but reiterated its request to publish information relating to both innovator and generic applications. The innovator sector also requested minor modifications to the timeframe for implementation and the level of detail of the information published.

The Department proposes to only publish a short, high level, description of the proposed indications (therapeutic uses) for the relevant medicines, rather than the full indication as initially proposed. This would still provide useful information to the public.

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

The Specification is compatible with 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 Specification is a disallowable legislative instrumentfor the purposes of the *Legislation Act 2003* and commences on 1 January 2021 on the Federal Register of Legislation.

**Attachment A**

**Details of the *Therapeutic Goods (Prescription Medicines⎯Transparency Measures) Specification 2020***

**Section 1 Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Prescription Medicines⎯Transparency Measures) Specification 2020* (“the Specification”).

**Section 2 Commencement**

This section provides that the Specification commences on 1 January 2021.

**Section 3 Authority**

This section provides that the legislative authority for making the Specification is subsection 61(5D) of the *Therapeutic Goods Act 1989* (“the Act”).

**Section 4 Definitions**

This section provides the definitions for certain terms used in the Specification, including ‘new indications medicine’, ‘new prescription medicine’ and ‘registered medicine’. The section also notes that a number of terms have the meaning given in subsection 3(1) of the Act, including ‘medicine’, ‘passed preliminary assessment’ and ‘registered goods’.

**Section 5 Release of therapeutic goods information**

This section provides that the kinds of therapeutic goods information mentioned in column 2 of the table in Schedule 1, as described in column 3 of the corresponding item, are specified for the purpose of subsection 61(5C) of the Act. The effect of this section is to enable the Secretary to release to the public therapeutic goods information of the kind set out in the table in Schedule 1 to the Specification.

**Schedule 1 Specified kinds of therapeutic goods information**

This Schedule specifies the kinds of therapeutic goods information, for the purposes of section 5 of the Specification, which may be released to the public by the Secretary under subsection 61(5C) of the Act.

**Attachment B**

**Statement of Compatibility with Human Rights**

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

***Therapeutic Goods (Prescription Medicines⎯Transparency Measures) Specification 2020***

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**

The *Therapeutic Goods (Prescription Medicines⎯Transparency Measures) Specification 2020* (“the instrument”) is made under subsection 61(5D) of the *Therapeutic Goods Act 1989* (“the Act”). The purpose of the instrument is to specify kinds of therapeutic goods information that may be released to the public by the Secretary under subsection 61(5C) of the Act.

The instrument facilitates the publication of certain therapeutic goods information relating to applications for marketing approval for prescription medicines for which registration in the Australian Register of Therapeutic Goods is sought by pharmaceutical companies responsible for their development and marketing.

The instrument is intended to address concerns from patients, carers and health professionals regarding a lack of information about the potential availability of new medicines in Australia. In response to such concerns, the Australian Government is proposing measures to increase transparency in relation to applications for new prescription medicines and new indications medicines that are being evaluated in a way that better informs patients, carers and health professionals with potential new treatment options, while balancing concerns from industry regarding confidentiality of commercial information.

The instrument enables earlier publication of certain information about significant, innovative new medicines that have passed preliminary assessment and are being evaluated for their suitability for registration in the Register. Specifically, the instrument authorises the publication of information relating to two categories of medicines of greatest interest to patients, carers and health professionals:

* a new prescription medicine, which is defined in regulation 2 of the *Therapeutic Goods Regulations 1990* (“the Regulations”) as a prescription medicine that contains a chemical, biological or radiopharmaceutical active ingredient that has not previously been included in an entry in the Register, or a fixed combination of chemical, biological or radiopharmaceutical active ingredients at least one of which has not previously been included in an entry in the Register;
* a new indications medicine, which is defined in regulation 2 of the Regulations as a medicine that has the same chemical, biological or radiopharmaceutical active ingredient (or fixed combination of such ingredients) as another prescription medicine included in the Register and does not have the same indications as that other medicine;

However, the Specification does not authorise the publication of information in relation to a medicine that is a biosimilar in relation to a registered medicine.

The instrument supports the approach of greater transparency in relation to applications for marketing approval of these medicines by enabling the Secretary to publish the following kinds of therapeutic goods information:

* the name of the medicine;
* the applicant for the registration of the medicine;
* the active ingredients of the medicine;
* a summary of indications for the medicine (being, the therapeutic uses of the medicine); and
* the application type—whether the medicine contains or is a new chemical entity (type A), a new combination of chemical, biological or radiopharmaceutical active ingredients (type B) or an extension of indications (where a medicine is the same as an existing medicine in the Register but has different indications) (type C).

**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 helping to ensure greater transparency and awareness about new prescription medicines and new indications medicines that are under evaluation for marketing approval in Australia. The publication of the kinds of therapeutic goods information specified in the instrument in relation to such medicines is intended to better inform patients, carers and health professionals regarding significant new medicines that may be able to be accessed in the near future, and thereby inform potential treatment options.

**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.