EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Information (Sharing of Committee Information) Specification 2017

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy/performance and timely availability of therapeutic goods that are used in or exported from Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health, is responsible for administering the Act.

Section 61 of the Act lists a number of persons or organisations, such as the World Health Organisation and State and Territory authorities that have functions relating to therapeutic goods, to which the Secretary of the Department of Health can release specified kinds of therapeutic goods information. Section 61 also allows the Minister for Health to make a legislative instrument setting out other circumstances in which the Secretary can release therapeutic goods information under that section.

The Therapeutic Goods Information (Sharing of Committee Information) Specification 2017 (the Specification) is made by the Minister under subsection 61(5AB) of the Act and specifies kinds of therapeutic goods information that can be released, bodies and kinds of persons to whom that information can be released, and the purposes for which it can be released, by the Secretary under subsection 61(5AA) of the Act.

The making of the Specification has the effect of permitting the Secretary to release therapeutic goods information of a kind mentioned in the Specification to the bodies and the kinds of persons mentioned in the Specification, for the purposes set out in the Specification.

Therapeutic goods information in this context is defined in subsection 61(1) of the Act as, relevantly, information in relation to therapeutic goods that is held by the Department and which relates to the performance of the Department's functions.

The Specification repeals the previous *Therapeutic Goods Information (Sharing of Committee Information) Specification 2014*. The purpose of the Specification is to reflect changes that have been made recently to the Committees established under the *Therapeutic Goods Regulations 1990* (the Regulations) to ensure appropriate sharing of Committee information may continue, and to make certain other minor amendments to keep the Specification up- to- date.

The Specification commenced on the day after it was registered on the Federal Register of Legislation.

BACKGROUND

In 2014 and 2015, an independent panel examined Australia's medicines and medical devices regulatory framework- the Expert Review of Medicines and Medical Devices Regulation (the MMDR) and made a number of recommendations.

Consistent with the MMDR, the Government agreed to rationalise the number of statutory advisory committees from the nine committees previously established in Divisions 1-1EB of Part 6 of the Regulations, to a more streamlined structure of five advisory committees, from 1 January 2017.

The previous nine committees were the Therapeutic Goods Committee (TGC), the Advisory Committee on Prescription Medicines (ACPM), the Advisory Committee on Non-prescription Medicines (ACNM), the Advisory Committee on the Safety of Medicines (ACSOM), the Advisory Committee on Medical Devices (ACMD), the Advisory Committee on the Safety of Medical Devices (ACSMD), the Advisory Committee on Complementary Medicines (ACCM), the Advisory Committee on Biologicals (ACB) and the Advisory Committee on the Safety of Vaccines (ACSOV).

The committees that constitute the new structure are the Advisory Committee on Medicines (ACM), the Advisory Committee on Medical Devices (ACMD), the Advisory Committee on Complementary Medicines (ACCM), the Advisory Committee on Biologicals (ACB) and the Advisory Committee on Vaccines (ACV).

The ACM will now cover the roles of the previous ACPM, ACNM and ACSM, each of which has been replaced. The ACMD will continue (with some changes), and will cover the role of the previous ACSMD, which has also been replaced. The ACCM and the ACB will continue (with some changes) and the previous ACSOV has been replaced by a broader ACV.

The Therapeutic Goods Committee has also been abolished, but its core role of advising and making recommendations about standards for therapeutic goods (other than medical devices) is preserved across relevant new or continuing committees (the ACM, ACCM, ACB and ACV).

The committees established under Part 6 of the Regulations provide advice and make recommendations to the Minister or the Secretary on a range of matters relating to therapeutic goods.

The Specification has the effect of permitting the Secretary to release to those bodies listed in it, and to their employees, members or agents, therapeutic goods information relating to the TGA advisory committees established under Divisions 1A-1EB of Part 6 of the Regulations.

The kinds of information that will be able to be released by the Secretary regarding these committees include the advice and/or recommendations provided by an advisory committee, committee agenda papers and minutes of committee meetings and brief descriptions of any outcomes arising from such meetings.

From time to time, the advice or recommendations provided by one of these committees is needed by another committee or body established to provide specialist advice to the Government on particular matters, in their consideration of matters before them.

For example, advice provided by the (previous) ACSOV about the safety of a vaccine proposed to be included as part of the National Immunisation Program may be shared with the National Immunisation Committee (which is responsible for overseeing the development,

implementation and delivery of the National Immunisation Program), the Australian Technical Advisory Group on Immunisation and the National Centre for Immunisation Research and Surveillance (which undertakes research aimed at reducing the incidence of vaccine preventable diseases and improving vaccine uptake in adults and children).

The bodies to whom the Secretary will be able to provide committee information are principally entities established to advise the Government on matters relating to human health including, for example, the Drug Utilisation Sub Committee of the Pharmaceutical Benefits Advisory Committee, which assesses estimates of the projected usage and financial cost of medicines in Australia.

The purpose of releasing the information to other bodies and advisory committees is to facilitate the sharing of information in the interest of public health and safety.

The kinds of therapeutic goods information that the Secretary can decide to release, the bodies and kinds of persons to whom the Secretary can decide to release that information and the purposes for which the Secretary can decide to release that information, are set out in Schedule 1 to the Specification.

There may be instances where it would be of benefit for an advisory committee to have regard to advice or recommendations made by an earlier committee, or agenda papers considered by earlier committees, previously established under the Regulations- for example, if a relatively rare kind of product is being considered that is not often seen, and an earlier committee previously discussed a similar product. As such, the definition of Committee has been expanded in the Specification to accommodate that.

CONSULTATION

Consultation was not undertaken in relation to the Specification as the provision of committee information as set out in the instrument is considered to be of a minor and machinery nature and is not considered to substantially alter existing arrangements.

This is because the provision of the information concerned to the bodies listed in the Specification reflects an administrative practice that has occurred from time to time of providing such information to those bodies to strengthen collaboration between the TGA and its advisory committees and those other bodies.

However, consultation on the committee restructure was carried out during, and as part of, the Expert Review's processes as part of MMDR in 2014-2015.

The Specification is a legislative instrument for the purposes of the *Legislation Act 2003*.

In relation to compatibility with human rights, it is considered that the Specification 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*, and a Statement of Compatibility setting that out in further detail is set out below.

Statement of Compatibility with Human Rights for a legislative instrument that raises human rights issues

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

Therapeutic Goods Information (Sharing of Committee Information) Specification 2017

This 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 Instrument

The *Therapeutic Goods Information (Sharing of Committee Information) Specification 2017* (the Specification) is made by the Minister for Health under subsection 61(5AB) of the *Therapeutic Goods Act 1989* (the Act). The effect of making the Specification is that it will permit the Secretary of the Department of Health to release information that relates to the committees established under Divisions 1A-1EB of Part 6 of the *Therapeutic Goods Regulations 1990* (the Regulations), or any of the committees previously established under the Regulations, to the bodies or kinds of persons specified in the instrument, in the interests of public health and safety. For example, the Specification will allow the Secretary to provide advice of the previous Advisory Committee on the Safety of Vaccines to the National Immunisation Committee, or the National Centre for Immunisation Research and Surveillance.

Human rights implications

The information authorised to be released under the Specification will contain a small amount of personal information within the meaning of the *Privacy Act 1988* – engaging the right to privacy in article 17 of the International Covenant on Civil and Political Rights (the ICCPR).

This will principally be in the form of:

- the names and, on occasion, contact details, of committee members and TGA staff as part of the agenda papers for committee meetings;
- the names of a small number of TGA staff members as contact points for further information as part of the meeting statements; and
- the names of attending committee members, special advisors and other guest experts, and the names and positions of attending TGA staff members as part of the minutes of those meetings.

The release of this information is considered to be justified in relation to the engagement of article 17:

- in relation to committee member information, the release will be either consistent with information about such committee members already present on the TGA's website (with committee members' consent), or its release will be subject to the specific consent of the relevant members; and

- in relation to the staff member details, because this information is necessary to allow the bodies to whom the committee information is being provided to be able to contact the TGA for further information or discussions if necessary (e.g. to clarify a particular point of advice or a recommendation made by a committee).

Both of the above points ultimately relate to supporting the protection of public health.

Conclusion

This legislative instrument is compatible with human rights because, to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate.

ROSS HAWKINS, delegate of the Minister for Health