**EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*

*Therapeutic Goods Information (Sharing information about in-house in vitro diagnostic medical devices) 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 information about in-house in vitro diagnostic medical devices) 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 effect of making the Specification is that it will permit the Secretary of the Department of Health to release certain therapeutic goods information that relates to in-house in vitro diagnostic (IVD) medical devices, to NATA, the National Association of Testing Authorities, of Australia, to facilitate the sharing and considering of information in the interest of public health and safety, including in particular, the sharing and considering of information relating to the quality, safety or performance of in-house IVDs.

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

**BACKGROUND**

The IVD medical device regulatory framework was introduced on 1 July 2010 and is designed to ensure all IVD medical devices, including in-house IVD medical devices, undergo a level of regulatory scrutiny that is commensurate with the risks associated with their use. The framework has a four-tier classification scheme with Class 4 IVD medical devices representing the highest risk classification. The relevant conformity assessment procedures for laboratories that manufacture in-house IVD medical devices are set out in Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the TG MD Regulations). The conformity assessment procedures for in-house IVD medical devices utilise the existing system of laboratory oversight in Australia provided by NATA. NATA is Australia’s national authority for accreditation of testing laboratories.

Laboratories engaged in the manufacture of Class 4 in-house IVD medical devices are required to include these in the Australian Register of Therapeutic Goods (ARTG) and can apply the conformity assessment procedures set out in Part 6B of Schedule 3 to the TG MD Regulations which allows the use of existing NATA accreditation to support an application for inclusion in the ARTG. Upon application, the laboratory is requested to provide information to the TGA to allow assessment of compliance of the device with the essential principles. Laboratories engaged in the manufacture of Class 1-3 in-house IVD medical devices are exempt from the requirement to include these in the ARTG, subject to compliance with the conformity assessment procedures set out in Part 6A of Schedule 3 to the TG MD Regulations. Laboratories are able to meet these procedures provided they maintain the required NATA accreditation and submit a notification to the TGA of the Class 1-3 in-house IVD medical devices being manufactured. Regulatory oversight of these laboratories is therefore designated to NATA, without the need for additional assessment of these devices by the TGA. All laboratories engaged in the manufacture of in-house IVD medical devices are required to have procedures in place for post market monitoring and must report adverse events to the TGA.

A memorandum of understanding (MOU) has been developed between the TGA and NATA to facilitate the achievement of the regulatory objective of ensuring that only properly manufactured and validated in-house IVD medical devices are used in laboratories. The MoU clarifies the understanding of each party in relation to their roles, responsibilities and undertakings in relation to ensuring laboratories engaged in the manufacture of in-house IVD medical devices comply with the relevant conformity assessment procedures, including post market reporting requirements; and formalises the arrangements for the exchange of information and material between the two parties on matters relating to the accreditation of laboratories engaged in the manufacture of in-house IVD medical devices.

**CONSULTATION**

The Specification is intended to support the operation of the MOU between TGA and NATA (as per Clause 5.7 of the MoU). The MOU was developed in consultation with NATA and facilitates the exchange of information on matters relating to the compliance of NATA-accredited laboratories engaged in the manufacture of in-house IVD medical devices with conformity assessment procedures set out in Schedule 3 to the TG MD Regulations.

The MOU is a publicly available document that can be viewed without charge on the NATA website, <https://www.nata.com.au/nata/about-nata/agreements>. Laboratories engaged in the manufacture of in-house IVD medical devices are aware of the MoU and upon submission of an application for inclusion (for a Class 4 in-house IVD medical device) or a notification (for Class 1-3in-house medical devices) certify that the information provided is current and correct and acknowledge that any information provided to support an application for inclusion or notification may be shared with NATA.

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 information about in-house in vitro diagnostic medical devices) 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 information about in-house in vitro diagnostic medical devices) 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 certain information that relates to in-house in vitro diagnostic (IVD) medical devices, to NATA, the National Association of Testing Authorities, of Australia, to facilitate the sharing and considering of information in the interest of public health and safety, including in particular, the sharing and considering of information relating to the quality, safety or performance of in-house IVDs. For example, the Specification will allow the sharing of information, including technical or scientific data, relating to a reported adverse event for a Class 4 in-house IVD that raises safety concerns with respect to the performance or competence of a NATA-accredited laboratory engaged in the manufacture of in-house IVDs.

**Human rights implications**

This legislative instrument does not engage any of the applicable rights or freedoms. The information to be released does not include personal information within the meaning of the *Privacy Act 1988*.

**Conclusion**

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

**Adriana Platona, delegate of the Minister for Health**