Therapeutic Goods Information (Sharing information about in-house in vitro diagnostic medical devices) Specification 2017

Therapeutic Goods Act 1989

I, ADRIANA PLATONA, a delegate of the Minister for Health, make this Specification under subsection 61(5AB) of the *Therapeutic Goods Act 1989*.

Dated 25 July 2017

(Signed by)

ADRIANA PLATONA
Delegate of the Minister for Health

1 Name of Specification

This Specification is the *Therapeutic Goods Information (Sharing information about in-house in vitro diagnostic medical devices) Specification 2017*.

2 Commencement

This Specification commences on the day after it is registered.

3 Definitions

In this Specification:

Act means the *Therapeutic Goods Act 1989*.

ARTG means the Australian Register of Therapeutic Goods.

IVD medical device has the same meaning as in the MD Regulations.

in-house IVD medical device (in-house IVD) has the same meaning as in the MD Regulations.

MD Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

NATA means the National Association of Testing Authorities, of Australia.

TGA means the Therapeutic Goods Administration, which is part of the Department of Health.

4 Therapeutic goods information, persons and purposes

The kinds of therapeutic goods information, persons, bodies and purposes, mentioned in Schedule 1 are specified under subsection 61(5AB) of the Act, for the purposes of subsection 61(5AA) of the Act.

Schedule 1 Specified kinds of therapeutic goods information, persons, bodies and purposes

(section 4)

The following kinds of therapeutic goods information, persons, bodies and purposes:

Note 1: The following specified kinds of therapeutic goods information may be released by the Secretary under subsection 61(5AA) of the Act to the following specified bodies and kinds of persons, for the following specified purposes.

Note 2: References in the Table below to clauses are references to clauses in the Memorandum of Understanding between the Commonwealth of Australia and NATA, in relation to In-House In Vitro Diagnostic Medical Devices, made on 2 September 2016.

1. Therapeutic goods information:

The following kinds of therapeutic goods information, being information that relates to in-house IVDs and that is held by the TGA:

Item	Information	Description
(a)	Information relating to the assessment of laboratories engaged in the manufacture of in-house IVDs [clause 5.1(c)]	For example, sharing of information related to the assessment of a laboratory engaged in the manufacture of a Class 4 in-house IVD in relation to an application for inclusion in the ARTG, where the laboratory is utilising their existing NATA accreditation to support an application for inclusion.
(b)	Information relating to trends in technology and laboratory practice regarding in-house IVDs, including in relation to the clinical utility, misuse or performance of in-house IVDs [clause 5.5]	For example, sharing of information for the development of guidance for industry in relation to emerging technologies.
(c)	Information relating to concerns of the TGA about the performance or competence of NATA-accredited laboratories engaged in the manufacture of in-house IVDs [clauses 6.9 and 7.6]	For example, sharing of information relating to an adverse event for an in-house IVD that raises concerns with respect to the performance of the in-house IVD.
(d)	The following information relating to a laboratory engaged in the manufacture of in-house IVDs:	For example, sharing of information in relation to a notification provided to the TGA by a laboratory of their Class 1-3 in-house IVDs being manufactured, in order to assist

Item	Information	Description
	• a list of all Class 1-3 in-house IVDs manufactured by the laboratory, and the date the laboratory last notified the TGA of the details of the Class 1-3 in-house IVDs that it was manufacturing at that time; • a list of all Class 4 in-house IVDs manufactured by the laboratory; • details of any assessments being undertaken in relation to any technical or scientific data that supports the performance of a Class 4 in-house IVD that was provided by the applicant with their application for inclusion in the ARTG; and • details of any post-market investigations undertaken by the TGA relating to aspects of concern, including any technical or scientific data provided by a laboratory, in relation to any in-house IVDs manufactured by the laboratory; [clause 7.2] • information of a kind which the laboratory is required to notify the Secretary of as part of their post market system requirements in accordance with paragraph 6A.4(2)(c) of Schedule 3 to the MD Regulations (for Class 1, 2 or 3 in-house IVDs) or paragraph 6B.5(2)(c) of Schedule 3 to the MD Regulations (for Class 4 in-house IVDs); [clause 7.3]	NATA prepare for an accreditation assessment activity for that laboratory. For example, sharing of information relating to the number of Class 4 in-house IVDs manufactured by a NATA-accredited laboratory that are included in the ARTG (or are otherwise exempt from inclusion). For example, sharing of information in relation to the assessment of any technical or scientific data provided by a NATA-accredited laboratory to support their application for inclusion of a Class 4 in-house IVD in the ARTG (where the laboratory is utilising their NATA accreditation to support an application for inclusion). For example, 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.

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2. Persons and bodies:

(a) NATA.

3. Purposes:

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 being manufactured by NATA-accredited laboratories.

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislation kept under the *Legislation Act 2003.* See http://www.frl.gov.au