



**Australian Government**

**Department of Health and Ageing**  
Therapeutic Goods Administration

# Overview of the new regulatory framework for in vitro diagnostic medical devices (IVDs)

July 2011

**TGA** Health Safety  
Regulation



## About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

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## Disclaimer

This document is intended to provide an overview of the new regulatory framework for in vitro diagnostic medical devices (IVDs). Under the framework, IVDs are regulated as medical devices, and the provisions of the *Therapeutic Goods (Medical Devices) Regulations 2002* have been expanded to include IVDs.

The TGA is not liable for any loss whatsoever whether due to negligence or otherwise arising from the use of or reliance on this document.

## Further information

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## Introduction

In vitro diagnostic medical devices (IVDs) are, in general, pathology tests and related instrumentation used to carry out testing on human samples, where the results are intended to assist in clinical diagnosis or in making decisions concerning clinical management. IVDs are typically used in diagnostic laboratories, at the point of care, and in the home.

Until 1 July 2010, the level of IVD regulation in Australia was very limited. IVDs for Human Immunodeficiency Virus (HIV) and hepatitis C virus (HCV) were subject to extensive pre-market review and a small number of IVDs received limited review, whereas the vast majority of IVDs were exempt from pre-market regulatory scrutiny. This system has resulted in a high standard of IVDs available for HIV and HCV testing however most IVDs were not subject to appropriate regulatory control, there was potential for inadequate protection of public and personal health, and the system was out of step with international best practice.

A new regulatory framework commenced on 1 July 2010 that ensures all IVDs will undergo a level of regulatory scrutiny that is commensurate with the risks associated with their use. The framework adopts the philosophies and recommendations of the [Global Harmonization Task Force \(GHTF\)](#) for IVDs, ensuring that requirements are internationally aligned. The legislation incorporates accepted best practice relating to safety, quality and risk management procedures, and provides the flexibility and capacity to regulate new and changing technology and emerging diseases.

Under the new framework IVDs are regulated as a subset of medical devices. The Therapeutic Goods Regulations (Medical Devices) 2002 have been amended to include IVDs. Due to the unique nature of IVDs there are several points of difference between the regulation of IVDs and other medical devices. These include a separate classification system for IVDs and some additional essential principles specific to IVDs.

The *Therapeutic Goods Act 1989* defines a medical device as:

‘any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended by the person under whose name it is to be supplied, to be used for human beings for the purpose of one or more of the following:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; or

an accessory to such an instrument, apparatus, appliance, material or other article.’

The regulations define a medical device to be an IVD if:

- it is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with another diagnostic product for in vitro use; and
- it is intended by the manufacturer to be used in vitro for the examination of specimens derived from the human body, solely or principally for:

- giving information about a physiological or pathological state or a congenital abnormality; or
- determining safety and compatibility with a potential recipient; or
- monitoring therapeutic measures.

The definition of an IVD specifically excludes products intended for general laboratory use that are not manufactured, sold or presented for use as an IVD. Products that are not intended for therapeutic use, including tests for parentage and kinship testing, drug tests used in sport, most tests for alcohol or the detection of illicit drugs (unless a medical intended use is assigned), fall outside the legislation. Products that are intended exclusively for veterinary purposes will also fall outside the scope of the regulations.

The new regulatory framework has the following features:

- all IVDs for therapeutic use are included;
- continued inclusion in the Australian Register of Therapeutic Goods (ARTG) as a basis for legal supply;
- all IVDs to comply with a set of essential principles for the quality, safety and performance of the IVD;
- an IVD classification scheme based on different levels of risk for each class of device;
- a choice of procedures (known as conformity assessment procedures), based on the risk classification, to be applied by manufacturers to demonstrate initial and on-going compliance with the essential principles;
- use of compliance with recognised standards as a means to demonstrate that the essential principles and conformity assessment procedures have been met;
- provision for post market activities, including compliance testing, adverse event reporting and recalls;
- mechanisms for access to IVDs not entered on the ARTG in cases of special need;
- transition periods to enable manufacturers and sponsors of IVDs that are currently supplied to meet the requirements of the new framework.

It should be noted that as well as the requirements of the new regulatory framework, other legislation relevant to the supply of an IVD will still apply, for example the Customs Act 1901.

## Key elements of the framework

Information on some of the more important elements of the framework can be found in separate guidelines on the TGA website. These documents are:

- [Classification of IVD medical devices](#)
- [Conformity assessment overview \(IVDs\)](#)
- [The use of GMDN codes for IVD medical devices in Australia](#)
- [Including IVD medical devices in the ARTG](#)

Other key elements are addressed below.

## Regulation of all IVDs for therapeutic use

The new framework applies to all products that fit the definition of an IVD and are for therapeutic use. An IVD must be included on the Australian Register of Therapeutic Goods (ARTG) prior to being imported, supplied in, or exported from Australia however provision has been made for

access to IVDs not included on the ARTG in the event of possible or actual emergencies. Information on IVDs included on the ARTG will be available for public access.

The new framework includes regulation of in-house IVDs. In-house IVDs are developed within a laboratory or laboratory network and are not supplied in a commercial context.

An in-house IVD is:

- developed de novo; or
- developed or modified from a published source; or
- developed or modified from any other source, or
- used for a purpose other than that intended by the manufacturer, within the confines or scope of a laboratory or a laboratory network, and
- is not supplied for use outside the laboratory or laboratory network.

## Essential principles

The essential principles set out the requirements relating to the safety and performance characteristics of medical devices, including IVDs. Compliance with relevant essential principles ensures that use of the IVD does not compromise the health or safety of patients, users or any other person, and that benefits arising from use of the IVD outweigh the risks.

The essential principles identify performance levels required, hazards to be addressed, or issues to be considered, but do not necessarily specify how the principles can be satisfied or complied with. This approach provides flexibility for manufacturers and allows for technological advances and future changes in the application of medical devices.

The essential principles are divided into two main types:

- general principles - which apply to all medical devices; and
- specific principles - which are only applicable to some medical devices, and include seven principles that are specific to IVDs.

It is a manufacturer's responsibility to demonstrate that their IVD complies with the relevant essential principles. Justification must be provided for any specific principle that the manufacturer considers is not applicable.

## Transition Period

The transition period to allow time for IVDs that are currently listed or registered on the ARTG, or that are currently exempt from entry, to be included on the ARTG in accordance with the requirements of the new framework, is 4 years.

IVDs that are currently listed, registered or exempt will be required to become included IVDs, or to have an effective application for inclusion with the TGA prior to 1 July 2014 in order to maintain continuous legal supply. Until an IVD transitions to the new framework, Chapter 3 of the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990* will continue to apply.

Any new IVDs introduced to the Australian market after commencement of the new framework on 1 July 2010 must be included on the ARTG prior to legal supply.

## Clinical trials and access to IVDs not included on the ARTG

The new framework provides for access to IVDs not included on the ARTG. The following special access and supply arrangements will be available:

- Clinical trial schemes - exemption (CTX) or notification (CTN) schemes, which both require human research ethics committee approval;
- Special Access Scheme - where arrangements are dependant on the risk categorisation of the patient;
- Authorised Prescribers;
- Importation for personal use.

There is also provision for samples of IVDs that are to be imported, exported or supplied for any purpose that does not involve the reporting of patient results, for example IVDs for submission to a regulatory authority, demonstration or laboratory analysis.

## Access to IVDs for self-testing (home use)

IVDs intended for self-testing are tests that are used in the home or a similar environment and are not carried out under the supervision of a health care provider. Certain types of self-testing IVDs will be prohibited from supply. These include:

- IVDs used to test for pathogens or diagnose notifiable infectious diseases;
- tests to determine genetic traits;
- IVDs used to test for serious disorders, for example cancer or myocardial infarction.

## Post-market vigilance and monitoring

Manufacturers and sponsors are required to actively monitor the performance of their products in the market place. Manufacturers must have in place systems to review experience from the use of a device once it is approved for supply, and if any malfunction, deterioration or inadequacy is identified with the design or production of the IVD, implement appropriate corrective action.

There is a requirement for sponsors/manufacturers to report adverse events involving their IVDs to the TGA within statutory timeframes that depend on the seriousness of the incident. Health care professionals and consumers are also able to report any suspected problems with an IVD which has or may present a health hazard. The TGA will review all adverse event reports and undertake investigations if required.

Post market surveillance activities for IVDs will include the compliance testing of IVDs and a review of technical files and certification by the TGA.

## Fees and Charges

The TGA recovers the full cost of its regulatory activities within the scope of the *Therapeutic Goods Act 1989* through fees and charges for services provided to the sponsors and manufacturers of therapeutic products.

The schedule of fees and charges under the new IVD framework will be available on the TGA website.

## **Offences, penalties and cancellations**

### ***Offences and penalties***

The *Therapeutic Goods Act 1989* includes penalties for a range of offences relating to the illegal importation, exportation, manufacture or supply of medical devices, making false declarations, non-compliance with the essential principles and so on.

### ***Cancellations***

An IVD that is included on the ARTG can only be cancelled by the TGA in situations where there has been a severe breach of the law or, more often, where there is a safety concern associated with the use of the product. If a sponsor cannot satisfactorily demonstrate the quality, safety and performance of their product and a decision to cancel relevant ARTG entries is confirmed, the sponsor will be required to recall any affected products that remain in circulation.

### ***Enforcement***

The Regulatory Compliance Unit of the TGA:

- monitors compliance with the legislation;
- investigates alleged breaches of the legislation; and
- initiates criminal prosecutions where appropriate.

Information regarding the illegal supply of IVDs should be referred to the TGA Regulatory Compliance Unit.



## **Therapeutic Goods Administration**

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