Australian Government
Department of Health
Therapeutic Goods Administration

The regulation of IVD medical devices

Euan Miller
Assistant Director, Devices Application and Verification
Devices Authorisation Branch
Market Authorisation Division, TGA
ARCS Scientific Congress 2015

7 May 2015

TGA Health Safety Regulation

Outline

- Overview of regulatory framework
- ARTG application process
- Application audit
- Summary of TGA approval
- IVD Reforms

IVD regulatory framework

- From 1990 to 2010 a limited number of IVDs were regulated in Australia under *Therapeutic Goods Act 1989* and *Therapeutic Goods Regulations 1990 including:*
  - HIV and Hepatitis C virus (HCV) tests
- In 2010 Australia introduced a more comprehensive regulatory framework for IVDs under the *Therapeutic (Medical Devices) Regulations 2002*
- New framework covers both commercial and in-house (laboratory developed) IVDs

Transitional arrangements

- New IVD framework commenced on 1 July 2010 with 4 year transition period

- Transition period was extended in 2014

Date	Requirement
30 June 2015	Deadline for applications for inclusion in the ARTG to commercial IVDs
30 June 2017	Deadline for manufacturers of in-house IVDs to comply with requirements

Key features of IVD framework

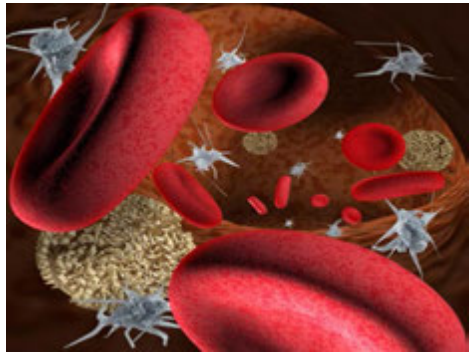
- IVDs are regulated as a subset of medical devices
- Four tier classification system based on different levels of risk for each class of IVD
- All IVDs to comply with a set of Essential Principles for quality safety and performance
- Provision for post-market monitoring

What is an IVD?

- A reagent, calibrator, control material, kit, specimen receptacle, instrument, software, equipment or system

- Intended for the in vitro examination of human specimens for:
  - giving information about a physiological or pathological state
  - giving information about a congenital abnormality
  - determining safety and compatibility with a potential recipient
  - monitoring therapeutic measures

[Therapeutic Goods (Medical Devices) Regulations 2002]



Types of IVDs

- Intended to be used by:
  - health professionals in the laboratory
  - health professionals at the point of care
  - lay-person (self-testing)
- Intended purpose: from the manufacturer and **not** the sponsor – instructions for use
- Does not include research use only (RUO) or analyte specific reagent (ASR)

- **No special subcategory for the regulation of companion diagnostics**

Classification of IVDs

Four Classes, determined by the risk posed to health of an individual or to the public

- Class 1 IVD – no public health risk or low personal risk
- Class 2 IVD – low public health risk or moderate personal risk
- Class 3 IVD – moderate public health risk or high personal risk

---

- **Class 4 IVD – high public health risk**

Classification examples

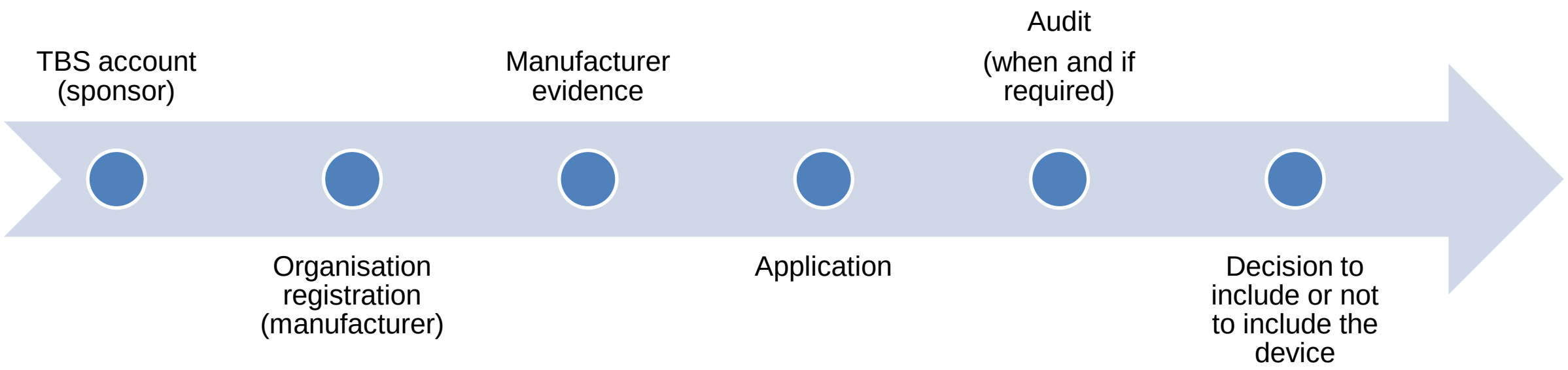
- Class 1 IVDs: Microbiological culture media; instruments/analysers

- Class 2 IVDs: Pregnancy self-tests

- Class 3 IVDs: Tests for sexually transmitted diseases; genetic tests
  - Majority of companion diagnostics are genetic tests (e.g. tests for KRAS, BRAF)

- Class 4 IVDs: Tests to screen blood donors for HIV, HCV

ARTG application process



Manufacturer evidence

- All manufacturers are required to provide evidence of conformity assessment
- Manufacturers of Class 4 IVDs
  - TGA conformity assessment certification is required prior to applying for inclusion in the ARTG
- Manufacturers of Class 2 and Class 3 IVDs
  - TGA conformity assessment not required
  - Alternative manufacturers evidence accepted
    - IVDD 98/79/EC (Certificate from European Council notified body)
    - ISO 13485 (CMDCAS recognised registrar (Health Canada), IAF)

Application for a ‘kind’ of device

- For entry in the ARTG, IVDs can be grouped under a single entry if they are the same ‘kind’ of device

- Kinds of medical device are defined under s41BE of the Act

- One application for a kind of device:
  - same manufacturer
  - same sponsor
  - same device nomenclature system code (GMDN)
  - same medical device classification

GMDN terms

- Global Medical Device Nomenclature (GMDN) terms allow for the grouping of products of the same ‘kind’ under single ARTG entry
- 3 levels of collective term (CT) and a single preferred term (PT)
- Classification dependent
- Manufacturer’s responsibility

GMDN Example

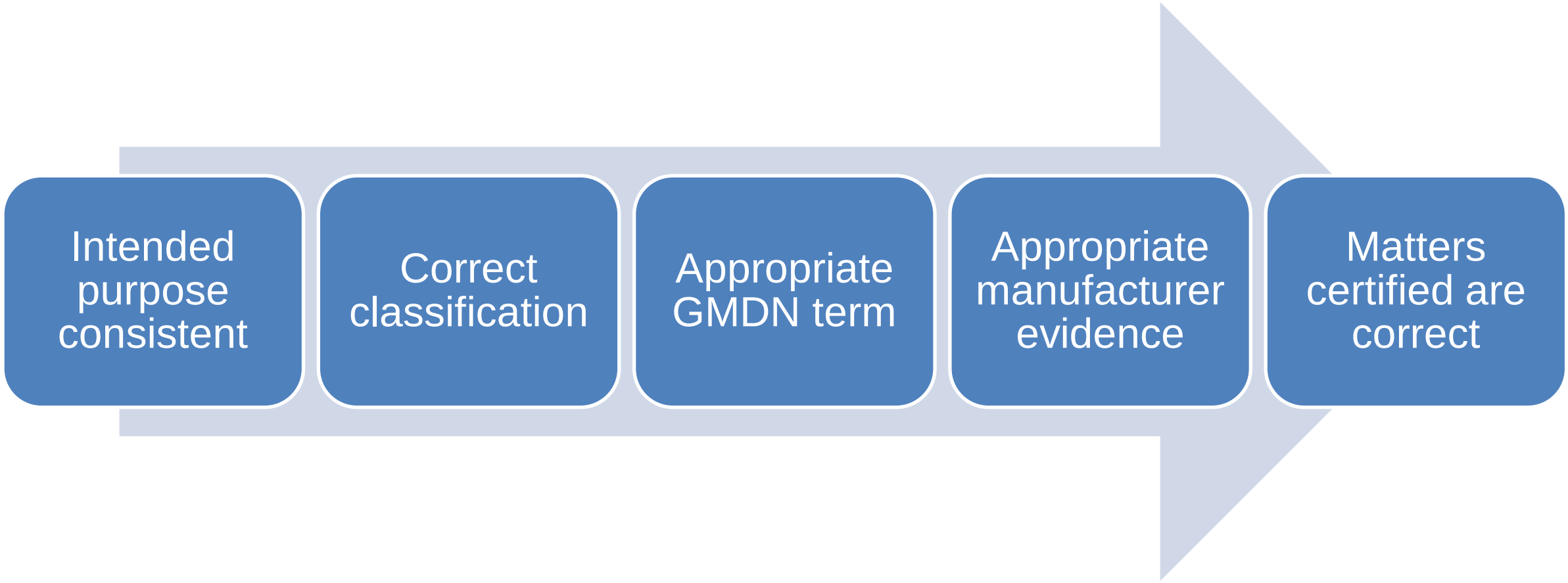
- Preferred term: P60255 Her2/neu/erbB2 mRNA expression IVD kit, nucleic acid technique (NAT)
  - L3 CT: N/A
  - L2 CT: Acquired genetic alteration IVDs [CT929]
    - IVDs that are intended to be used in genetic testing to provide information about acquired genetic alterations, which may include chromosomal alterations, mutations and/or alterations in gene expression, and which may be used to characterise haematological or solid tumour malignancies and/or provide prognostic information.
  - L1 CT: Human genetics IVDs [CT902]

Declarations of Conformity (DoC)

- When to be provided:
  - With an application for Class 3 & 4 IVDs
  - Application audits

- DoC made in accordance with Australian regulations
  - Templates available

Check before submitting application



Selection of applications for audit

Mandatory audit

- Applications for certain IVDs must be selected for audit, such as:
  - IVDs for self-testing or point-of-care testing
  - IVDs to detect sexually transmitted agents
  - IVDs for monitoring HIV, HCV
  - Class 3 IVDs where the application is supported by an ISO 13485 certificate and there is no evidence of suitable product review (e.g. Class III or IV licence, Health Canada)
    - Class 3 IVD companion diagnostics often fall into this category.

Non-Mandatory Audit

- Other applications may be selected for a non-mandatory audit

Application audit process

Selection notice & information required for audit
(20 working days) (s41FH)

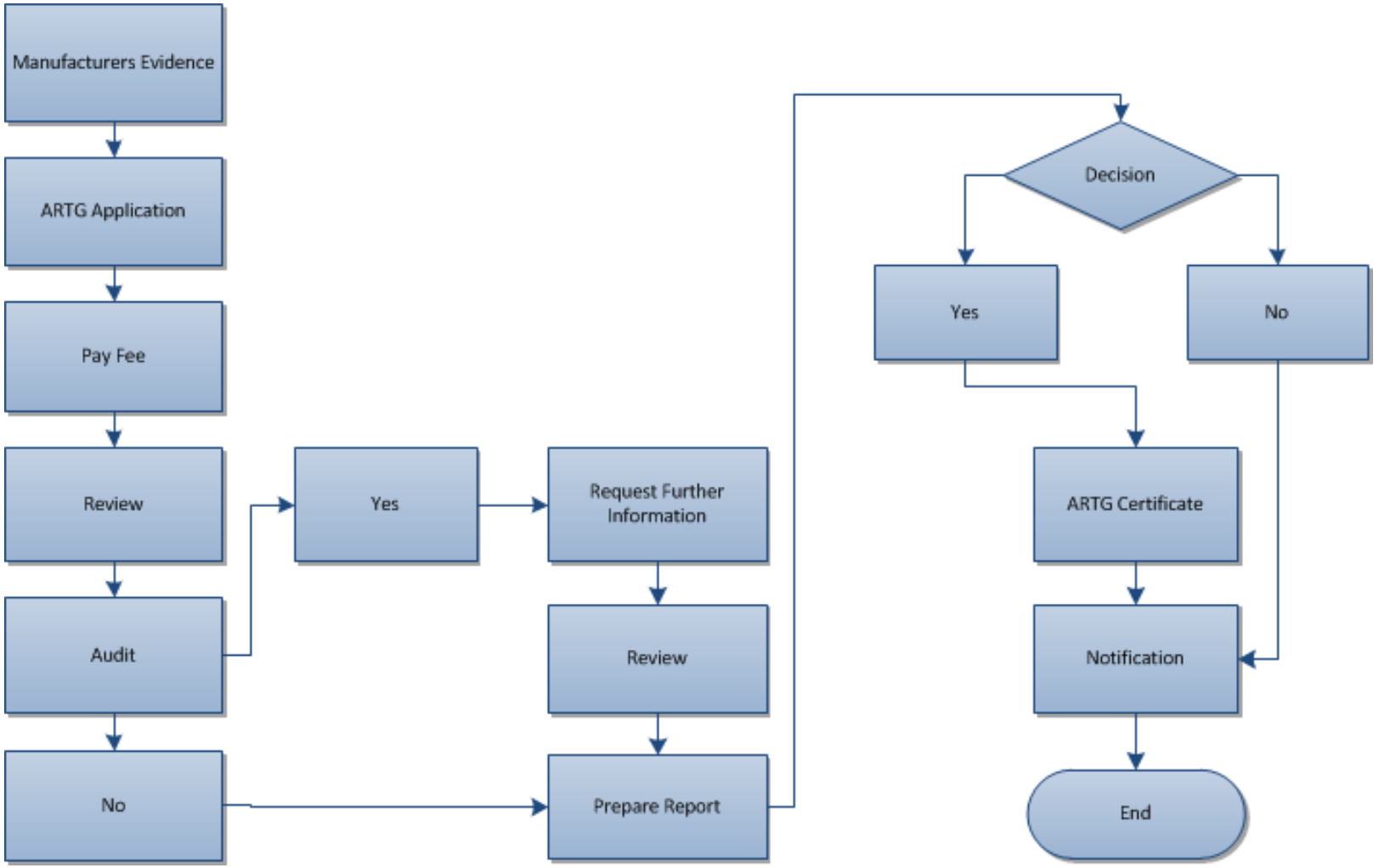
Provision of summary technical documents (STED) by sponsor
(20 working days)

Application audit – classification, compliance with essential principles and conformity assessment procedures.

Additional information request, if required
(s41JA)

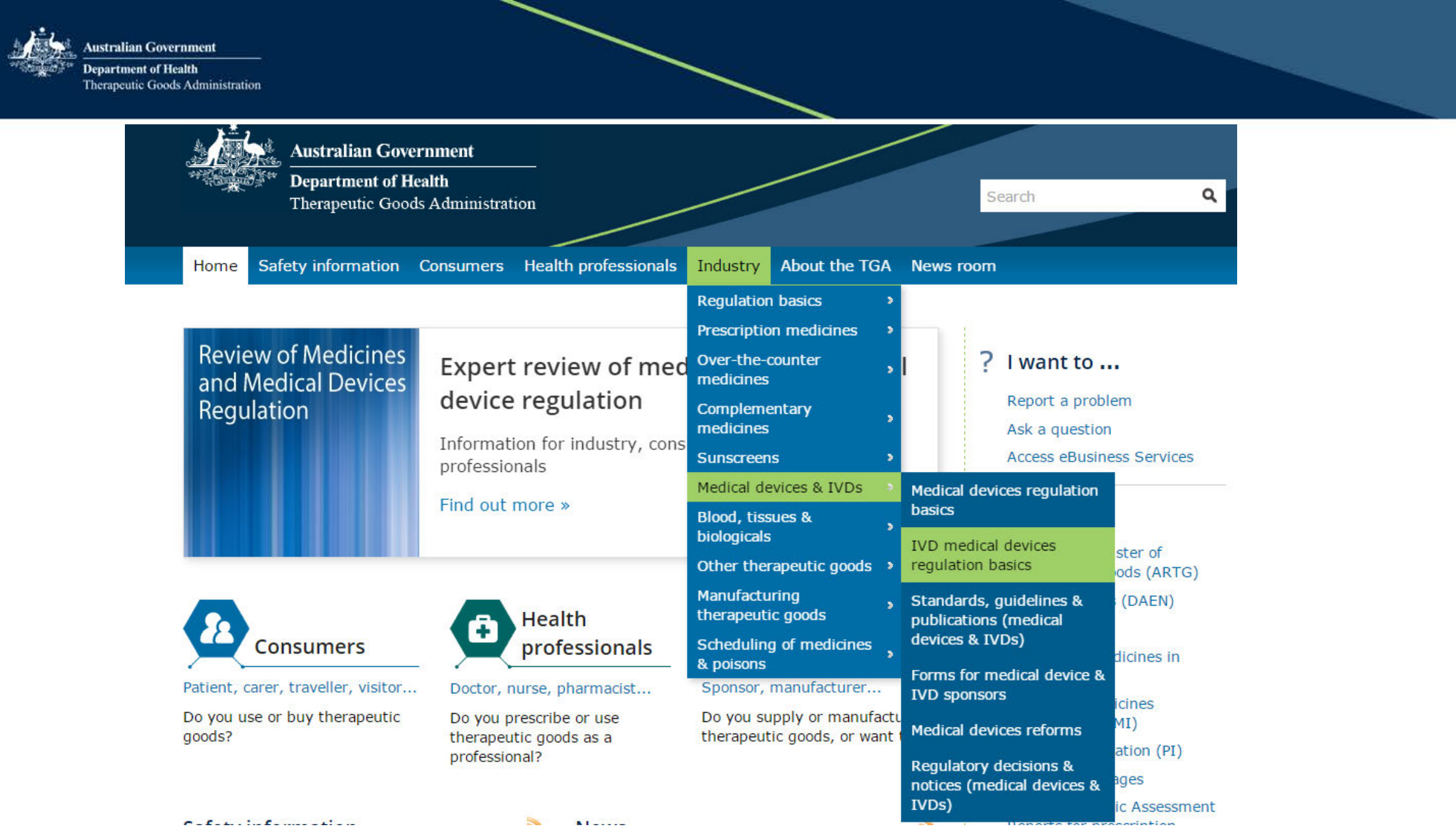
Notification of approval (inclusion in ARTG) or rejection

ARTG process



Summary - TGA approval of IVDs

- Supply of IVD medical device requires an inclusion of the kind of device in the ARTG
- Inclusion of kind of device based on compliance with essential principles (EPs), evidence of conformity assessment and other declarations made by sponsor
- Applications for companion diagnostic IVD are treated no differently to other IVD applications
- ARTG inclusion process for an IVD is independent of Medical Services Advisory Committee (MSAC) and Pharmaceutical Benefits Advisory Committee (PBAC), no parallel processing


Australian Government
Department of Health
Therapeutic Goods Administration
Search
Home
Safety information
Consumers
Health professionals
Industry
About the TGA
News room
Regulation basics
Prescription medicines
Over-the-counter medicines
Complementary medicines
Sunscreens
Medical devices & IVDs
Blood, tissues & biologicals
Other therapeutic goods
Manufacturing therapeutic goods
Scheduling of medicines & poisons
Medical devices regulation basics
IVD medical devices regulation basics
Standards, guidelines & publications (medical devices & IVDs)
Forms for medical device & IVD sponsors
Medical devices reforms
Regulatory decisions & notices (medical devices & IVDs)
Review of Medicines and Medical Devices Regulation
Expert review of med
device regulation
Information for industry, cons
professionals
Find out more »
? I want to ...
Report a problem
Ask a question
Access eBusiness Services
Consumers
Patient, carer, traveller, visitor...
Do you use or buy therapeutic goods?
Health professionals
Doctor, nurse, pharmacist...
Do you prescribe or use therapeutic goods as a professional?
Sponsor, manufacturer...
Do you supply or manufactu
therapeutic goods, or want

Industry

- Regulation basics
- Prescription medicines
- Over-the-counter medicines
- Complementary medicines
- Sunscreens
- Medical devices & IVDs
  - Medical devices regulation basics
  - IVD medical devices regulation basics
  - **Standards, guidelines & publications (medical devices & IVDs)**
  - Forms for medical device & IVD sponsors
  - Medical devices reforms
  - Regulatory decisions & notices (medical devices & IVDs)
- Blood, tissues & biologicals

Home › Industry › Medical devices & IVDs

A- A+ Share

Standards, guidelines & publications (medical devices & IVDs)

Medical devices & IVDs

All medical devices marketed in Australia must meet the requirements which are set out in Chapter 4 of the Therapeutic Goods Act 1989, and in the Therapeutic Goods (Medical Devices) Regulations 2002.

Related information

- Advertising
- Legislation & legislative instruments
- Labelling & packaging

- Australian regulatory guidelines for medical devices (ARGMD)
  This document is a guide to assist sponsors and manufacturers understand the regulatory requirements for medical devices in Australia.
- IVD guidance documents
  Guidance documents about regulatory requirements for in vitro diagnostic medical devices (IVDs)
- Clinical performance requirements and risk mitigation strategies for HIV tests
  Guidance document for manufacturers and sponsors of HIV tests
- Device-medicine boundary products
  TGA advises this document is currently under review. This November 2005 version will remain available for information purposes until a revised document is published.
- In vitro fertilisation (IVF) solutions
  Summarises requirements for IVF solutions to demonstrate compliance with the Essential Principles for safety and performance of medical devices, or the Australian Medical Device Requirements (DR4, for devices containing material of human origin)

IVD Reforms

- Extension to transition period
- Declaration to clarify that IVDs used to test for predisposition or susceptibility to disease are medical devices and regulated as IVDs
- Ban lifted on supply of HIV self-tests
  - Release of new guidance material on clinical performance requirements for HIV tests
- Proposed reforms
  - Modification to requirements for in-house IVDs

Questions?

Australian Government

Department of Health

Therapeutic Goods Administration