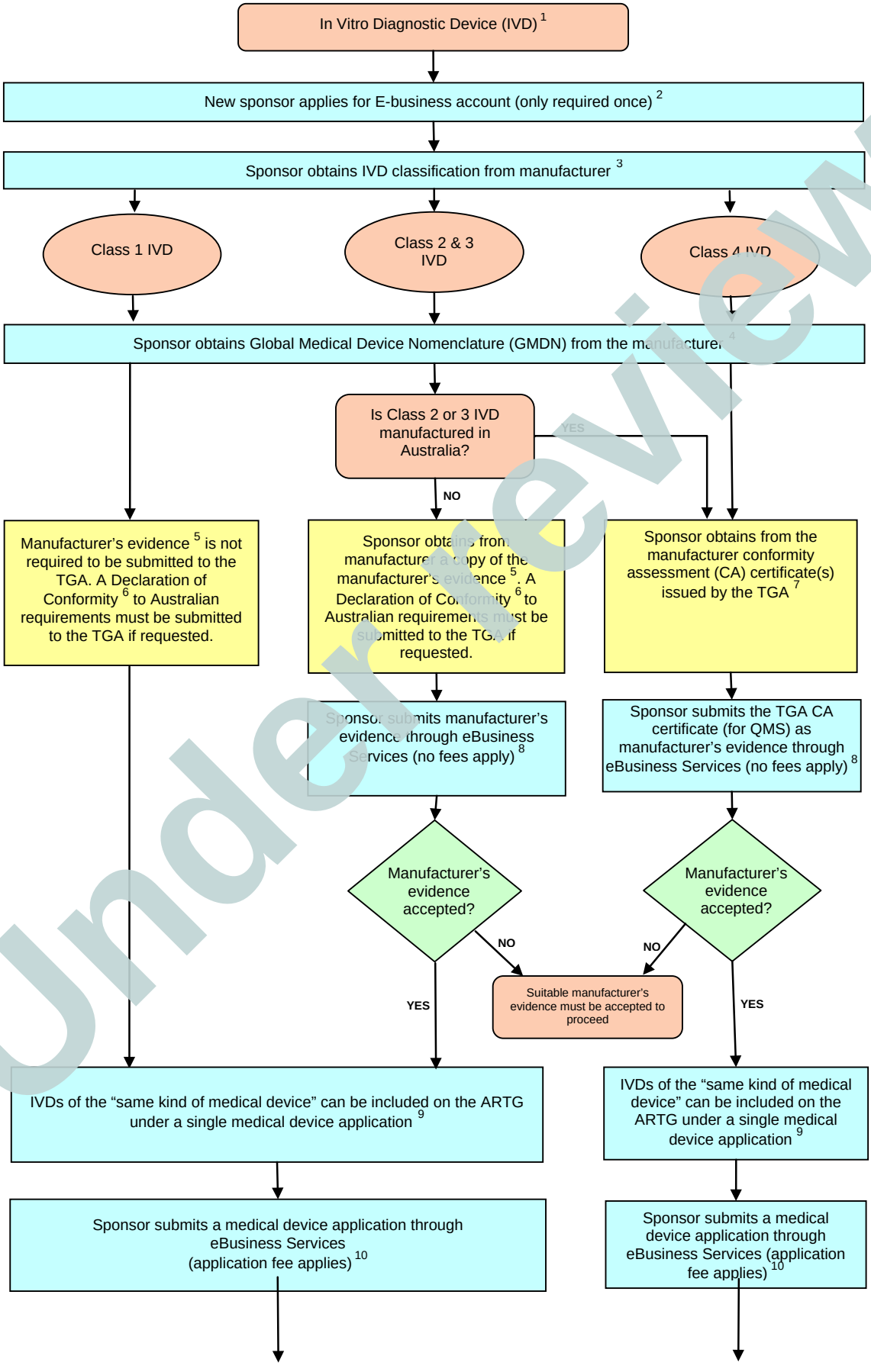
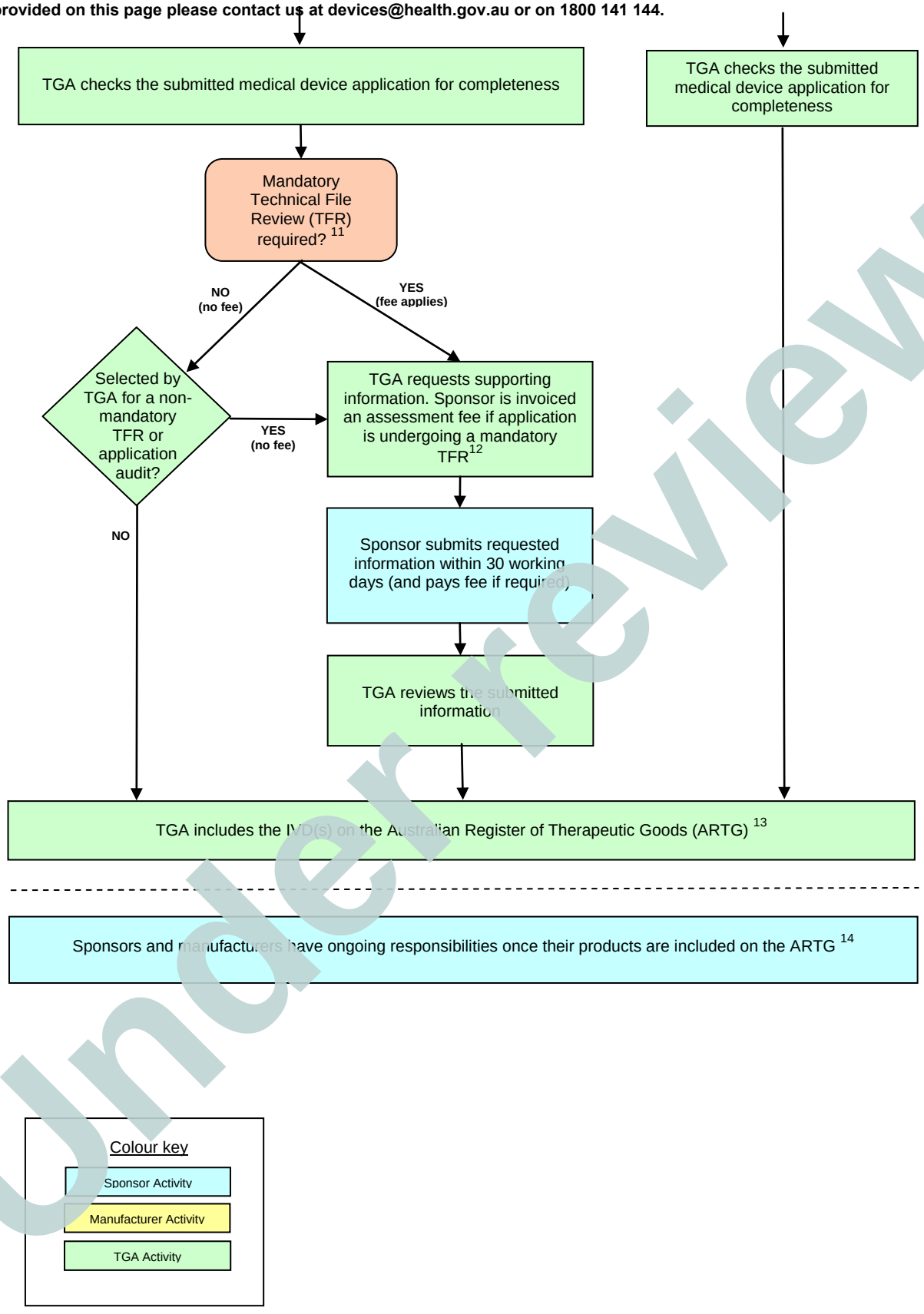
Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Guidance for IVD sponsors – A roadmap to market





Footnotes (and links to further information)

1. What is an IVD?

An IVD is any medical device which is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination (with other diagnostic goods for in vitro use), intended by the manufacturer to be used in vitro for the examination of specimens derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient or to monitor therapeutic measures.

- Regulation of therapeutic goods in Australia <http://www.tga.gov.au/industry/basics-regulation.htm>

2. New sponsor applies for E-business account (only required once)

Applications for inclusion on the Australian Register of Therapeutic Goods (ARTG) are submitted electronically through the eBusiness Services system. New users need to establish an e-business account to access eBusiness Services.

- Access for new users <http://www.ebs.tga.gov.au>

3. Sponsor obtains the IVD classification from the manufacturer

The manufacturer must classify the IVD according to the classification rules, based on the intended purpose of the IVD.

- Classification rules guidance document <http://www.tga.gov.au/industry/ivd-classification.htm>

4. Sponsor obtains GMDN from manufacturer

The Global Medical Device Nomenclature (GMDN) is a collection of internationally recognised terms, each with a unique number that is used to accurately describe and catalogue medical devices. It is the responsibility of the manufacturer to assign the appropriate GMDN.

- •The use of GMDN codes for IVD medical devices in Australia <http://www.tga.gov.au/industry/ivd-gmdncodes.htm>
- For background information about GMDN codes refer to the GMDN agency website <http://www.gmdnagency.com>

5. Requirements for manufacturer's evidence

Australian manufacturers of Class 2 and Class 3 IVDs must undergo conformity assessment by the TGA. All manufacturers of Class 4 IVDs to be supplied in Australia (including overseas manufacturers) must undergo conformity assessment by the TGA.

- Requirements for manufacturer's evidence under the new IVD framework guidance document <http://www.tga.gov.au/industry/ivd-ca-sponsor.htm>
- TGA Conformity Assessment guidance document <http://www.tga.gov.au/industry/ivd-ca-overview.htm>

6. Declaration of Conformity

It is strongly recommended that sponsors obtain the manufacturer's Declaration of Conformity before submitting an application to include a medical device on the ARTG.

- Details of what should be included in the declaration can be found in the Australian Regulatory Guidelines for Medical Devices (ARGMD) <http://www.tga.gov.au/industry/devices-argmd.htm>
- Essential Principles guidance document (not yet available)

- TGA Conformity Assessment guidance document <http://www.tga.gov.au/industry/ivd-ca-overview.htm>

7. Conformity Assessment procedure for IVDs

A separate roadmap for manufacturers undergoing TGA conformity assessment is to be developed.

- Conformity assessment procedures for IVDs guidance document (not yet available)
- Essential Principles guidance document (not yet available)

8. Sponsor submits manufacturer's evidence through eBusiness Services

Only the QMS certificate should be submitted as manufacturer's evidence; the Declaration of Conformity and other information will be requested by the TGA when required. When submitting new evidence through eBusiness Services, ensure ALL product GMDNs applicable to the scope of that evidence are entered prior to finalising the submission. Once manufacturer's evidence has been accepted, details relating to the manufacturer, sponsor and GMDN codes will be linked to the medical device application as it is submitted through eBusiness Services (Step 10).

- Requirements for manufacturer's evidence under the new IVD framework guidance document <http://www.tga.gov.au/industry/ivd-ca-sponsor.htm>

9. IVDs of the "same kind of medical device" can be included by a sponsor under a single medical device application

The "same kind" of medical device has

- same sponsor
- same manufacturer
- same GMDN
- same risk classification

Class 4 IVDs are only considered to be of the "same kind" if in addition to the above, they also have the same unique product identifier (UPI).

- Including IVD medical devices in the ARTG <http://www.tga.gov.au/industry/ivd-including-artg.htm>

10. Sponsor submits an IVD application through eBusiness Services (application fee applies)

When lodging an application, the sponsor must certify the following:

- the product is a medical device and is intended for a specific purpose
- the IVD is correctly classified according to the rules
- the IVD complies with the Australian essential principles for quality, safety and performance, and information is available to substantiate compliance
- an appropriate conformity assessment procedure has been applied to the IVD and sufficient information is available to substantiate the application of the conformity assessment procedures
- the IVD complies with advertising requirements
- the IVD does not contain any substances prohibited from import into Australia
- all information included in or with the application is complete and correct

- there are procedures in place with the manufacturer to obtain and submit to the TGA any information requested, within 30 days. This may include evidence of compliance, the declaration of conformity etc. (Refer to The *Therapeutic Goods Act 1989*, Section 41FD)

Also see:

- Fees and charges for IVD medical devices <http://www.tga.gov.au/industry/ivd-fees.htm>
- Business rules for reduced assessment fees for in vitro diagnostic medical devices (IVDs) <http://www.tga.gov.au/industry/ivd-business-rules-reduced-fees.htm>

11. Mandatory Technical file review (TFR) required?

The following IVDs will undergo a mandatory TFR:

- IVDs used for self-testing
- point of care tests
- IVDs for testing for notifiable sexually transmitted infections on the Australian National Notifiable Diseases List <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/cda-nndss-dislist.htm>
- non-assay specific quality control material
- IVDs for monitoring treatment of infections diagnosed using a Class 4 IVD (eg viral load assays, genotyping assays)

Any other application may be selected for a non-mandatory TFR

- Technical File Review guidance document <http://www.tga.gov.au/industry/ivd-application-audit.htm>

12. Sponsors are only invoiced an evaluation fee for IVDs undergoing a mandatory TFR

Applications that are selected by the TGA for a non-mandatory TFR or an application audit do not attract an evaluation fee

13. TGA includes the IVD on the ARTG

- Australian Register of Therapeutic Goods (ARTG) <http://www.tga.gov.au/industry/artg.htm>

14. Manufacturers and Sponsors have ongoing responsibilities once their products are included on the ARTG

- Medical device adverse event reporting by medical device manufacturers and sponsors <http://www.tga.gov.au/safety/problem-device-report-industry.htm>
- Monitoring the safety of therapeutic products in Australia <http://www.tga.gov.au/industry/safety-monitoring-devices.htm>
- Uniform recall procedure for therapeutic goods (URPTG) <http://www.tga.gov.au/safety/recalls-urptg.htm>