Overview

• Background
• Current Regulatory Requirements
• IVD Reforms
• Access to Unapproved IVDs
• How to Contact TGA
Background

New IVD regulatory framework implemented 1 July 2010

- IVDs regulated as a subset of medical devices
- Requirements apply to both commercially supplied and in-house IVDs
- Originally a 4-year transition - 1 July 2014 to comply with requirements
Key Features of the New Framework

• 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

• All commercial IVDs & Class 4 in-house IVDs to be included in ARTG

• Provision for post-market monitoring
What is a Medical Device?

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 disability;

• Investigation, replacement or modification of the anatomy or of a physiological process;

• Control of conception
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:
  – in the laboratory
  – by health professionals at the point of care
  – by lay-person (self-testing)

• Does not include research use only (RUO) or analyte specific reagent (ASR)
  – Unless incorporated in an in-house IVD
What is an In-House IVD?

Manufactured by a laboratory for use in that laboratory or laboratory network

- Developed from first principles
- Developed or modified from a published source
- Developed or modified from any other source (e.g., commercial IVD, RUO products, ASRs)
- Used for a purpose other than the manufacturer’s intended purpose
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 rules – Schedule 2A, Therapeutic Goods (Medical Devices) Regulations 2002]
Classification Examples

- Class 1 IVDs: Microbiological culture media; instruments/analysers
- Class 2 IVDs: Pregnancy self-tests, H&E stain
- Class 3 IVDs: sexually transmitted diseases; genetic tests (inc FISH)
- Class 4 IVDs: screen blood donors for HIV & HCV; ABO
Regulation of Commercial Class 4 IVDs

Two step process

- TGA conformity assessment certification must be obtained prior to applying for inclusion in the ARTG
  - Evaluation of QMS
  - Design examination for each Class 4 IVD

- Inclusion in the ARTG
Regulation of Commercial Class 1-3 IVDs

Included in the ARTG as a ‘kind’ of device

- Lower risk IVDs can be grouped for entry in the ARTG as a ‘kind’

- Classification of IVD will determine what level of QMS evidence required to support application

- Majority of Class 1 IVDs are auto-included

- Mandatory Application audits, for example
  - PoCTs, self-tests
  - Tests for sexually transmitted diseases
  - Class 3 IVDs without evidence of product review
Regulation of Class 4 in-House IVDs

Subject to the same requirements as commercial Class 4 IVDs

• Require TGA conformity assessment certificates covering:
  – Full QMS certificate (ISO 13485); and
  – Design examination certificate for each Class 4 in-house IVD

• Inclusion in the ARTG
Regulation of Class 1-3 In-House IVDs

Exempt from inclusion in ARTG, conditional on:

- NATA accredited as a medical testing laboratory
- Meet ISO 15189
- Meet NPAAC Requirements for in-house IVDs
- Notify TGA of in-house Class 1-3 IVDs
- Renotify Annually
Extension to Transition Timeframe

• Industry having difficulty complying with timeframe for transition of 1 July 2014

• Laboratories experiencing difficulties, particularly for those tests based on modifications to commercial IVDs
  – Laboratories need to know the commercial IVD has been included in the ARTG
  – Laboratories cannot submit applications for conformity assessment for Class 4 in-house IVDs unless commercial IVD is included in ARTG
  – Laboratories may need time to revalidate new in-house IVDs
Extension Approved – May 2014

Staged transition to the new IVD framework to allow additional time for compliance

<table>
<thead>
<tr>
<th>Deadline</th>
<th>Requirement</th>
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<tbody>
<tr>
<td>31 August 2014</td>
<td>Application for TGA conformity assessment for Australian commercial manufacturers of Class 2-3 IVDs and all commercial manufacturers of Class 4 IVDs</td>
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<tr>
<td>30 June 2015</td>
<td>Application for inclusion in the ARTG for all commercial IVDs</td>
</tr>
<tr>
<td>30 June 2016</td>
<td>Application for TGA conformity assessment for laboratory manufacturers of Class 4 in-house IVDs</td>
</tr>
<tr>
<td>30 June 2017</td>
<td>Application for inclusion in the ARTG for all Class 4 in-house IVDs &amp; notification of Class 1-3 in-house IVDs</td>
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Proposed Reforms for In-house IVDs

- New alternative conformity assessment procedure for Class 4 in-house IVDs
- Modifications to the requirements for Class 1-3 in-house IVDs
- Expected introduction in 3rd quarter 2015
- Will require modification to current electronic submission processes
Proposed Reforms for Class 4 In-House IVDs

Option 1
- Same as for commercial Class 4 IVD
  - TGA CA (Apply by 1 July 2016)
  - Inclusion in ARTG

Option 2
- NATA accreditation to ISO 15189 or a TGA GMP licence
  - Apply for inclusion of each Class 4 in-house IVD in ARTG (by 1 July 2017)
  - Subject to mandatory application audit
Proposed Reforms for Class 1-3 In-House IVDs

- NATA accredited
  - ISO 15189
  - ISO 17025 (for non-medical testing laboratories)

Meet NPAAC Requirements for in-house IVDs

Notify TGA of ‘types’ in-house Class 1-3 IVDs by 1 July 2017

Declaration that meet essential principles

Only renotify for new types of IVDs
What Do Laboratories Need to Do?

• Identify your in-house IVDs

• Determine if you have any Class 4 in-house IVDs
  – Inclusion in ARTG required by 1 July 2017

• Ensure laboratory is NATA accredited for Class 1-3 in-house IVDs
  – Notification to TGA required by 1 July 2017

• Reforms expected to be implemented by 3rd quarter 2015
  – Wait until after reforms implemented to submit notifications

• In interim can set up your Client ID & Access to TGA business services
TGA Business Services

TGA Business services: getting started with the TGA

20 April 2011

If you are a manufacturer, importer or agent who wants to use our online services you will need a client identification number (Client ID) and also apply to access our secure online TGA Business Services (TBS).

This access will allow you to manage some therapeutic good registration applications and you will need a Client ID and access to TBS if you want to:

- Supply in Australia
- Manufacture
- Import into Australia
- Export from Australia
- Notify us about adverse events or recalls.

With access to TBS you will also be able to view and cancel current Australian Register of Therapeutic Goods (ARTG) entries and generate certificates online.

Applying for your Client identification number

If you do not have a Client ID, you need to:

1. Complete the Organisation details form
2. Submit the TGA TBS Helpdesk using the address on the bottom of the form.

How to complete the organisation details form

- **Organisation Information**: Complete the form to provide the information about the company or individual who will be operating, importing, manufacturing or sponsoring the therapeutic goods or sponsoring a clinical trial.

It is important that you tick the boxes for all the different interactions you will have with us; all fields are mandatory.
Access to IVDs for Evaluation Purposes

• Samples of an IVD can be imported or supplied for:
  – Demonstration or display purposes (with notification not available for general supply)
  – Evaluation purposes – not for reporting patient results

• Prior approval from TGA not required
Access to IVDs not included on the ARTG

- Clinical trial exemption (CTX) or notification (CTN) schemes
- Special Access Scheme
- Importation for personal use
- Exemptions for Emergency use
  - stockpiled to deal with a possible emergency
  - made available to deal with an actual emergency
What falls outside the Regulations?

**Deliberately excluded**
- products not intended by the manufacturer for therapeutic use
  - tests for parentage and kinship testing
  - drug tests used in sport
  - tests for alcohol or the detection of illicit drugs

**Accidently excluded**
- predisposition and susceptibility tests
  - fall within definition of therapeutic use BUT ambiguous as to whether met definition of a medical device
  - Amendment made to declare them to be ‘medical devices’
Guidance

Regulation of In Vitro Diagnostic Medical Devices
Questions?