Sensible regulation - is it possible?
How Australia has chosen to regulate In-House IVDs.

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Terminology

- **Aus** = Australia
- **TGA** = Therapeutic Goods Administration
  - Australian Regulator of Therapeutic Goods
  - MHRA/AFSSAPS/BfArM/FDA
- **Lab** = medical pathology laboratory
- **IVD** = in vitro diagnostic medical device = lab assay
- **IH IVD** = in house IVD/laboratory developed test
- **GHTF** = Global Harmonization Task Force
- **GLP** = Good Laboratory Practice
- **GMP** = Good Manufacturing Practice
Regulation of IVDs – Pre 2010

- Only applied to commercial IVDs
  - In House (IH) IVDs exempt

- HIV and HCV commercial assays had high level requirements

- Home-use IVDs minimal level requirements

- All other commercial IVDs exempt
Regulation and Review of IH IVDs – Pre 2010

- No oversight of in-house IVDs by regulator

BUT

- Validation data and on-going performance potentially checked during laboratory accreditation process

IF

- Manufactured by a laboratory seeking government funding, and
- in the scope of the accreditation, and
- data is requested for review.
Australian Path Lab Lab Accreditation

NATA
National Association of Testing Authorities, Australia

ACCREDITATION

Function
Accreditation Body

Activities
Compliance with all relevant NPAAC standards
Assessment of technical competence (peer review)
Consultation – Pre 2010

- Industry demanded “ensuring a level playing field”
  - same standard of manufacture
  - “supplying” of IH IVDs to other labs on commercial basis

- Pathology sector issues
  - Financial burden of any regulation
  - New regulations dictate clinical practice
  - Duplication of efforts
  - Impact on access to certain IH IVDs
  - variable quality of pathology in non-accredited labs
Consultation – Pre 2010

- Negotiations by TGA with industry and pathology sector
- Agreements and understandings
  - Patient safety always first priority
  - GLP not the same as GMP
  - Clinical practice not part of IVD regulation therefore not impacted
- New regulation to incorporate existing mechanisms already in place for accreditation for lower risk IH IVDs
- Regulation not to block access to urgently needed IH IVDs, and or those for rare diseases.
Making it happen

- Gap analysis performed between ISO 13485:2003 and
  - ISO 15189:2003
  - other NPAAC standards
- Revision of NPAAC std for manufacture of an IH IVD
  - to incorporate gaps in regulatory requirements
  - Multisector subcommittee, chaired by DOHA
- Agreement for TGA to commission NATA for 3rd party assessment
Changes to the NPAAC Std Definitions

In House in-vitro diagnostic medical device (IH IVD)

- An IVD that is
  - developed de novo
  - or developed or modified from a published source,
  - or developed or modified from any other source, or its intended purpose
- This includes commercial IVDs being used clinically for a purpose other than that originally intended by the manufacturer.
Changes to the NPAAC Std Definitions

**Medical laboratory network**
- Laboratory organisations whose activities
  - span more than one field of testing or program,
  - or that operate at multiple sites within a field,
  - or that involve a combination of multiple sites and fields/programs
  and operate under a single approved pathology authority,
  and have a single quality management system.

- Distribution of an IH IVD in a multi-site organisation that does not fulfil this definition will be considered as commercial supply
Changes to the NPAAC Std Content

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Revised Standard

Outcome

New regulation of all IVDs implemented in July 2010

- Laboratories are responsible for classifying IH IVDs using new IVD classification rules
- NATA to act as 3rd party assessment body for all Class 1 – 3 IH IVDs
- Class 4 IH IVDs subject to full conformity assessment by TGA
- Laboratories to notify all IH IVDs to the TGA for entry onto a database (AUD 810) and to pay an annual fee (~AUD 810)
Impact of the regulations

- All IH IVDs are subject to meeting the Essential Principles and standard of manufacture as commercial IVDs (enhancing patient safety)

- The definition of an IH IVD captures off-label use eg new clinical indication, new sample type (enhancing patient safety)

- IH IVDs supplied in a multi-site organisation not meeting the definition of medical laboratory network must undergo full TGA conformity assessment.
Impact of the regulations

- Minimal regulatory burden for laboratories for Classes 1-3 IH IVDs
- Costs kept to minimum for laboratories with fees for reporting and maintenance of a TGA list of IH IVDs
- Concerns regarding access to certain IH IVDs met in legislation
  - Ministerial exemption of some IVDs (eg urgent use)
  - Low value/Low volume fees for rare Class 4 IH IVDs
### Safety information
- Safety information
- Product recalls
- Report a problem
- Safety monitoring

### About the TGA
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### Information for
- Consumers
- Health professionals
- Manufacturers
- Laboratories
- Travellers
- Importers/exporters
- Media

### Australian Register of Therapeutic Goods
- About the ARTG
- Medicines on the ARTG
- Medical devices on the ARTG
- Consumer Medicines Information (CMI) & Product Information (PI)

### Regulation
- Regulated by the TGA
  - Medical devices
  - Complementary medicines
  - OTC medicines
  - Prescription medicines
  - Blood & tissues
  - Tissues & other therapeutic goods
- Related information
  - Advertising
  - Clinical trials
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Thank You