Reliance in Action

Case Study: Australia Comparable Overseas Regulator Pathway
DPX - Class 4 IVD, Simultaneous Parvovirus B19 and Hepatitis A Testing in Blood Products

Tammy Steuerwald, Global Head of Regulatory Policy Foundational Principles & Supranational Orgs, Roche Diagnostics, March 11, 2024

Special thank you to Merrilyn Colussi,
Regulatory Affairs and Quality Manager
Roche Diagnostics Australia

IMDRF International Medical Device Regulators Forum

DPX - Class 4 IVD Blood Screening Test
Registration in 20 days

Reliance

- **Dramatically accelerates patient access to safe and effective products**

- **Does not lower regulatory requirements for the product**
- **Relying agency maintains autonomy & final decision**

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Australia Reliance Journey

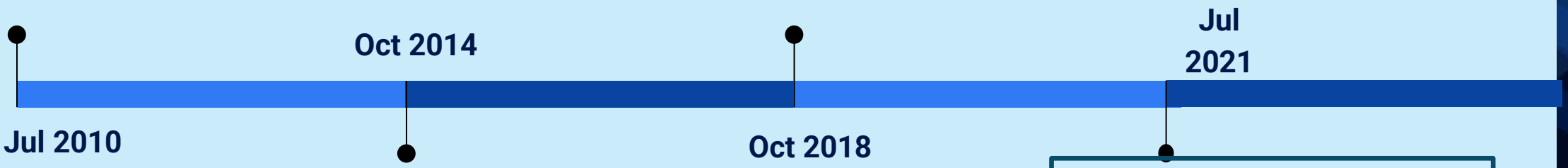
Over a decade in the making

New IVD Regulation

Consultation with Health Canada prior to implementation. Limited reliance in place (EU IVDD and HC licenses). TGA required conformity assessment for Class 4 IVDs

Expanded list of comparable overseas regulators

Outcome of the Review in 2014 was to better utilize marketing approvals from comparable regulators



Expert Panel Review of Medicines and Medical Devices Regulation
Assessment of the regulatory framework and recommendations to improve the way in which therapeutic goods were regulated in Australia

Major change to recognize IVDR for Class 4 IVDs. If the product was review by the NB under IVDR, it is not required to go through a mandatory technical file review. However, still under TGAs discretion

Reliance Accelerates the Review and Time to Decision

Class 4 IVD	TGA conformity assessment –*prior to 2021*	Reliance on IVDD evidence – *after 2021*	Reliance on IVDR evidence – *after 2021*
Submission requirement	Full technical dossier review required	Reduced dossier review	Significantly reduced dossier review
Time	12 months	6-12 months as application is reviewed	1 month (Note: will be longer than 1 month if selected for non mandatory review)
QMS inspection requirement	Yes	No	No

See TGA Fees and charges: summary, From 1 July 2023, version 2

UPI = Unique Product Identifier

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Reliance Expedites Patient Access

Product	Intended Use	Registration (working days)	Expected Registration (working days)
Elecsys PIVKA II – New Registration - Class 3	Immunoassay for the quantitative measurement of protein induced by vitamin K absence or antagonist-II (PIVKA-II) in human serum and plasma. The assay is **used as an aid in the diagnosis of hepatocellular carcinoma (HCC).**	**5**	90*
Elecsys HSV-1 and Elecsys HSV-2 – Change Registration – Class 3	Immunoassay for the **qualitative determination of IgG-antibodies to Herpes Simplex Virus type 1, 2**.	**43**	90*
cobas HPV on cobas 5800 (addition of cobas 5800) Change Registration – Class 3	Qualitative in vitro test for the **detection of Human Papillomavirus in clinician-collected cervical specimens**	**9**	90*
DPX - Parvo B19 & Hep A – New Registration – Class 4	In vitro test for the direct **quantitation of parvovirus B19 genotypes 1, 2, and 3 DNA and the direct qualitative detection of Hepatitis A virus (HAV) genotypes I, II, and III RNA in human plasma.** This test is intended for use as an in-process test to quantify parvovirus B19 DNA alone or to simultaneously quantify parvovirus B19 DNA and detect HAV RNA in plasma intended for further manufacture collected from donors of whole blood, blood components, or plasma.	**20**	255** (Based on TGA conformity assessment)

* Based on Roche experience

** Legislative timeline. See Regulation 4.3, Therapeutic Goods (Medical Devices) Regulation 2002

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Trust Based

Pre-sub meeting with TGA

Document	Explanation
IVDR Quality Management Certificate	Evidence the NB has assessed the **manufacturers Quality Management System**.
IVDR Technical Documentation Assessment Certificate	Evidence the **NB has reviewed the technical file** and approved the assay for market. (high level document).
IVDR Performance Evaluation Assessment Report (PEAR)	**Confirmed the clinical evidence was verified and deemed compliant with IVDR** (scientific validity, analytical performance, and clinical performance).
IVDR Technical Documentation Assessment Report (TDAR)	A **summary document that describes the NB's entire assessment of the technical documentation**. (cobas DPX 96 test kit size)
Kits sample size change	**IVDR Change Notification and Work Authorization Form** (IVDR) (addition of cobas DPX 192 test kit size configuration)
IFUs, Labels, Risk Management Report, cover letter	Provided by Roche as part of the TGA application.

TGA leveraged the NB review to meet their Essential Principle requirements

Reliance improves timely access leading to faster diagnosis

- **Reliance dramatically reduces the time to decision**

- **Does not lower regulatory requirements for the product**
- **Relying agency maintains autonomy & final decision**

Regulator maintained final decision & post market controls ensure continued product safety and effectiveness

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Reliance. *It's not if, it's how.*

Trust	Build trust through understanding of the reference agency requirements, their review and output
Converge	Converge to internationally accepted best practices, Standards and to common dossier
Capacity Building	Bring together regulators and industry to build capacity and understanding of best practices
Modernize	Modernize regulatory processes (e-submissions/e-labeling/cloud submissions) to facilitate reliance

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HCP: Healthcare Practitioners


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