



**Global Harmonization Working Party**

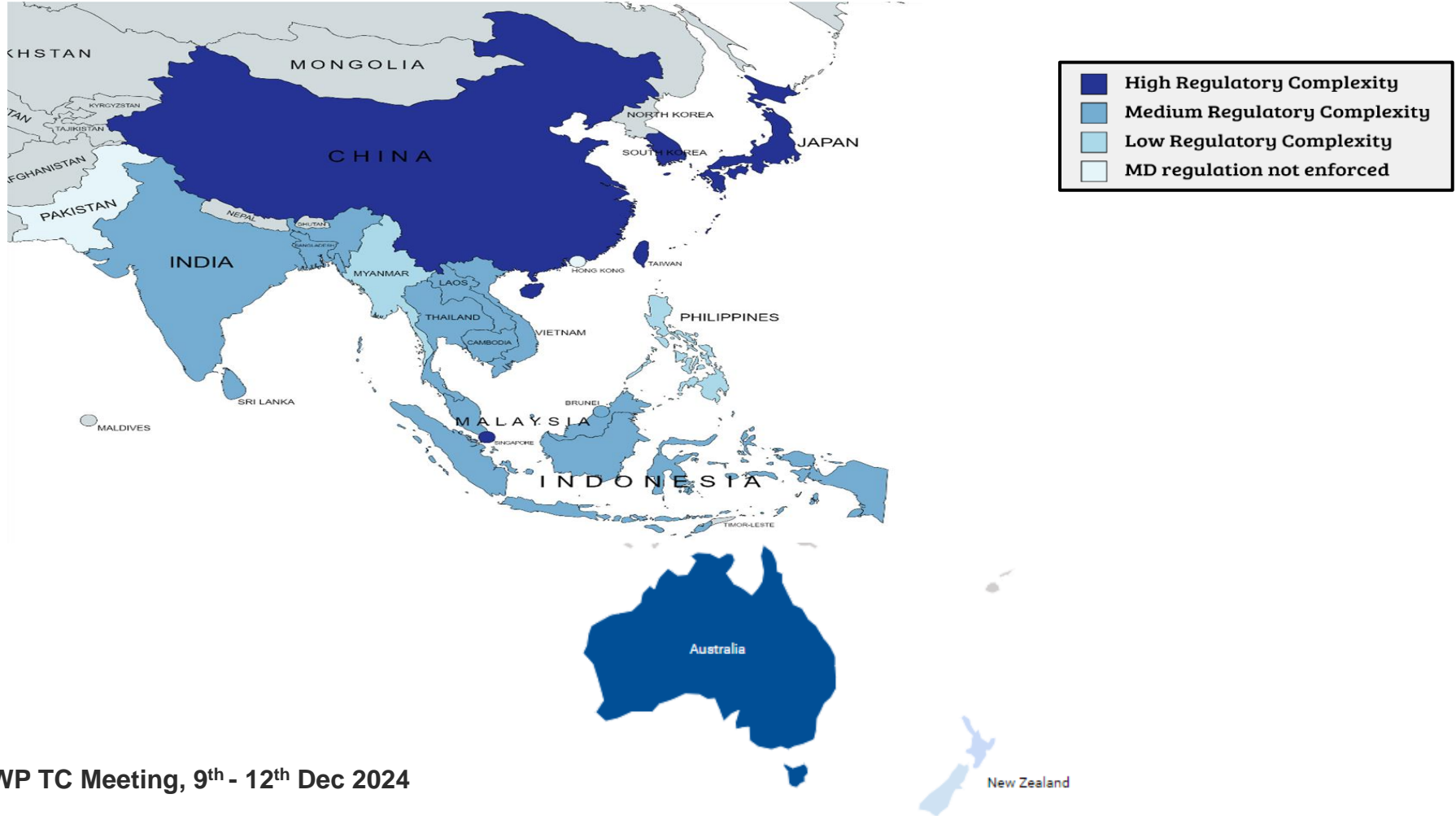
GHWP Towards Medical Device Harmonization

# Regulatory Convergence & Reliance in Asia Pacific





## Regulatory Maturity among Asia Pacific Markets





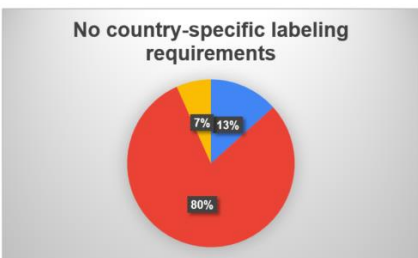
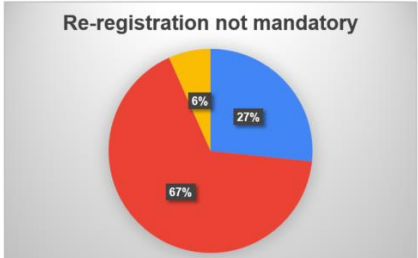
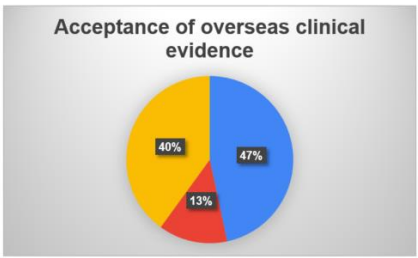
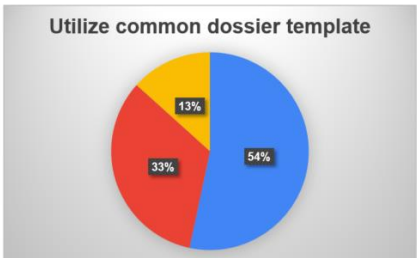
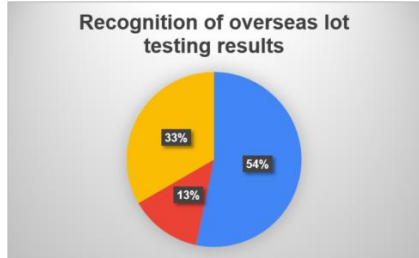
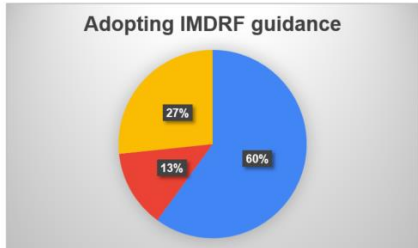
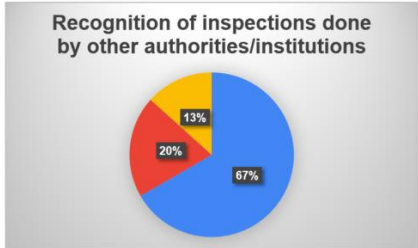
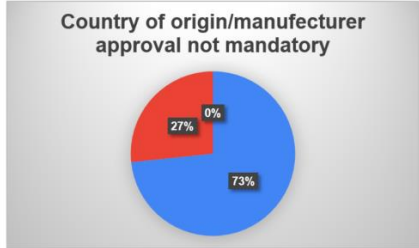
## APAC Markets' Engagement at Global/Regional Regulatory Harmonization Platforms

	 <b>IMDRF</b>	 <b>GHWP</b>	 <b>APEC</b>	 <b>asean</b>	 <b>SAARC</b>
<b>Singapore</b>	Yes	Yes	Yes		Yes
<b>China</b>	Yes	Yes	Yes		
<b>Japan</b>	Yes	Yes	Yes		
<b>South Korea</b>	Yes	Yes	Yes		
<b>Malaysia</b>		Yes	Yes		Yes
<b>Philippines</b>		Yes	Yes		Yes
<b>Indonesia</b>		Yes	Yes		Yes
<b>Thailand</b>		Yes	Yes		Yes
<b>Vietnam</b>		Yes	Yes		Yes
<b>Australia</b>	Yes		Yes		
<b>Chinese Taipei</b>	Yes*	Yes	Yes		
<b>Hong Kong SAR, China</b>		Yes	Yes		
<b>India</b>	Yes*	Yes			Yes
<b>Pakistan</b>		Yes			Yes
<b>Myanmar</b>		Yes			Yes
<b>New Zealand</b>			Yes		

\*IMDRF observer or affiliate member



## Convergence towards Good Regulatory Practices



\*Data based on analysis of 15 APAC markets

## The Interplay between Convergence and Reliance

### Convergence

A voluntary process whereby the regulatory requirements in different countries or regions become more similar or “aligned” over time. Convergence results from gradual adoption of internationally recognized technical guideline documents, standards and scientific principles, common or similar practices and procedures or the establishment of appropriate domestic regulatory mechanisms that align with shared principles to achieve a common public health goal.







### Reliance

The act whereby a regulatory authority in one jurisdiction takes into account and gives significant weight to assessments by another regulatory authority or trusted institution or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

Source: Annex 11 of the [Fifty-fifth report](#) of WHO Expert Committee on Specifications for Pharmaceutical Preparations: (TRS 1033), 25 March 2021



**Which product lifecycle do we practice reliance**

Total Product Lifecycle	Markets with formal reliance mechanism
Pre-market registration	
QMS	
Clinical	
Post-approval changes	
Vigilance	

- The eSTAR Pilot between Canada and US is for pre-market submission but not a formal pathway yet
- The UK reliance proposal for MDs/IVDs is currently under public consultation ([link](#))
- Huge variation in reliance practice creates great opportunities to improve existing reliance mechanism even if they check the boxes



**What kind of reliance models exist**

Country	Abridged Pathway	Work Sharing	Regional Reliance	Unilateral Recognition	Mutual Recognition
Australia	✓	✓			✓
Japan		✓			
Vietnam	✓				
Singapore	✓				
India	✓				
Thailand	✓				
Malaysia	✓				
South Korea	✓				
Philippines**	✓				
USA *	✓	✓			
EU			✓		✓
Canada *	✓	✓			
Brazil	✓				
UK	✓			✓	✓



## Case Study: Singapore

### Summary of Evaluation Routes for Class B Medical Device Registration

Evaluation Route	Full	Abridged	Immediate Class B registration – IBR
<b>Criteria</b>  (at the point of submission)	Not approved by any of HSA reference regulatory agencies	Approval from at least 1 of HSA's reference regulatory agency	<b>For all Class B medical devices</b>  <b>Condition 1</b> <ul style="list-style-type: none"> <li>Approval from at least 1 of HSA's reference regulatory agencies</li> <li>Marketed for ≥ 3 years in the above independent reference regulatory agency's jurisdiction*</li> <li>No safety issues globally</li> <li>No prior rejection/ withdrawal/rejection/ performance/efficacy</li> </ul> <b>OR</b> <b>Condition 2</b> <ul style="list-style-type: none"> <li>Approvals from at least 2 of HSA's independent reference regulatory agencies</li> <li>No safety issues globally</li> <li>No prior rejection/ withdrawal/rejection/ performance/efficacy</li> </ul> <b>For standalone medical devices</b> <ul style="list-style-type: none"> <li>Approval from at least 1 of HSA's independent reference regulatory agencies</li> <li>No safety issues globally</li> <li>No prior rejection/ withdrawal/rejection/ performance/efficacy</li> </ul>

\*Or the medical device has been marketed in Singapore for at least 3 years

### Summary of Evaluation Routes for Class C and D Medical Device Registration

Evaluation Route	Full	Abridged	Expedited Class C registration - ECR	Expedited Class D registration - EDR	Immediate Class C registration - ICR
<b>Criteria</b>  (at the point of submission)	Not approved by any of HSA's reference regulatory agencies	Approval from at least 1 of HSA's reference regulatory agencies	<b>ECR-1</b> <ul style="list-style-type: none"> <li>Approvals from at least 1 of HSA's <u>independent</u> reference regulatory agencies</li> <li>Marketed for ≥ 3 years in the above <u>independent</u> reference regulatory agency's jurisdiction*</li> <li>No safety issues globally</li> <li>No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues.</li> </ul> <b>OR</b> <b>ECR-2</b> <ul style="list-style-type: none"> <li>Approvals from at least 2 of HSA's <u>independent</u> reference regulatory agencies</li> </ul>	<ul style="list-style-type: none"> <li>Approvals from at least 2 of HSA's <u>independent</u> reference regulatory agencies</li> <li>No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues.</li> </ul>	<b>For standalone medical mobile applications</b> <ul style="list-style-type: none"> <li>Approval from at least 1 of HSA's <u>independent</u> reference regulatory agency</li> <li>No safety issues globally</li> <li>No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues.</li> </ul>



**Case Study: Singapore**

• **What**

- Class B,C & D medical devices (GMD & IVD) Abridged Evaluation Route
- Approval from one of the reference regulatory agencies (RFA): US FDA, EU, Aus TGA, Japan MHLW, Canada HC
- Labelled use identical to that intended for marketing in Singapore at the point of submission
- ~ most products registered using abridged route!

• **Pro**

- No assessment report from RFA is required

Class D	Full Evaluation	Abridged
TaT	310 WD	220 WD
Documents	Full reports	Summary reports
Registration fees	s\$12330	S\$6580

**Case Study: Singapore**

- Immediate Class B (GMD & IVD) Registration (IBR) Evaluation Route
  - 2 RFA approval with no safety issue globally, registration rejection OR 1 RFA approval with 3 years marketing history with no safety issue globally and RFA registration rejection
- Immediate Class B & C Registration Evaluation Route for **SaMD**
  - 1 RFA approval with no safety issue globally and RFA registration rejection
- Labelled use identical to that intended for marketing in Singapore at the point of submission

Class B	Full Evaluation	Immediate Registration
TaT	160 WD	0
Documents	Full reports	Selected documents, summary reports
Fees	\$2440	\$1480

## Case Study: Australia

### New IVD Regulation

Consultation with Health Canada prior to implementation.

Limited reliance in place (EU IVDD and HC licences).

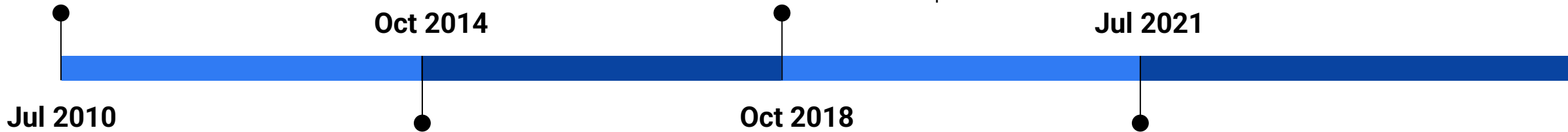
TGA conformity assessment for Class 4 IVDs (onerous and costly).

### Expanded list of comparable overseas regulators

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

Improved time to market.

EU IVDD, HC licences + US FDA, MDSAP certificates and reports



**Jul 2010**

**Oct 2014**

**Oct 2018**

**Jul 2021**

### Expert Panel Review of Medicines and Medical Devices Regulation

Assessment of the regulatory framework and recommendations put forward to the Government on options to improve the way in which therapeutic goods were regulated in Australia

### Major change to recognise IVDR for Class 4 IVDs

TGA will now accept conformity assessment documents issued by EU Notified Bodies for Class 4 IVDs.

Technical File Review of applications will still take place but will be limited if supported by IVDR certification



## Case Study: Australia

**Reliance Pathways applicable for both new registrations and change submissions**

Regulators / Approvals	Manufacturer Evidence (QMS Certificate)	Evidence of Product Assessment		
		Class 2	Class 3	Class 4
EU IVDD	Annex IV.3	N/A	N/A	Annex IV – Design examination
	Annex VIII	N/A	Annex V – Type Examination	Annex V - Type Examination
EU IVDR	Annex IX (QMS) Chapter I	Annex IX, Sections 4.4 to 4.8 (based on representative sample) For self-testing and near-patient testing: Assessment of Technical Documentation set out in Section 5.1 of Annex IX	Annex IX, Chapter II (at least one representative device per group). For self-testing and near-patient testing: Assessment of Technical documentation set out in Section 5.1;	Annex IX (QMS) Chapter II – Design examination
	Annex XI (Production QMS) except Section 5	N/A	Annex X –Type Examination	Annex X -Type Examination
FDA 510(k)	MDSAP Certificate	510(k) Summary	510(k) Summary	<span style="color: red;">Since Jul 2021</span>  Cannot be used
FDA PMA	MDSAP Certificate or PMA	N/A	PMA	
Health Canada	MDSAP Certificate	N/A	Medical device licence Class III	
Since Sep 2022	<b>Singapore HSA</b>	Class B licence	Class C licence	
MDSAP	MDSAP Certificate	N/A	N/A	



**Global Harmonization Working Party**

Towards Medical Device Harmonization

Thank you  
for your attention

Any questions, please contact: [yasha.huang@roche.com](mailto:yasha.huang@roche.com)