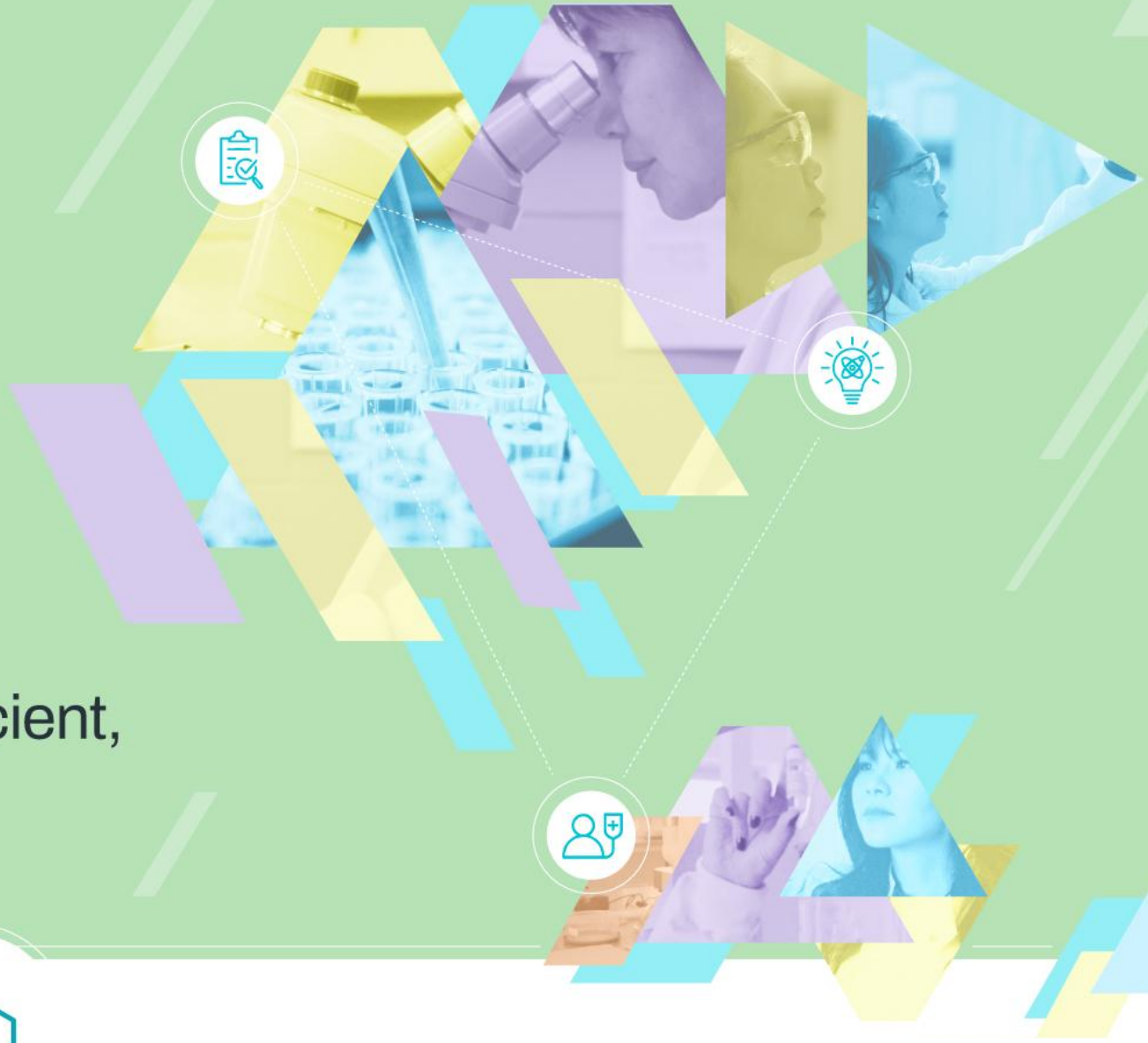
03-06 December 2024

ARC 2024

ASIA REGULATORY CONFERENCE

EVOLVING LANDSCAPES

Asia's role in driving a more efficient, innovative and patient-centric regulatory environment



Organized by IFPMA

In partnership with Medicines Australia

4 December
07:30 – 09:00 CET

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RELIANCE CASE STUDIES & LESSONS LEARNED

Navigating Reliance: Practical Applications in South-East Asia and Western Pacific region

Noraisyah Mohd Sani
NPRA

Wenzel Asprec
Philippines FDA

Yee Hoo Looi
HSA

Céline Bourguignon
IFPMA

Moderator
Alice Chee (PhAMA)

Organized by IFPMA

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Online conference, free to attend. Register at ifpma.org

Thank you for joining! A few guidelines for participants

The conference is held in English.

The detailed conference programme and speakers' biographies are available on arc.ifpma.org.

All participants are muted. Please use the Q&A box to raise questions to the speakers. If a question you would like to ask has already been raised, you can also "like" that question.

Polls will be used during the sessions to get feedback from participants. These will appear on screen.

We encourage you to join all conference days. There is still time to register for other sessions.

The conference is recorded. All speaker presentations and videos will be made available on the website after the conference.

Adapting to the Changing Times: Overview of the FDA Philippines' Reliance Mechanisms for Marketing Authorization

Presented by Wenzel Cabotage Asprec, RPh

04 December 2024

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Presentation Outline

Introduction

Facilitated Registration Pathways Adopted and Implemented in the Philippines

- → Abridged Review
- → Verification Review
- → WHO Collaborative Registration Procedure (CRP)
- → ASEAN Joint Assessment (JA) Procedure

Challenges, Lessons Learned, and Recommendations Moving Forward

Introduction: FDA Philippines

Food and Drug Administration (FDA) Philippines

National drug regulatory authority (NDRA) under the Department of Health.

Established in 1963 by virtue of Republic Act No. 3720, as amended by Executive Order No. 175, series of 1987, “Food, Drugs and Devices, and Cosmetics Act”.

Strengthened by Republic Act No. 9711, “The Food and Drug Administration Act of 2009”.

- → Center for Drug Regulation and Research (CDRR)
- → Center for Food Regulation and Research (CFRR)
- → Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
- → Center for Device Regulation, Radiation Health and Research (CDRRHR)

Introduction: FDA Philippines

Food and Drug Administration (FDA) Philippines

Mandate:

To protect the general public by ensuring the safety, efficacy and quality of health products.

Mission:

To guarantee the access of the general public to safe, quality, pure and efficacious health products through sound and innovative regulations.

Vision:

For the Organization: An efficient regulatory agency providing modernized solutions in ensuring access to regulated health products.

For the Society: A nation with well-informed consumers with access to regulated health products.

Introduction: Adapting to the Changing Times via Reliance

Why is there a compelling need for Regulatory Reliance?

Globalization and advancement in drug development, manufacture and distribution

Regulatory convergence, harmonization and benchmarking – regional and global level

→ ASEAN e.g. Pharmaceutical Product Working Group (PPWG)

- ACTD/ACTR, MRA on GMP, BE Study Reports, ASEAN JA Procedure

→ WHO

Resource constraints at the NDRA level

→ Manpower and technical capacity

→ Infrastructure, equipment and systems

→ Backlogs

- Partially attributed to the duplication of assessments already done by competent (stringent) regulatory authorities

Ensure timely access and/or improved availability of needed health products

Facilitated Registration Pathways – Abridged Review

"A limited independent assessment of specific parts of the dossier, or submission for suitability of use under local conditions and regulatory requirements while relying on prior assessment from a reference drug regulatory agency (RDRA) to inform the local decision."

Eligibility Criteria

- → May be availed when the drug product, vaccine or biological has been approved by **1 RDRA**.
- → Eligible product shall be the same as the one approved in the RDRA, including its intended use in the Philippines.
- → Proposed Package Insert (PI)/Patient Information Leaflet (PIL) shall be identical to that approved by the RDRA with the addition of applicable country-specific labeling information.
- → All documentation must be in English.

Key Documentary Requirements

- → Assessment Report and CPP from the identified RDRA, Complete ACTD or ICH CTD, Climatic Zone IVb stability studies

Timeline

- → Not more than 45 working days

Facilitated Registration Pathways – Verification Review

"An assessment process by which the submission has been evaluated and approved by at least two (2) RDRAs, and the FDA only validates the submission and ensures that the product conforms to the registration conditions, standards and requirements as approved by the RDRAs."

Eligibility Criteria

- → May be availed when the drug product, vaccine or biological has been approved by **at least 2 RDRAs**.
- → Eligible product shall be the same as the one approved in the RDRAs, including its intended use in the Philippines.
- → Proposed Package Insert (PI)/Patient Information Leaflet (PIL) shall be identical to that approved by the RDRAs with the addition of applicable country-specific labeling information.
- → All documentation must be in English.

Key Documentary Requirements

- → Assessment Reports and CPPs from the identified RDRAs, Complete ACTD or ICH CTD, Climatic Zone IVb stability studies

Timeline

- → Not more than 30 working days

Facilitated Registration Pathways – List of RDRAs

Therapeutic Goods Administration (TGA) – Australia
Federal Agency for Medicines and Health Products (FAMHP) – Belgium
Health Canada (HC) – Canada
European Medicines Agency (EMA) – European Union
French National Agency for Medicines and Health Products Safety (ANSM) – France
Federal Institute for Drugs and Medical Devices (BfARM) – Germany
Paul-Ehrlich-Institut (PEI) – Germany
Italian Medicines Agency (AIFA) – Italy
Pharmaceuticals and Medical Devices Agency (PMDA) – Japan
Medicines Evaluation Board (MEB) – Netherlands
Health Sciences Authority (HSA) – Singapore
Swiss Agency for Therapeutic Products (Swissmedic) – Switzerland
Medicines and Healthcare Products Regulatory Agency (MHRA) – United Kingdom
US Food and Drug Administration (USFDA) – United States of America
Ministry of Food and Drug Safety (MFDS) – Republic of Korea
Saudi Food and Drug Authority (SFDA) – Saudi Arabia

Facilitated Registration Pathways – List of RDRAs

Criteria for Selection

Founding members of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)

Stringent Regulatory Authorities (SRAs) and WHO Listed Authorities (WLAs)

Other national (or regional) drug regulatory authorities operating at Maturity Level 4 via the WHO Benchmarking Tool

→ 16 RDRAs for medicines and vaccines unilaterally recognized by FDA Philippines.

→ Progress of formal bilateral engagement via a memorandum of understanding/cooperation with the following RDRAs are currently at various stages:

- TGA Australia
- MFDS Korea
- PMDA Japan

Facilitated Registration Pathways – Collaborative Procedure

"An assessment process recognized by the FDA through reliance, work-sharing, or joint reviews with other international organizations like the World Health Organization Prequalification of Medicines Programme (now known as Prequalification Team – Medicines) or other drug regulatory agencies, as may be identified by the FDA."

Eligibility Criteria

- → May be availed when the drug product, vaccine or biological has been reviewed through a collaborative registration procedure recognized by the FDA.
- → Eligible product shall be the same as the one approved or prequalified under the collaborative registration procedure recognized by the FDA, including its intended use in the Philippines.
- → Proposed Package Insert (PI)/Patient Information Leaflet (PIL) shall be identical to that approved by the RDRA with the addition of applicable country-specific labeling information.
- → All documentation must be in English.

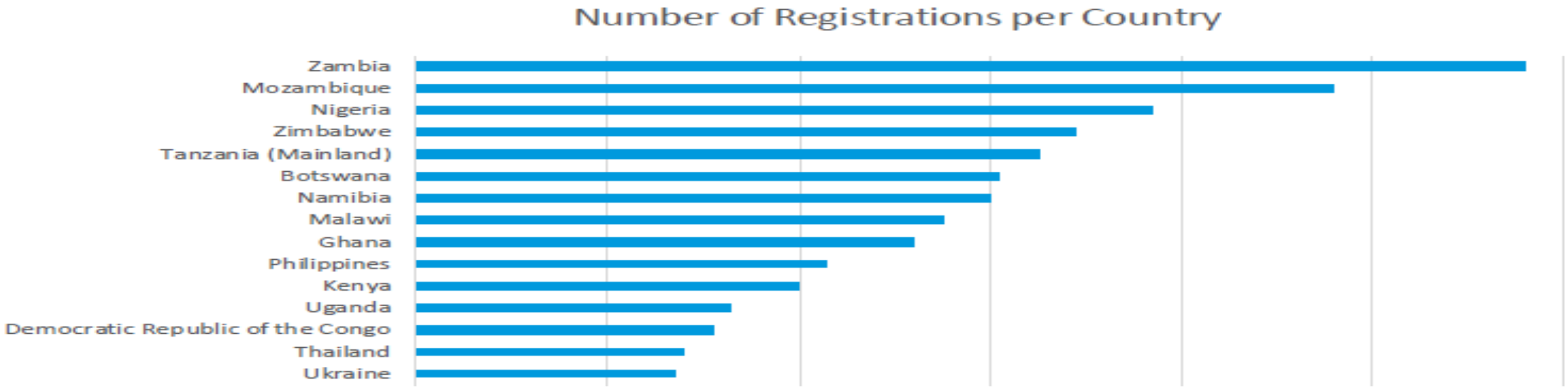
Timeline

- → Not more than 65 working days

Facilitated Registration Pathways – Collaborative Procedure

WHO Collaborative Registration Procedure via Full Prequalification Route

- Entailed the adoption of the WHO Technical Report Series 996, 2016, Annex 8 *Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines.*
- FDA Philippines became a participating authority on 08 October 2015, among the first in the Asian region.
- There are currently 66 participating national and regional authorities in the PQ CRP.
- More than 65 prequalified medicines have already been registered in the Philippines via the PQ CRP, mainly for tuberculosis and HIV/AIDS.



Facilitated Registration Pathways – Joint Assessment

"Formal procedure in which the same application is simultaneously submitted to all participating NDRAs."

ASEAN Joint Assessment (JA) Procedure for Pharmaceutical Products

Application Routes

→ Responsive Application Route: Applications concerning products that are included in the priority list published by ASEAN NDRAs

→ Proposed Application Route: Applicants proposed products that are not included in the priority list published by ASEAN NDRAs

→ Invited Application Route: Applicants are approached by ASEAN NDRAs or by WHO and invited to submit an application for a product of high public health impact

Online Platform

→ ASEAN Joint Assessment Integrated Management System (JAIMS) funded and managed by WHO

Timeline

→ 150 calendar days for ASEAN Joint Assessment Process + 30 working days for FDA Philippines' regulatory decision-making

Facilitated Registration Pathways – Joint Assessment

JA Participated by FDA Philippines

- → Artesunate + Pyronaridine tetraphosphate granules for oral suspension *and* film-coated tablet [Pyramax] – Antimalarial
  - NPRA Malaysia as Lead NRA
- → Tafenoquine film-coated tablet [Kozenis] – Antimalarial
  - Thai FDA as Lead NRA
- → Cabotegravir film-coated tablet *and* prolonged-release suspension for injection [Apretude] – HIV Pre-Exposure Prophylaxis (PrEP)
  - FDA Philippines as Lead NRA
- → Ocrelizumab concentrate for solution for intravenous infusion [Ocrevus] – Selective immunosuppressant, MAb for multiple sclerosis
  - NPRA Malaysia as Lead NRA

Upcoming Products for JA with FDA Philippines' Participation

- → Ocrelizumab [Ocrevus] Post-Approval Change (PAC) and Line Extension (LE) – Pilot Project via JAIMS Platform
- → Vildagliptin Tablet of Macleods Pharmaceuticals Limited
- → Aztreonam-Avibactam Powder for Concentrate for Solution for Infusion [Emblaveo] of Pfizer

Challenges, Lessons Learned, and Recommendations (1)

Reliance implementation in the Philippines has still so much room for improvement.

- → Meeting the committed timelines
  - Growing interest from the Pharmaceutical Industry would expectedly translate to a greater number of MA submissions.
  - There is a need to address staffing issues internally (including multitasking) to ensure committed timelines are met. A dedicated assessment team with sufficient number and technical capacity should be maintained for this specific purpose.
- → Concept of regulatory reliance is still not instilled among all the assessors.
  - A shift in mindset and attitude among assessors, and openness in doing things differently (i.e., beyond a full review) is needed. This should be complemented by appropriate training and capacity-building.
- → Currently, there is no formal channel to communicate and collaborate with the 16 unilaterally recognized RDRAs.
  - Though usually a long and painstaking process, establishment of formal working relationships with RDRAs via an MOU/MOC is imperative to open the communication channel in the processing of MA submissions via Abridged Review and Verification Review.
- → There is a relatively high refusal rate for MA submissions during the pre-assessment/validation stage due to completeness issues.
  - There is a need to continue FDA Philippines' advocacy and information-dissemination activities for the Pharmaceutical Industry in order for the latter to meet the former's submission expectations.

Challenges, Lessons Learned, and Recommendations (2)

Reliance implementation in the Philippines has still so much room for improvement.

- → Having recently joined as a participating authority in the WHO CRP via SRA-approval route (i.e., 15 July 2024), FDA Philippines still needs to come up with the specific implementing guidelines in the form of an FDA Circular.
  - With the help of the CDRR's standards development arm, the issuance of the FDA Circular is targeted within CY 2025.
- → Though institutionalized among the FRPs, FDA Philippines' participation in the ASEAN JA Procedure is still considered voluntary in the absence of specific implementing guidelines in the form of an FDA Circular.
  - With the help of the CDRR's standards development arm, the issuance of the FDA Circular is targeted within CY 2025.

References

Administrative Order No. 2020-0044: Adoption of the Collaborative Procedure for the Accelerated Registration of World Health Organization (WHO) Prequalified Pharmaceutical Products and Vaccines

→ FDA Circular No. 2022-009: *Implementing Guidelines of Administrative Order No. 2020-0044*

Administrative Order No. 2020-0045: *Establishing Facilitated Registration Pathways for Drug Products including Vaccines and Biologicals*

→ FDA Circular No. 2022-004: *Implementing Guidelines on the Abridged and Verification Review Pathways for New Drug Registration Applications;* and its amendment by virtue of FDA Circular No. 2022-004-A

Administrative Order No. 2024-0013: *General Rules and Regulations on the Registration of Pharmaceutical Products an Active Pharmaceutical Ingredients Intended for Human Use*

ASEAN Joint Assessment Procedure for Pharmaceutical Products – Information for Applicants (Revision 3)

Thank you very much!

Maraming salamat po!

wcasprec@fda.gov.ph
https://www.fda.gov.ph

FDA Food and Drug Administration PHILIPPINES

BAGONG PILIPINAS

Overview of the National Reliance Mechanism: NPRA’s perspectives

Presented by Noraisyah Mohd Sani, PhD (NPRA, Malaysia)

04 December 2024

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Presentation Outline

- Introduction
- Facilitated Registration Pathway (FRP) Guideline – key features & tools
- Challenges in practicing reliance
- Reliance: Lesson learned
- Best Practices: Recommendations for implementing reliance

INTRODUCTION

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Reliance: NPRA previous approach

NPRA has been using reliance (in various forms) for > 20 years

Pre-marketing assessment – partial reliance

Public assessment report of the reference agencies
EDQM certificate of suitability (CEP) for DS
GMP inspection reports/certificate for overseas manufacturing sites (PIC/S)
Certificate of Pharmaceutical Product
Batch Release Certificate

Post-market activities

Safety alert
Variations

"RELIANCE….an act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision…."

Preparing for the FRP framework - step by step

Political will – direction by the top management to mandate the establishment of a new pathway

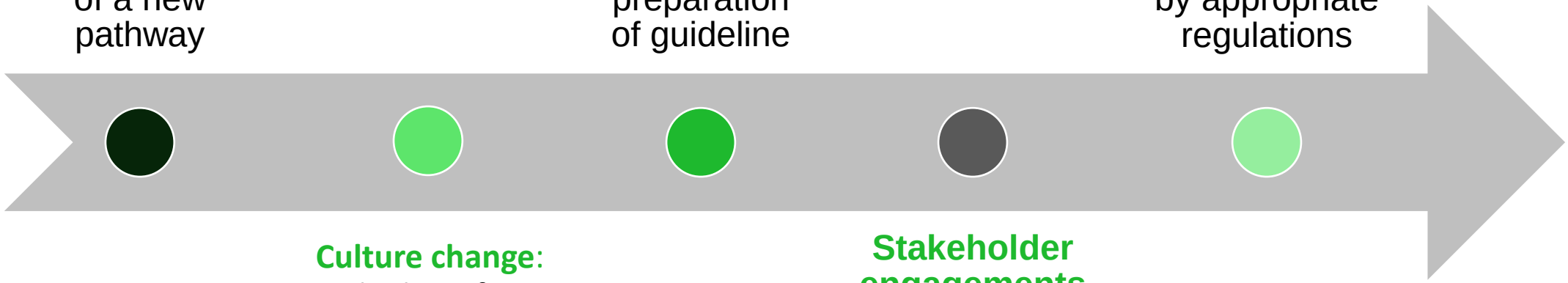
Culture change: The benefits were explained to all staff expected to implement reliance approaches

Investment of resources & time – task force: preparation of guideline

Stakeholder engagements

List of questions, clarifications

Finalising and endorsement of the guidance and supported by appropriate regulations



FACILITATED REGISTRATION PATHWAY (FRP)

Key Features & Tools

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Facilitated Registration Pathways (FRP): First guideline, 2019

- First Guideline was issued in 2019
- Limited scope & reference agencies - to sensitize the evaluators with new procedure
- Application must be submitted within 2 years from the date of approval by the chosen reference agency/procedure

Monitoring the impact: how many products were registered, timeline

Scope

New Drug Products including NCEs

Biologics including Biosimilars

Reference Agencies

US FDA & EMA

WHO Pre Q Medicinal Products covered by the alternative listing procedure (approved by US FDA & EMA)

Route

Abbreviated review: approved by at least 1 reference agency (120 WD)

Verification review: approved by 2 reference agencies (90WD)

Revised FRP guideline, November 2023 (effective implementation 1st Jan 2024)


Ministry of Health Malaysia

GUIDELINE FOR
FACILITATED REGISTRATION PATHWAY

Revision 1 (November 2023)

National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia

Key features

- *Expansion of the scope of products*
- *Addition of more reference agencies/ procedures*
- *Redefine the abbreviated and verification review*
- *Extension of time limited from date of reference country approval*
- *Revision of the timeline*
- *Addition of a template for the declaration statement by the applicant, dossier template and flow charts*

Revised FRP guideline – key features

Scope of products

New drug products (NCEs)

Generic medicines

Biologics including **cell and gene therapy products**

Reference agencies & Procedures

EMA, US FDA, **Health Canada, PMDA, Swiss Medic, TGA, UK MHRA**

WHO Collaborative Registration Procedure (CRP)- SRA & PreQ

ASEAN Joint Assessment (JA)

Routes

Abbreviated review (**90 WD**):Product approved by any of the reference agencies or approved via WHO CRP

Verification Review (**30WD**):Product approved via ASEAN JA

Eligibility criteria: Submitted within 3 years from the date of approval by the chosen reference agency/procedure & approved/reviewed via a full evaluation process (standalone), all aspects are the same as approved by reference agencies (except CCS, manufacturing sites if clearly justified)

Not eligible: Product that has been approved under exceptional circumstances e.g. Conditional marketing authorization or via reliance pathway & products requiring a more stringent assessment as a result of differences in local disease patterns and/or medical practices

Documents required & regulatory tools

Full Dossier

- *Complete Common Technical Document -stability study complies with ASEAN stability guideline (where relevant)*

Assessment Report

- *Complete assessment report*
- *Q&A documents between the PRH and reference agency Documents pertaining to post approval variations*

Proof of Approval

- *Proof of approval from the chosen reference agency/procedure*

Declaration Letter & statement

- *All aspects - identical to the currently approved by the reference agency*
- *Information and documents submitted in this application are true and authentic*

Other Tools

Dossier Checklist

1. Product details

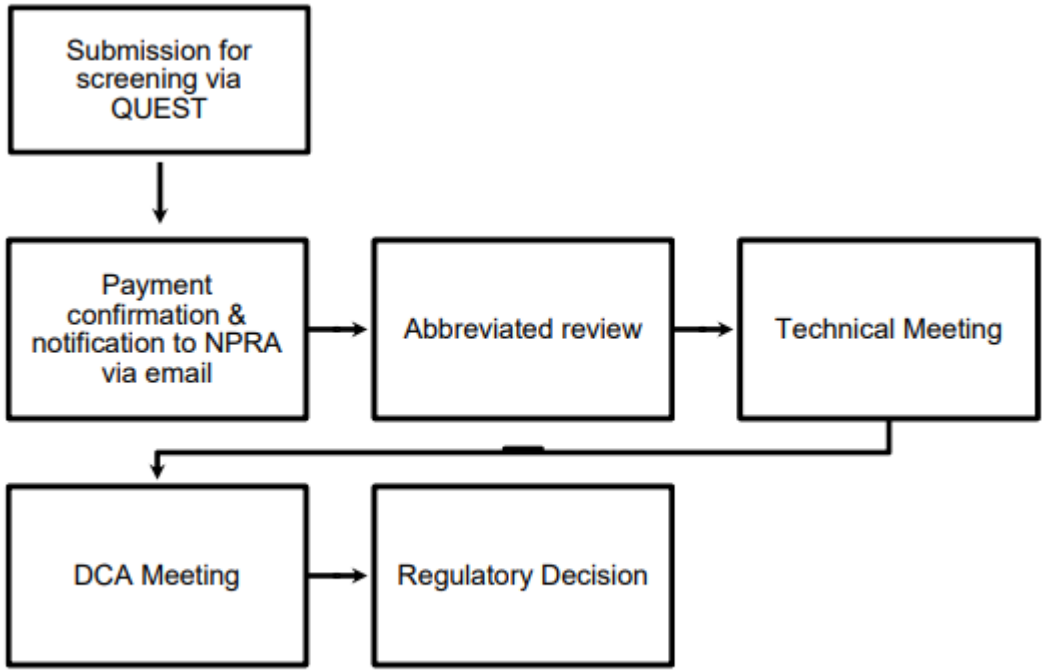
Product Name	
Active Pharmaceutical Ingredient (API) name, strength, pharmaceutical form	
Product registration Holder	
Date of Application to NPRA	
Call number (QUEST)	

2. Similarity of Data Set

Item	Data approved by the chosen reference agency or procedure	Data submitted to NPRA	Comments
Active Pharmaceutical Ingredient (API)/ Drug Substance			

Flow chart

e.g. Product approved by reference agencies



Other Tools

Evaluators' Guide/SOP

EVALUATORS' GUIDE FOR PRODUCTS SUBMITTED VIA A FACILITATED REGISTRATION PATHWAY

Version 1 2024

National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia

FAQs (NPRA website)

Frequently Asked Questions (FAQs):
Registration application submitted via Facilitated Registration Pathway (FRP)

1. **Does the removal of checklists for protocol of analysis (PoA) and analytical method validation (AMV) from the 2019 FRP guideline imply that PoA and AMV are no longe ?**

AMV w
data f

2. **Is the nt by the ap on?**

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Item	Data approved by reference agency	Data submitted to NPRA	Comments
Drug Substance			
Manufacturer(s) S2.1	Initial assessment report Name & address of Manufacturer A XXX variation report Addition of Name & address of	1) Name & address of Manufacturer A 2) Name & address of Manufacturer B	

CHALLENGES IN PRACTICING RELIANCE

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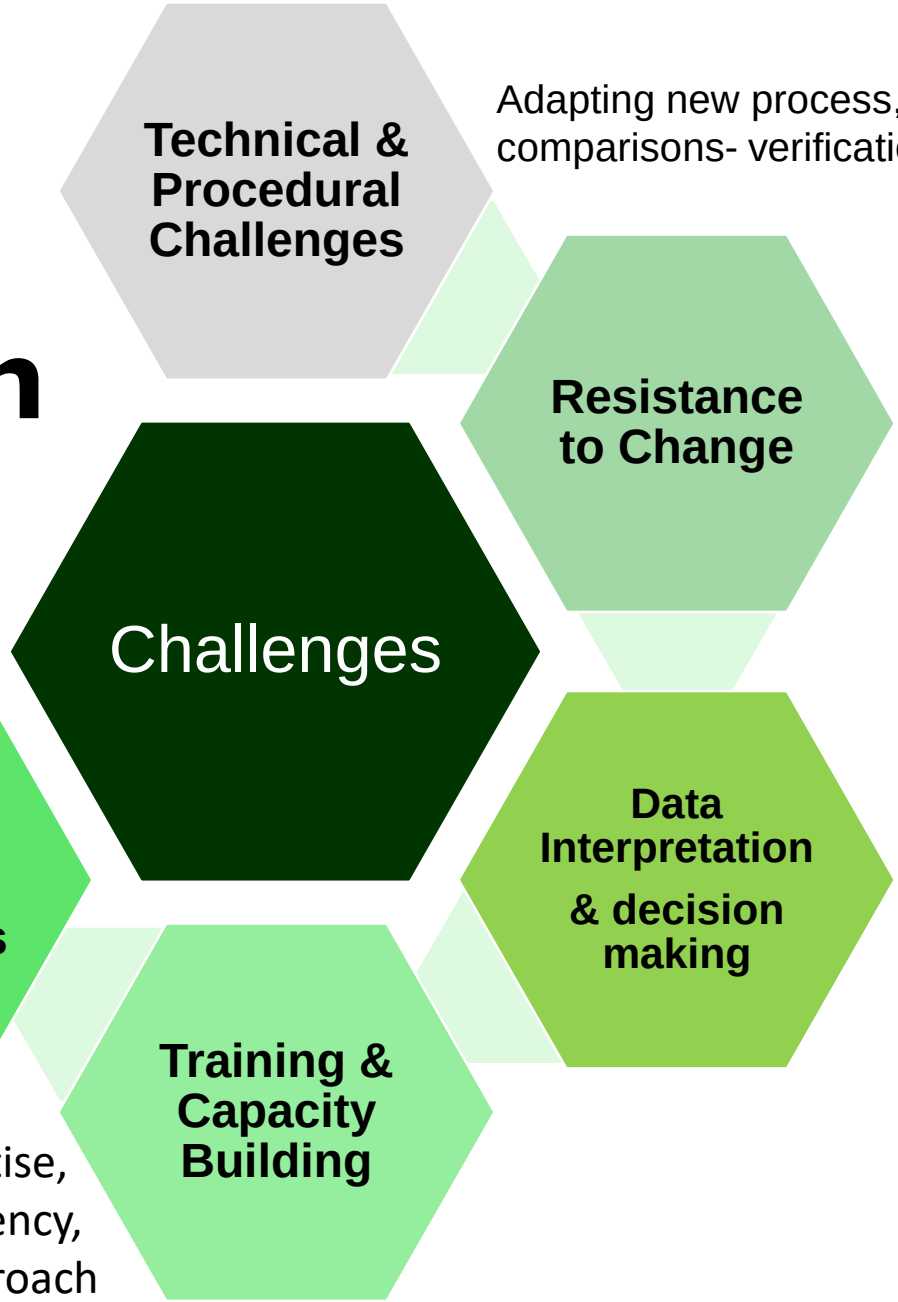
Challenges in practicing reliance



RELIANCE – LESSON LEARNED

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Reliance– Lesson learned

- Evaluators must understand the reference agency's processes, decision-making, & data quality to establish confidence

- Verification of critical aspects from reference agencies is important- ensures the reliability & relevance of decisions

- Reliance should be viewed as a dynamic process. Regular reviews of outcomes and feedback is important.

- Evaluators should implement robust risk management strategies when relying on reference agencies - identify scenarios where reliance may not be appropriate

BEST PRACTICES – RECOMMENDATIONS IN IMPLEMENTING RELIANCE

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Establishing a Clear and Transparent Framework:

Comprehensive guideline & defined review pathways

Leveraging Reliance to Streamline Processes:

Focus on sameness verification, SOP for evaluators

Optimizing Digital Tools for Reliance –

e.g. Quest system

Capacity Building and Training

Monitoring & Continuous Improvement:

Data-driven: updating guideline

Best practices: Recommendations for implementing reliance

Thank you

noraisyah@npra.gov.my

How different document can be used to support reliance *Industry perspective*

Presented by Céline BOURGUIGNON

On behalf of IFPMA

4th December 2024

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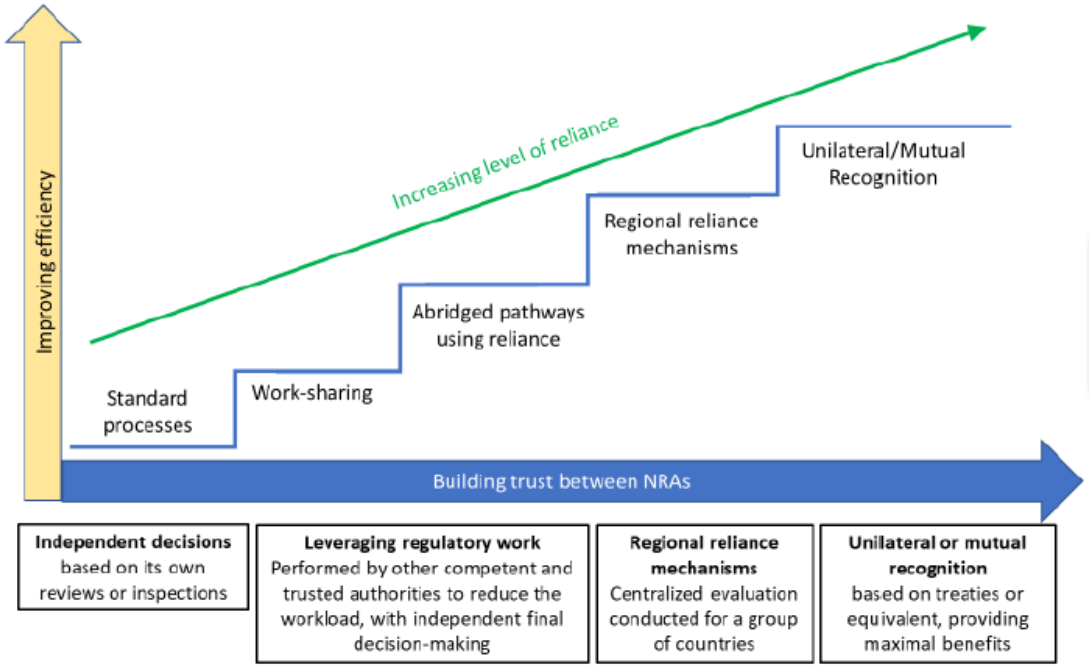
Why is Reliance important ? Access to medical products is a global challenge

Applying reliance mechanisms enables quicker and more equitable access of drugs and vaccines to populations who need them around the world



RELIANCE

When a regulatory authority takes into account/gives significant weight to assessments performed by another regulatory authority in reaching its own decision

The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others

Image taken from WHO ‘Good reliance practices in regulatory decision-making: high-level principles and recommendations’ Working document QAS/20.851 June 2020

Industry is strongly committed to bring reliance into action

Accelerate Access to Innovative Medicines & Vaccines for Patients

Reliance is not a new concept…

Long history of improving efficiency through reliance
e.g. Certificate of Pharmaceutical Products Scheme

"Regulate through reliance" as the hallmark of a modern and efficient regulatory authority.

Increasing role of reliance

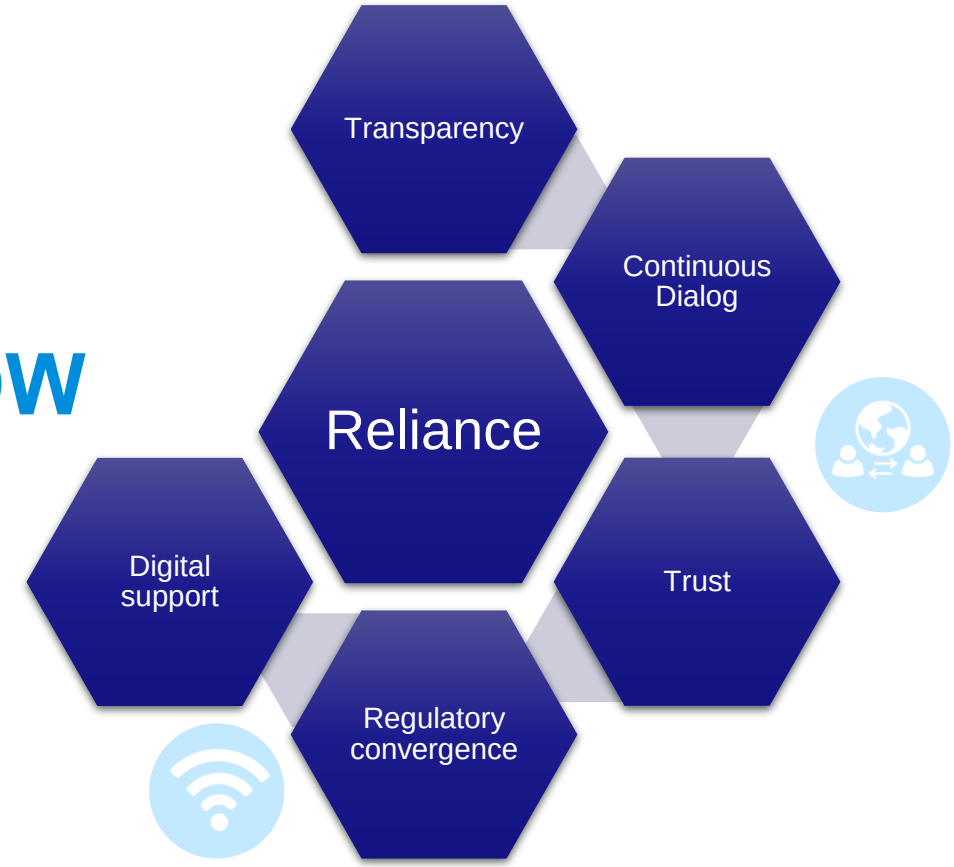
Promoting "informed" reliance

COVID-19 response as a strong accelerator for the use of reliance

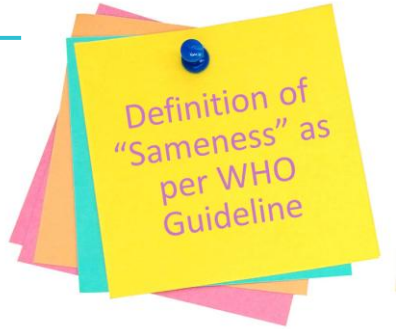
World Health Organization

It's not the WHY - it's the HOW

Increased use of efficient reliance across the entire product lifecycle by NRAs of all maturity levels, leveraging different reliance tools that speed up decision-making and reduce duplication of work.



Verification of Sameness is essential for reliance



All relevant aspects are to be considered e.g:

- Same qualitative and quantitative composition
- Same strength
- Same pharmaceutical form
- Same intended use
- Same manufacturing process
- Same suppliers of active pharmaceutical ingredients
- Same quality of all excipients

But sameness of product does not mean dossiers sameness

MCNs provide dossiers that comply with each jurisdiction's specific requirements.

Global harmonization of dossier structure and content is a work in progress. Differences of documentation should not preclude from using reliance approaches (but transparency is key).

There may be also differences in the level of detail provided between SRA and NRA dossier but essentially the same quality attributes apply.

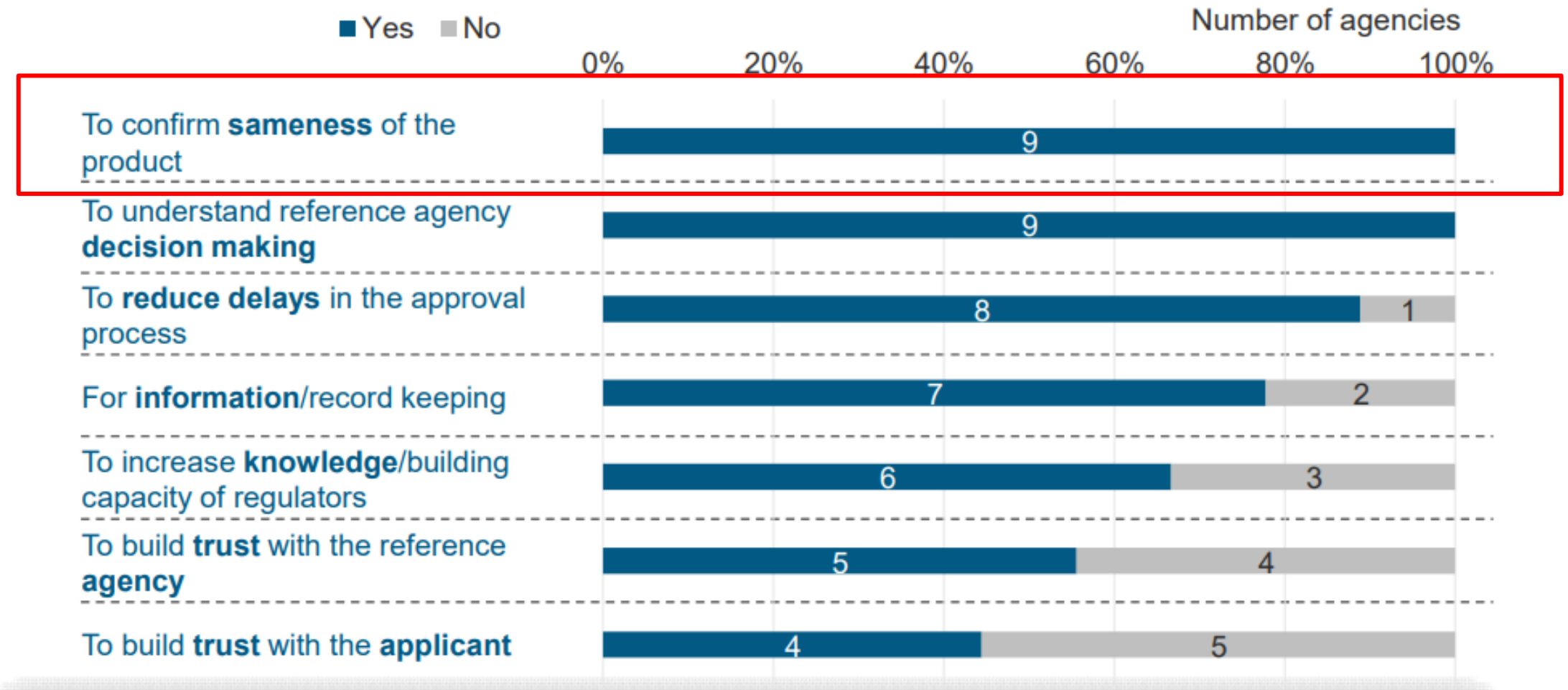
New applications:
Dossier submitted to relying authority will be **embedding variations** submitted after **initial SRA approval** and may differ from the assessment report.

Post-Approval changes:
Misalignment on classifications and timelines for variations globally may lead to dossier lag and supply issues
More **changes need prior approva**l (including minor changes) with slower approvals compared to SRA so these dossiers lag behind SRA
Potential supply **shortages if changes are not approved** before reserved supplies are depleted.

Introduction - Outcome of a recent CIRS study*

Study link

Part 2 - Agency rationale for requesting non-public documents?



(N) = number of agencies = 9

Question 18

CIRS Centre for Innovation in Regulatory Science

*CIRS 2024 Workshop, Sao Paulo, Dr. Magda Bujar

Usefulness of Public Assessment Reports (PARs) for Reliance

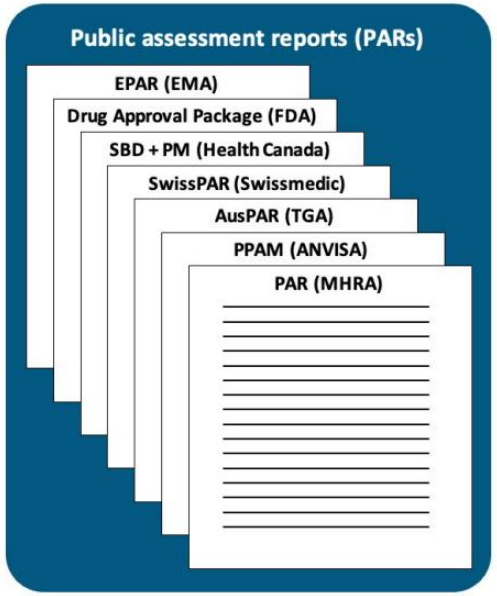
7 reference agencies in scope :

US Food and Drug Administration (FDA), European Medicines Agency (EMA), Health Canada (HC), Swissmedic, Therapeutic Goods Administration (TGA),

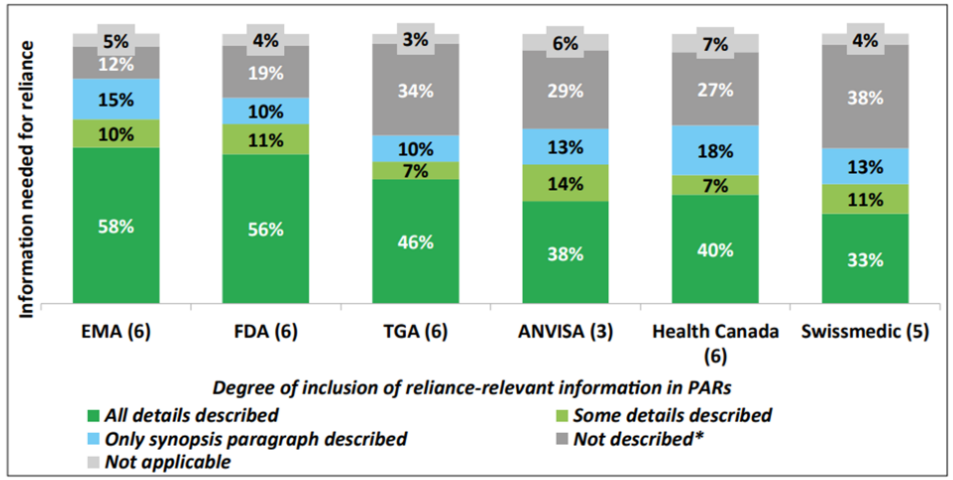
Goal: To compare reference agencies PARs and to assess whether the information needed for reliance is included.

Methodology : 33 PARs corresponding to 6 NAS (New active substances submission) assessed against a CIRS generic list of information of value for risk-based reviews

5 main sections Regulatory background, CMC, Non clinical, Clinical, Benefit-Risk Assessment



Publicly available reference agency documentation contains the majority of the information that relying agencies may require for risk-based reviews. However, none of the agency PARs contained all the identified reliance-relevant information.



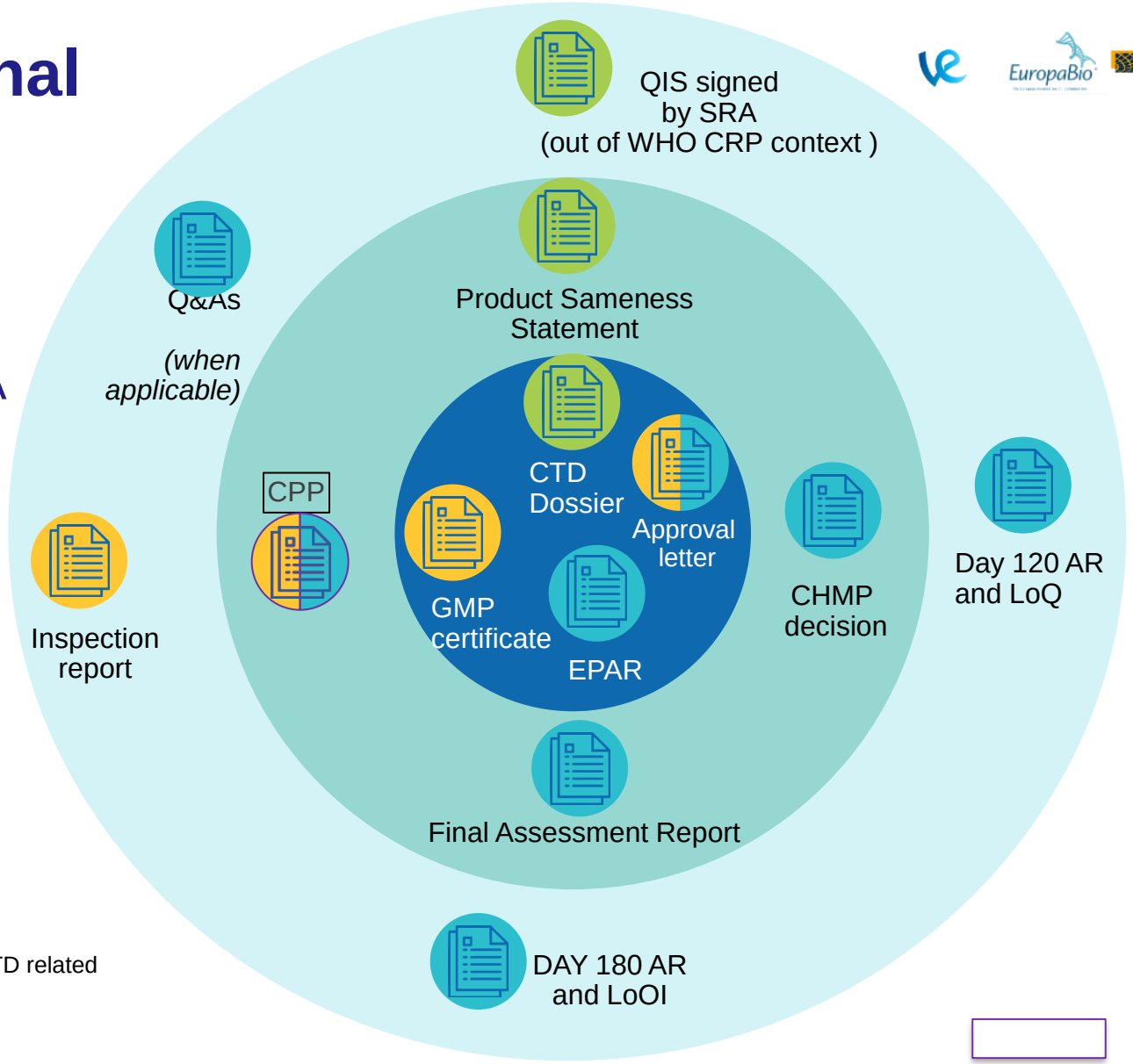
- Regulatory background, Clinical and Benefit-Risk assessment sections contain greatest amount of Reliance relevant information

- CMC and Non-Clinical sections contain the least amount of Reliance relevant information

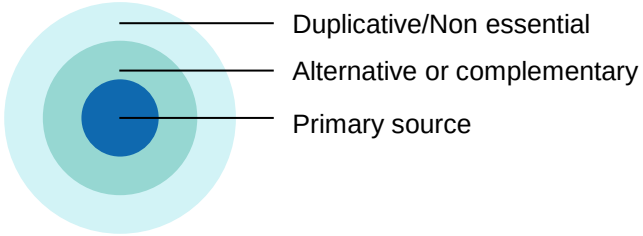
CIRS-RD-Briefing-92-Appraisal-of-public-assessment-reports-as-tools-for-reliance.pdf

Conclusions & additional recommendations -

Documents
to streamline reliance for MAAs
leveraging EMA as reference NRA



Level of documentation Importance to apply reliance



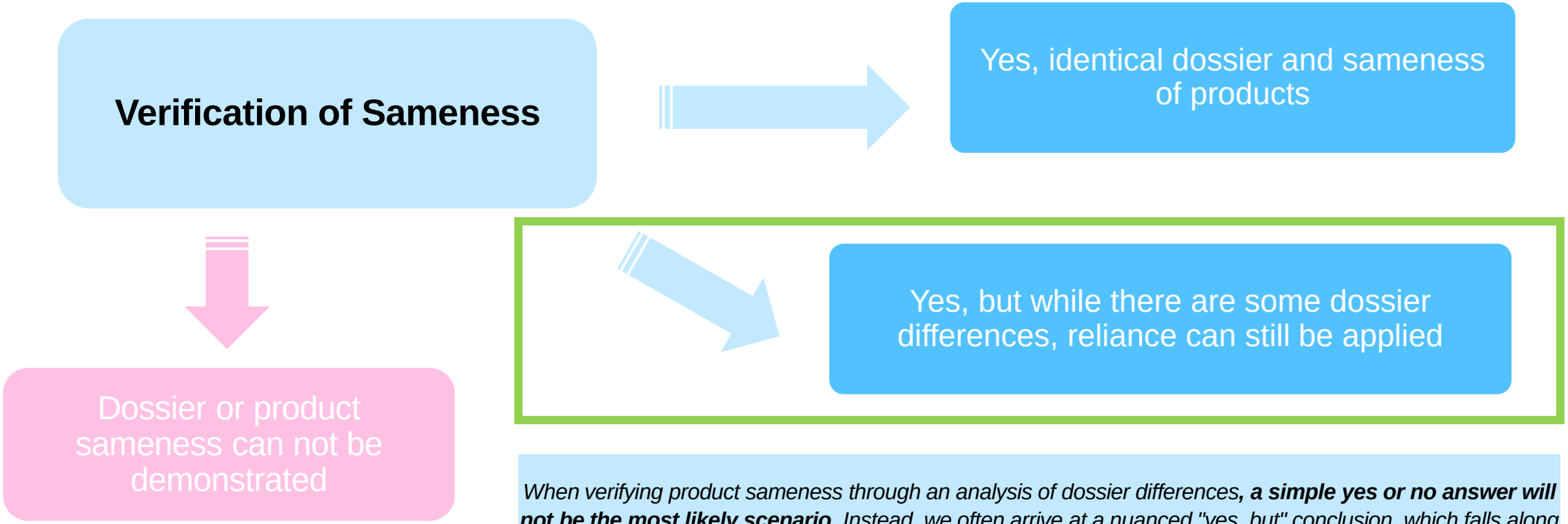
Document family

GMP Regulatory Assessment CTD related

Existing reliance tool

Streamlined documentation requirements incentivize use of reliance, through efficient use of resources… leading to timely access of product to patients

How can sameness of product be verified?



*When verifying product sameness through an analysis of dossier differences**, a simple yes or no answer will not be the most likely scenario**. Instead, we often arrive at a nuanced "yes, but" conclusion, which falls along a spectrum ranging from significantly different to identical.*

While reliance is always an option, the approach chosen by NRAs may vary depending on the degree of differences in the dossier. This could range from verification of sameness to an abridged review.

Reliance is not all or nothing…..

Transparently Highlighting Differences – A Uniform IFPMA Template (link)

Problem statement:

Relying NRAs often do not have a single simple procedure and format which could be used by both NRAs and Industry to be transparent about product sameness. This leads to redundant and duplicative quality information being requested in multiple local formats, causing delay and potential for copy-paste error.

Proposed solution:

How can dossier comparison be streamlined and differences compared?	Industry highlights key differences between reference and relying NRA dossiers	NRAs receive all relevant information regarding differences in dossier in a convenient format
Harmonized IFPMA Template For transparency of differences across all reliance procedures		
What differences can be accepted and which ones would require further review?	NRA decision	

IFPMA Template for description of differences

Example:

COLUMN A	COLUMN B	COLUMN C	COLUMN D
Module 3/Submodule	**Documents included in this application**	**Dossier sameness as compared to Reference NRA (Yes/No)**	**Brief discussion and justification that the difference has no impact on product quality (including reference to supporting data as appropriate)**
3.2.P: DRUG PRODUCT			
3.2.P.1 Description and Composition of the Drug Product	Y	Y	
3.2.P.2. Pharmaceutical Development	Y	Y	
3.2.P.2: Manufacture			
3.2.P.2.1: Manufacturer	Y	N	Finished drug product release site is different from EU. EU regulations specify that the qualified person shall certify that each batch underwent analysis in an EU Member State. Therefore the finished product release site for the EU market has to be in EU territory, which is different from that for rest of the world. The same release criteria and release procedure are applied to all release sites to ensure that the products have identical quality
3.2.P.2.2: Batch Formula	Y	Y	

IFPMA Template for description of differences

Example:

COLUMN A	COLUMN B	COLUMN C	COLUMN D
Module 3/Submodule	**Documents included in this application**	**Dossier sameness as compared to Reference NRA (Yes/No)**	**Brief discussion and justification that the difference has no impact on product quality (including reference to supporting data as appropriate)**
3.2.P.8: Stability			
3.2.P.8.1: Stability Summary and Conclusion	YES	YES	
3.2.P.8.2: Post-approval Stability Protocol and Stability Commitment	YES	YES	
3.2.P.8.3: Stability Data	YES	NO	Updated with primary stability data from additional time points in accordance with the stability protocol

Thank you

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/company/ifpma

@ifpma

QUESTIONS AND ANSWERS

We encourage you to use the Q&A box to raise questions to the speakers.

If a question you would like to ask has already been raised, you can also “like” that question.

QUESTION TO THE AUDIENCE!

PLEASE ANSWER THE QUESTION THAT WILL POP UP ON YOUR SCREEN

4 December
07:30 – 09:00 CET

ARC 2024
ASIA REGULATORY CONFERENCE

RELIANCE CASE STUDIES & LESSONS LEARNED

Navigating Reliance: Practical Applications in South-East Asia and Western Pacific region

Noraisyah Mohd Sani
NPRA

Wenzel Asprec
Philippines FDA

Yee Hoo Looi
HSA

Céline Bourguignon
IFPMA

Moderator
Alice Chee (PhAMA)

Organized by IFPMA

In partnership with Medicines Australia

Online conference, free to attend. Register at ifpma.org

KEY TAKEAWAYS AND INSIGHTS

1. **Strengthen Regional Cooperation through Standardized Documentation Access:** Develop frameworks for sharing essential documents such as assessment reports and GMP certificates across NRAs. Leverage lessons learned ACCESS, ORBIS, ICMRA pilots and OPEN experiences in regulatory cooperation to create efficient, mutually beneficial frameworks that are adaptable to each country's unique context.
2. **Integrate Reliance as a Strategic Tool with Consistent Training Programs:** Embed reliance as a core element of the regulatory toolkit to enable risk-based decision-making and optimize resource use. Reliance should not be limited to specific pathways but integrated across regulatory functions through structured processes and capacity-building efforts. Support regular training programs for regulators and industry stakeholders on applying reliance models, interpreting shared documents, and using international harmonized guidance (e.g., WHO, ICH). WHO's regional reliance workshops are a valuable example of collaborative training approaches, while also raising awareness about reliance, its advantages, and its implementation status globally.
3. **Establish Best Practices for Documentation Formats and Use:** Develop global best practices for regulatory documentation aligned with risk-based principles and internationally recognized standards. This includes fostering a better understanding of documents provided by reference agencies—such as approval letters, assessment reports, GMP certificates, and product information—and their respective roles in supporting reliance. By clarifying what information each document offers and how it can be leveraged effectively, regulatory authorities can ensure flexibility in their reliance strategies, adapting sources to fit specific needs. Practical examples in the Asia region highlight the benefits of reliance-based approaches, demonstrating how simple yet robust documentation (such as approval letters and product information for the case of PACs reliance) can support sound, risk-based regulatory decisions, enabling faster access to safe, innovative medicines globally.

03-06 December 2024

ARC 2024

ASIA REGULATORY CONFERENCE

EVOLVING LANDSCAPES

Asia's role in driving a more efficient, innovative and patient-centric regulatory environment

Organized by IFPMA

In partnership with Medicines Australia

Virtual coffee/tea break

4 December

09:15 – 10:30 CET

ARC 2024

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RELIANCE ACROSS THE LIFE CYCLE

Navigating Reliance: Practical Applications in South-East Asia and Western Pacific region

Hamada Sherief
EDA

Stephen Farrell
TGA

Achiraya Praisuwan
Thailand FDA

Isabelle Colmagne-Poulard
IFPMA

Moderator
Stephan Roenninger
(EFPIA)

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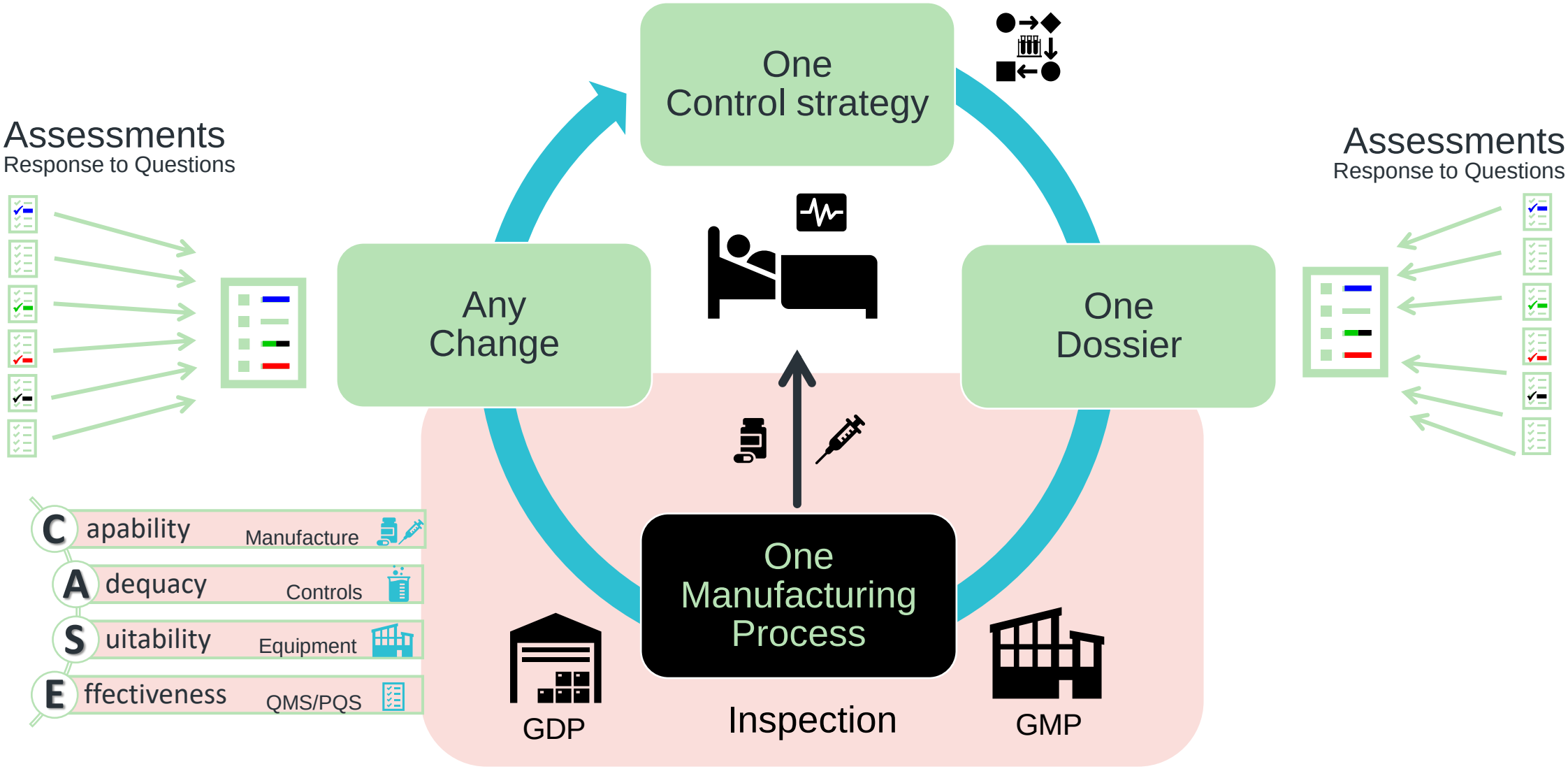
Is reliance possible across the product life cycle?



QUESTION TO THE AUDIENCE!

PLEASE ANSWER THE QUESTION THAT WILL POP UP ON YOUR SCREEN

Reliance practices within EDA

Hamada Gamal Sherif

Chairman associate for updating & developing registration systems & general manager for human drug registration –Egyptian Drug authority(EDA)

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Agenda

1-Development of reliance in EDA

2-Scope of reliance

3-Type & routes of implementation of reliance in EDA

4-Case study to show impact of reliance

5-EDA Achievements in reliance I post approval changes

6-Challenges in implementation of reliance in PAC

- **History & development of reliance**

1-Before EDA reliance was introduced in new registration process only and it was concentrated on decrease time for registration of new products especially EMA or/& FDA approved.

2- After establishment of EDA , Eda Chairman released ministerial decree to allow for the practice of reliance in 2022

3-The reliance decree to add more agility for implementation , it allow the release for regulatory guide to give more detailed description of reliance rules & practices

To be continued…….

Now we have released version 4 of the regulatory guide with :

1-Addition of Reliance based - review pathways and its eligibility criteria

2-Addition of submission requirements for each pathway

3-Updating list of reference countries

Update Criteria of Reference Countries:

- ICH member
- WHO Listed Authority (WLA)
- ML4 benchmarked by WHO

Clarify Scope Of Reliance

- **Imported** finished products approved by reference authority (SRA)

- **New registration and Life-Cycle Management**

Reliance in new registration

Verification Route

- Not a scientific assessment to reach a regulatory decision,

- Product approved by at least **two** SRAs
  Or Product approved in one SRA & WHO prequalification

An Administration process

Abridged Route

- Relying on prior assessment from SRAs or WHO prequalification.

- Product approved by at **least one** SRA
  Or WHO prequalification

A limited assessment

Requirements

- ✓ Valid CPP of the product & proof of approval from other SRAs &/or WHO prequalification
- ✓ Verification of sameness through :
  **Letter of sameness
  **Unredacted Assessment Report (if applicable)

Reliance in PAC

Eligibility Criteria for Reliance Evaluation Route	Submission Criteria
For Imported Finished Product That has been Approved by at least one reference regulatory authority (SRA) or WHO prequalification	The applicant will Submit the variation request which includes: 1.Valid Certificate of Pharmaceutical Product. 2. Updated relevant sections of CTD dossier. 3. Verification of Sameness* (for example sameness letter). 4. Unredacted Assessment report (otherwise justified with evidence). 5. Proof of approval from at least one reference regulatory authority.

To be continued…….

Reliance in PAC

EDA acknowledges the different evaluation criteria, variation categorization and approval process between each individual SRA as well as the difference between the SRA and the EDA procedures. Examples but not limited to the below difference between the EMA and FDA evaluation procedures

	Type of change	Implementation Criteria according to other SRAs	Approval Document
EMA	Type II	Change can only be implemented after approval	Approval letter Assessment report (if available)
	Type IB	If within 30 days following the acknowledgement of receipt of a valid notification, EMA has not sent the applicant an unfavorable opinion, the notification shall de deemed accepted	IB notification including approval information Assessment report (if available)
	Type IA/ Type IAIN	Change can be implemented up to 1 year before submission	Acknowledgement letter
FDA	PAS	After approval	Approval letter
	CBE-30	Change can be implemented 30 days after submission	Approval letter
	CBE-0	Change can be implemented immediately after submission	Approval letter
	Annual report	Up to 1 year before submission	NA

Egypt- SM PAC approved under official reliance pathway

Registration of an additional DP manufacturer

P.O.C	Standard Pathway	Reliance Pathway
Reference Authority	FDA	FDA
Reliance documents	n.a.	- FDA Approval on the change - A declaration on the differences between Egypt & US packages
Package	The package is customized to be submitted into three different departments	The full FDA package submitted to one department only
Q&A	Several queries raised by the HA	No Q&A raised by the HA, they fully rely on FDA package
Timelines	9 months	2 months
Post approval commitments	Stability & analysis	No commitments
Impact on supply	No release of batches reflected by the change until commitments are fulfilled	Immediate release for the batches & enhance supply secure to patient

Impact Of Reliance

No. of Reg License*

164

No of Variation Approvals*

100

- Swiss Medic: 51
- Germany: 7
- Australia: 3
- EMA: 17
- FDA: 4
- Sweden: 1
- France: 5
- Austria: 4
- MHRA: 8

*Since May 2023

Reliance Approach

Faster & sustainable access to medicine

Authority

- Assessor Building capacity with update of the national guidelines to latest standard
- Focus on Local Production
- Better knowledge of the practices of the mature or stringent countries pave the road for relying countries to who ML 4 & WLA

Industry

- Repetition in preforming studies .
- Save time & cost.

Main Challenges

01 **Different dates of submissions between authorities.**

02 **Different packages of PAC submitted to different authorities**

03 **Lack of clear guidelines of PAC reliance practices.**

04 **Mindset of assessors**

Global Frameworks for Post-Approval Changes in biological products

Reliance as an opportunity for convergence

Isabelle Colmagne-Poulard
Head of International Global Regulatory & Scientific Policy (Merck KGaA)

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

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Practical Considerations | IFPMA Messages

Key elements for NRAs to consider when establishing and implementing effective regulatory reliance mechanisms

Guidance on documentation

Providing guidance on what documents are required and how they are used for the assessment. Clarity on who is providing which documents (e.g. reference NRA vs applicant) should also be given and confidentiality should be assured.

Timelines

Regulatory reliance should result in a reduction of regulatory burden and offer an opportunity for faster approvals compared to standard pathways to increase attractiveness of use.

Predictability in terms of timeline for reliance-based procedures is a key element that will make it attractive for industry

Other considerations

Reliance-based regulatory procedures can be implemented at many stages in the product lifecycle. When products are approved through reliance-based regulatory procedures, then post-approval changes should also be managed through reliance-based procedures.

Pilot programs for reliance-based regulatory procedures will provide initial practical experience for NRAs and applicants. Robust evaluation of results from these programs, including feedback and dialogue between NRA and Industry users, could swiftly capture opportunities to improve processes and procedures leading to increased trust and acceptability by all stakeholders.

IFPMA Position Paper on Reliance

PACs Frameworks Comparison

Project overview

Scope

Review of **available regulatory frameworks** on Post-Approval Changes (PACs) in 21 countries (*not Industry experience*)

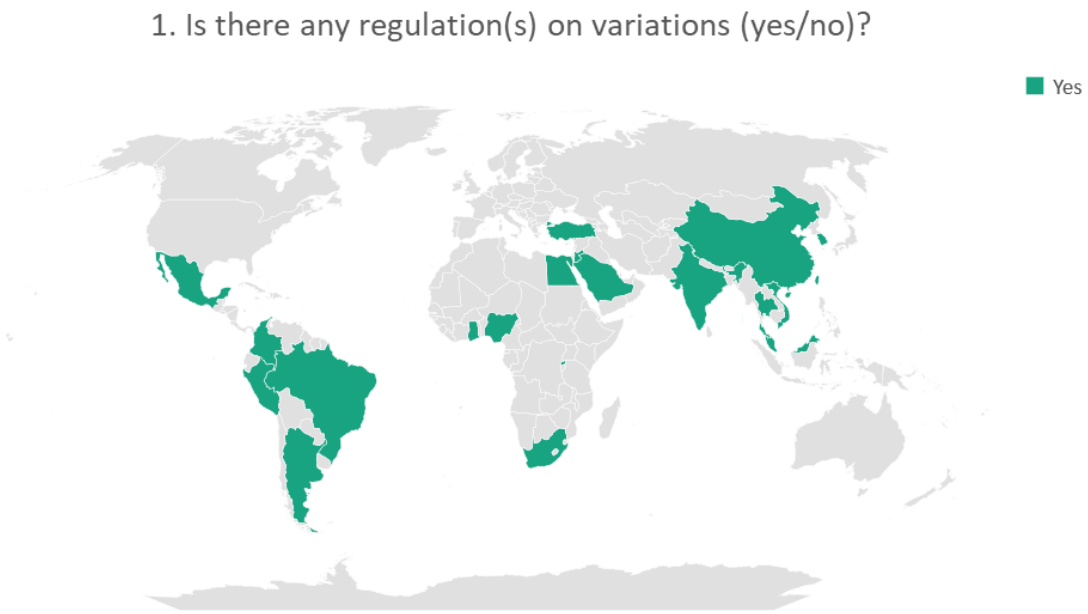
Compare the level of convergence of specific PACs for biological products in countries vs WHO guideline on procedures and data requirements for changes to approved biotherapeutic products, Annex 3, TRS No 1011

Countries

Region	ICH RA Members	ICH Observers	Non-ICH Members
APAC (8)	China, South Korea, Singapore, Taiwan	India, Malaysia	Thailand, Vietnam
LATAM (5)	Brazil, Mexico	Argentina, Colombia	Peru
MEA (8)	Egypt, Saudi Arabia, Turkey	Jordan, Nigeria, South Africa	Ghana, Rwanda

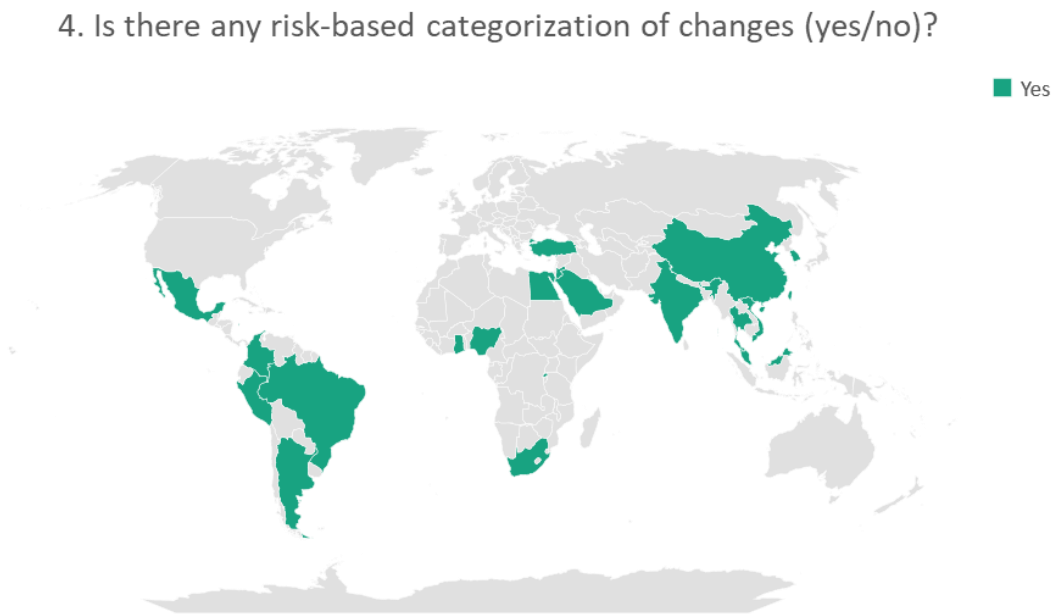
General PACs regulatory framework

Q1. Regulation(s) on variations



100%	of countries have regulations on variations.

Q4. Risk-based categorization



100%	of countries (21) have risk-based categorization of changes. Changes are classified in major and minor. Though moderate classification is contemplated in only 9 countries.

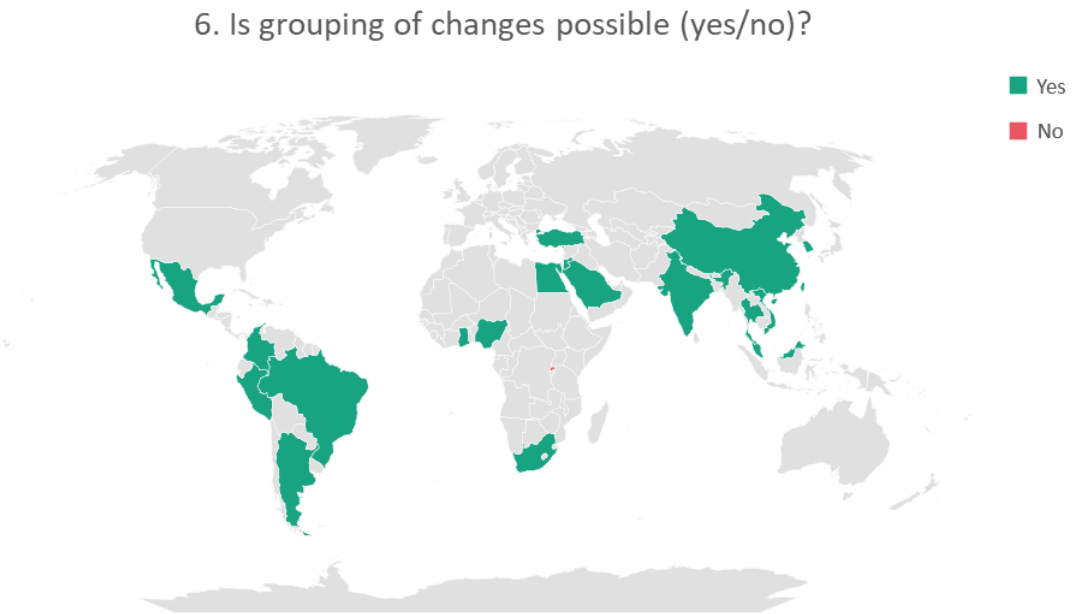
Source and Provider: Clarivate Inc.

General PACs regulatory framework

Q5. Timelines

100%	of countries (21) have timelines for approval.
0-60	days are the target timelines for minor variations across regions (including automatic approval)
30-270	days are the target timelines for major variations

Q6. Grouping changes

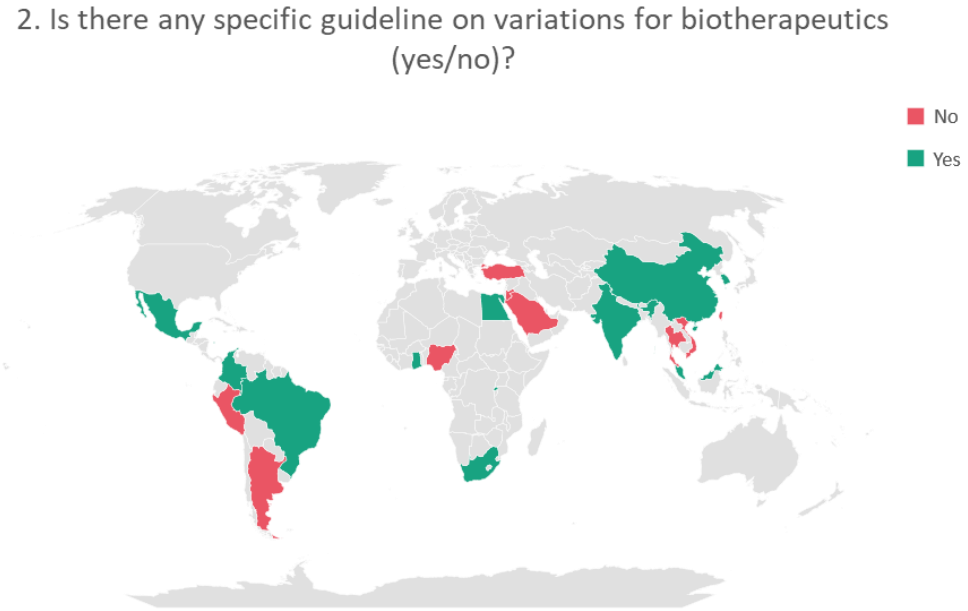


95%	of countries (20) allow grouping of changes. *Grouping is considered if the same variations are applied to multiple products or if multiple variations are applied to the same product.. Grouping applies to both minor and major variations.*

Source and Provider: Clarivate Inc.

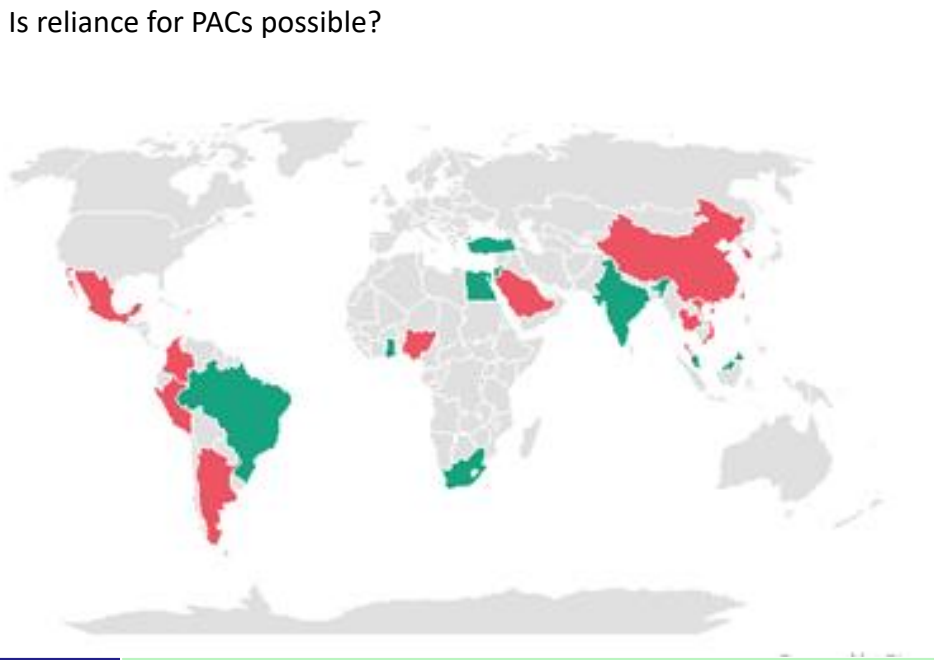
General PACs regulatory framework

Q2. Specific guideline on variation for biotherapeutics



57% of countries (12) do have specific guideline on variations for biotherapeutics

Q9. Reliance



43% of countries allow reliance for variations

Source and Provider: Clarivate Inc.

General PACs regulatory framework

Q7. Submission format (CTD)

86%	of countries (18) require/accept CTD submission format of which 5 countries accept eCTD
14%	of countries (3) have other CTD formats

Q8. Scientific Advice

52%	of countries (11) offer scientific advice. This support may be in a pre-submission meeting, via email or submitting a form depending on the country.

Q3. Applicability to other modalities

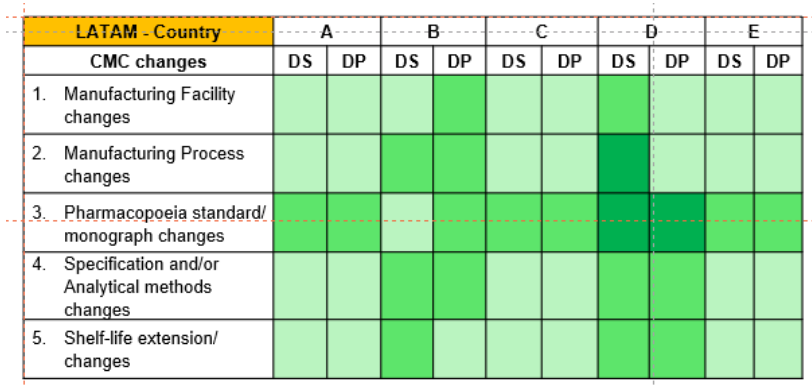
81%	of countries (17) include other modalities
76%	of countries (16) include vaccines. Other modalities included in the guidelines are plasma fractioned products (blood products) (9), ATMPs (2), and CGTs (5).

Q10. Grace period for implementention

62%	of countries (13) include grace periods
6-12	months are the grace periods contemplated in the countries or to be requested to the Authorities.

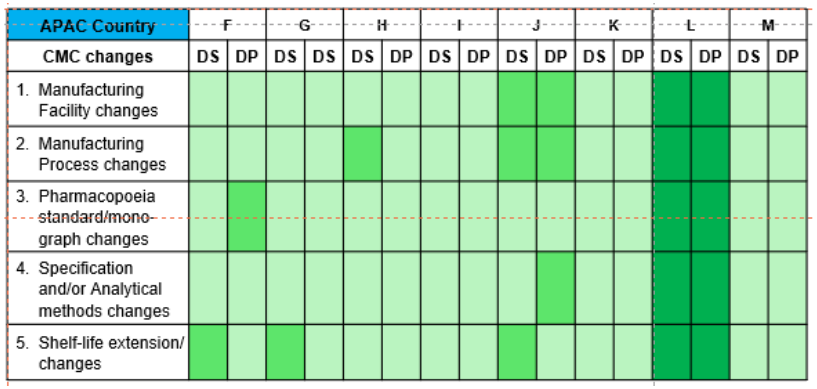
Source and Provider: Clarivate Inc.

Level of convergence of specific PACs vs WHO



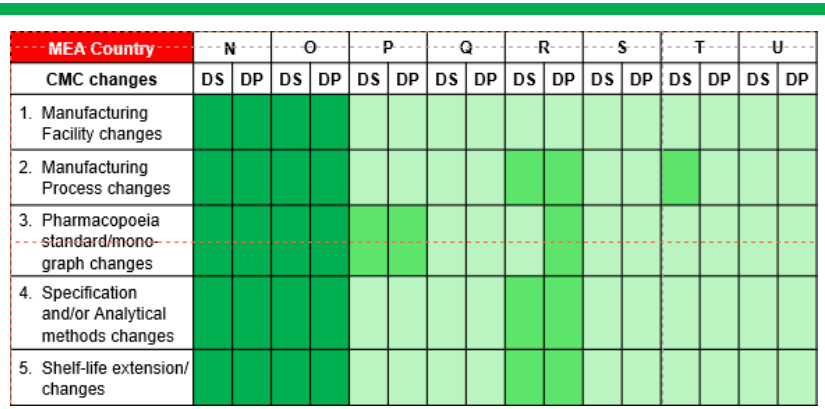
LATAM - Country	A		B		C		D		E	
CMC changes	DS	DP	DS	DP	DS	DP	DS	DP	DS	DP
1. Manufacturing Facility changes										
2. Manufacturing Process changes										
3. Pharmacopoeia standard/ monograph changes										
4. Specification and/or Analytical methods changes										
5. Shelf-life extension/ changes										

Level of convergence **58%** **36%** **6%**



APAC Country	F		G		H		I		J		K		L		M	
CMC changes	DS	DP	DS	DS	DS	DP	DS	DP	DS	DP	DS	DP	DS	DP	DS	DP
1. Manufacturing Facility changes																
2. Manufacturing Process changes																
3. Pharmacopoeia standard/mono-graph changes																
4. Specification and/or Analytical methods changes																
5. Shelf-life extension/ changes																

Level of convergence **76%** **11%** **13%**



MEA Country	N		O		P		Q		R		S		T		U	
CMC changes	DS	DP	DS	DS	DS	DP	DS	DP	DS	DP	DS	DP	DS	DP	DS	DP
1. Manufacturing Facility changes																
2. Manufacturing Process changes																
3. Pharmacopoeia standard/mono-graph changes																
4. Specification and/or Analytical methods changes																
5. Shelf-life extension/ changes																

Level of convergence **62%** **13%** **25%**

Low convergence
(1 or none of the 3 parameters are aligned)

Medium convergence
(2 parameters are aligned)

High convergence
(all 3 parameters are aligned)

Legend: Parameters analyzed: Categorization, Requirements and Timeframes | DS: drug substance, DP: drug product.
Source and Provider: Clarivate Inc.

Project Takeaways

General framework on PACs

All countries (21) have **risk categorization**, **timelines** and **95%** (20) allow **grouping**.

86% of countries (18) **require/ accept CTD** submission format, of which 5 accept also eCTD.

52% of countries (11) offer **scientific advice**

48% of countries (10) have **reliance** for PACs

62% of countries (13) include **grace periods** for implementation

Specific to PACs for Biologics

Only 57% of countries (12) have **specific guidance for PACs for biologics**

81% of countries (17) include other modalities (Vaccines, blood products, ATMPs)

The level of convergence between countries and vs WHO guideline for changes to biotherapeutics is very diverse

Pharmacopoeia compliance changes are the most convergent (minor change) in 6 countries whereas facility changes are the least convergent in 17 countries for both DS and DP

Discussion and next steps

These survey results related to PACs regulatory framework are aligned with those from A Global Industry Survey on Post-Approval Change Management and Use of Reliance (2024). It highlights:

- → **Global regulatory convergence** using a science and risk-based regulatory framework enables a more efficient management of PACs, especially when specifically adapted to biologics (and other modalities)
- → Establishing national or regional variation guidelines in line with **international standards (e.g., WHO, ICH Q12) in terms of categorization, requirements and timelines** allows predictability and consistency in the handling of changes without need for additional local requirements
- → It will also facilitate the **expansion of reliance to life cycle management**, accelerating approval of changes and facilitating patients access to innovative products of the highest quality and safety

Next steps:

- → Share report on IFPMA website before the end of the year
- → IFPMA welcomes continued dialogue with National Regulatory Authorities, NTAs and any stakeholder to discuss our findings in greater detail.

Thank you

Isabelle Colmagne-Poulard

Mónica Perea-Vélez

Sergio Cavalheiro

Gert Thurau

Lesbeth Rodriguez

Wan Li Liao

Karim Kacimi

Maria Guazzaroni Jacobs

Lyne Le Palaire

Maria Lucia de Lucia

Meet our Project Team

Our matrix structure ensures a Subject Matter Expert approach to all engagements

Regina Galera

Director, Regulatory & Clinical Consulting
Acting as Project Sponsor and SOW point of contact

Manuel Pardo

Manager, Regulatory Consulting
Acting as Deputy Project Manager

Ariadna Balada

Regulatory Consultant
Acting as Project Manager

Romina Pirraglia

Regulatory Consultant
Acting as Subject Matter Expert

Nathalia Solarte

Regulatory Consultant
Acting as Subject Matter Expert

Aritz Ateka

Senior Regulatory Consultant
Acting as Subject Matter Expert

Questions?

For questions about research results or further detailed information, feel free to reach out to IFPMA

Contact: sergio@ifpma.org

Website: www.ifpma.org

GMP Inspection Reliance: PIC/S and TGA

Stephen Farrell

Director, GMP Clearance, Therapeutic Goods Administration (TGA)

Chair, PIC/S Inspection Reliance Working Group (IRWG)

PIC/S Strategic Plan

2023-2027

"With the complexity of global supply chains, the demand for inspecting pharmaceutical manufacturing facilities far exceeds what any one regulatory authority can accomplish"

PIC/S
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

Over the next 5 years, the efforts and successes of PIC/S and the PIC/S Working Group on Inspection Reliance will be paramount to deliver on strategic priorities related to inspection reliance

- **Promote** greater use of the PIC/S inspection reliance initiative among PIC/S Participating Authorities
- **Provide** a forum to continuously monitor and improve upon the implementation of inspection reliance

Inspection Reliance Working Group

- Established in October 2020
- Operates under Sub-committee on Strategic Development (SCSD)
- Members include:
  - Australian Therapeutic Goods Administration (TGA)
  - European Medicines Agency (EMA)
  - United States Food and Drug Administration (USFDA)
  - Health Canada
  - UK Medicines and Healthcare products Regulatory Agency (MHRA) and Veterinary Medicines Directorate (VMD)
  - Swissmedic
  - Brazilian Health Regulatory Agency (ANVISA)
  - Singapore Health Sciences Authority (HSA)

Inspection Reliance Working Group

Work to date

PIC/S ‘Inspection Reliance Survey’ in 2022 investigating barriers to Inspection reliance

Several recommendations endorsed by the committee of officials

Pilot Single Inspection Program (SIP)

Inspection Reliance Working Group

Pilot Single Inspection Program (SIP)

- *TGA – Health Canada - MHRA*
- Focus on inspections outside of PIC/S member's jurisdiction
- Sites preferably manufacture medicines for all three jurisdictions but sites who only supply two of the three can be considered

"This pilot aims to establish a coordinated approach to GMP inspections of overseas manufacturing sites of common interest. Using our collective inspection resources, each authority has agreed to extend the scope of an inspection to cover products of interest to one another, where possible, reducing the need for multiple inspections of the same site."

TGA Inspection Reliance

Desktop Inspection Reliance Evaluation of GMP evidence

- An onsite inspection conducted by Recognised Regulatory Authority (RRA) forms the basis of a desktop Inspection Reliance Evaluation (IRE)
- Extent of additional data required from manufacturer or sponsor/Marketing Authorisation (MA) applicant or holder depends on multiple factors
- More product-focused than inspections as each one is specifically linked to an application for MA
- Issued to Sponsor/MAH only….not to manufacturers

TGA Inspection Reliance

Several factors influence the extent reliance is used

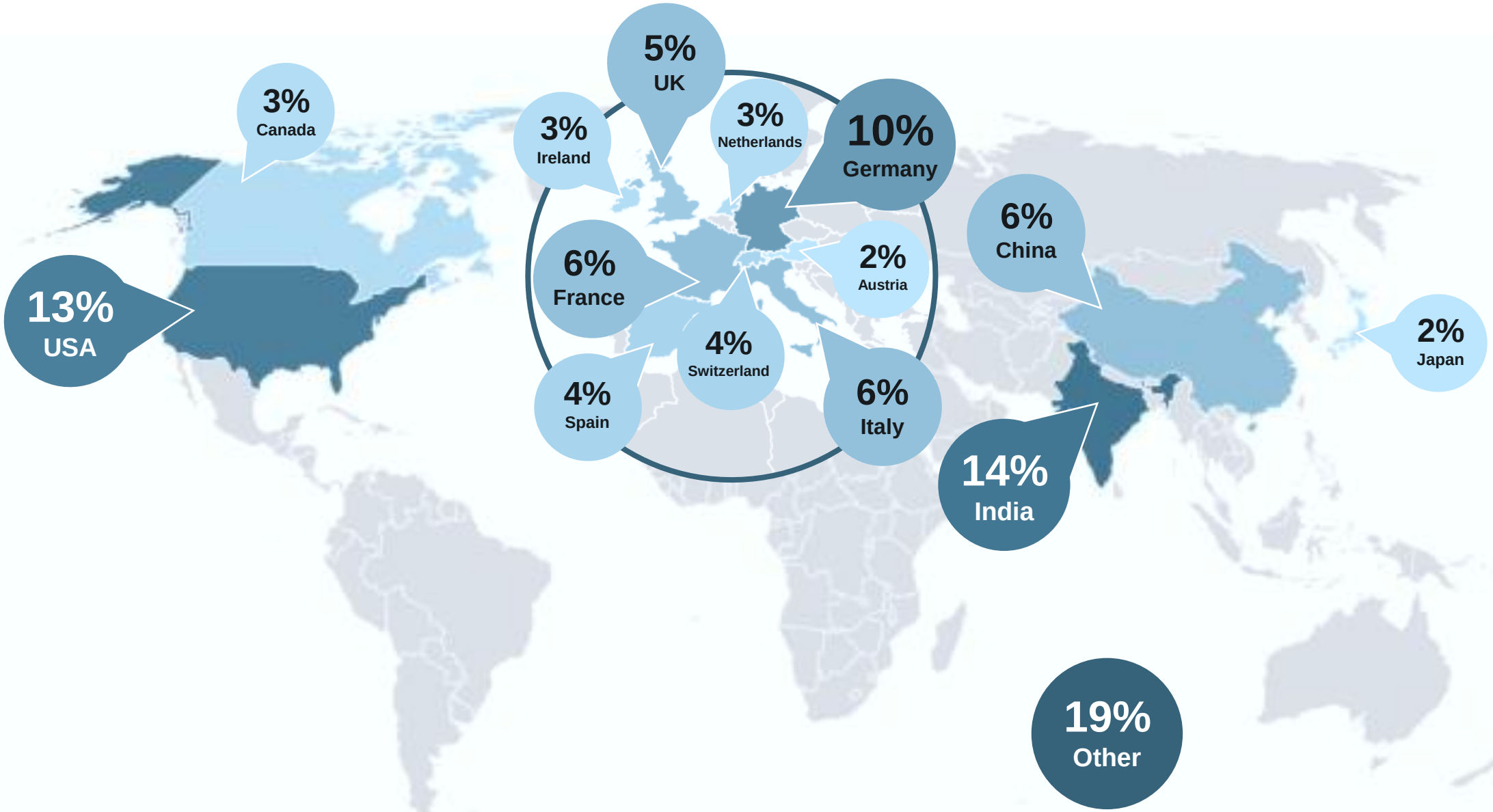
- Evaluation of another regulator's equivalence
- History of collaboration and confidence building
- Type and scope of the bi-lateral agreement – is it binding or non-binding?
- Broader understanding of how each regulatory framework operates
- Alignment where possible or mitigation to address potential risks

TGA Inspection Reliance

Differences in regulatory frameworks

- Australia's regulatory framework influences our risk-based inspection reliance approach
- New inspection tools and methods challenge historical reliance processes
- Complexity in global supply chains and distribution networks
- New and innovative medicines and biologicals (platform technologies)
- Constant evolution of global regulations and GMP guides

GMP Clearance considers these differences, adjusting the level of desk-top evaluation accordingly



- Over 90% of medicines supplied to Australia are manufactured overseas
- Inspection Reliance remains crucial component of lifecycle management

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

QUESTIONS AND ANSWERS

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If a question you would like to ask has already been raised, you can also “like” that question.

QUESTION TO THE AUDIENCE!

PLEASE ANSWER THE QUESTION THAT WILL POP UP ON YOUR SCREEN

4 December

09:15 – 10:30 CET

ARC 2024

ASIA REGULATORY CONFERENCE

RELIANCE ACROSS THE LIFE CYCLE

Navigating Reliance: Practical Applications in South-East Asia and Western Pacific region

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IFPMA

Moderator
Stephan Roenninger
(EFPIA)

Organized by IFPMA

In partnership with Medicines Australia

Online conference, free to attend. Register at ifpma.org

KEY TAKEAWAYS AND INSIGHTS

1. **Standardize Variation Categories for PACs:** Harmonize post-approval change (PAC) categories to align with internationally recognized frameworks such as ICH Q12 and WHO guidelines. Adopt clear classification schemes, such as prior approval (major changes), notification (moderate or low-risk changes), and not reportable (changes managed within the pharmaceutical quality system). This alignment facilitates reliance using similar risk-based categorization, requirements and timelines as well as worldwide implementation of changes when using standard pathways.
2. **Adapt Documentation Requirements for PACs Reliance process:** For reliance-based evaluations of PACs, ensure documentation requirements are adjusted to risk categorization and purpose-specific (e.g Assessment report and approval letters can be used when available). Companies may add declarations of differences between the reference variation package and the one submitted to the relying NRA, when applicable. “Informed” reliance process with streamlined documentation requirements will incentivize use of reliance across the full product life cycle, ensuring patients have continued access to high quality, safe and efficacious products.
3. **Foster Practical GMP Inspection Reliance through Global Frameworks:** Build trust in shared GMP inspection outcomes based on similar information available in inspection reports, GMP certificates, and other key documentation. NRAs should leverage collaboration frameworks like PIC/S to enable unilateral reliance or mutual recognition, reducing duplication and / or length of inspections to improve resource efficiency and sustainability. Practical implementation should focus on ensuring processes for verifying inspection outcomes align with different terminologies used in domestic legal frameworks while maintaining global inspection standards.

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