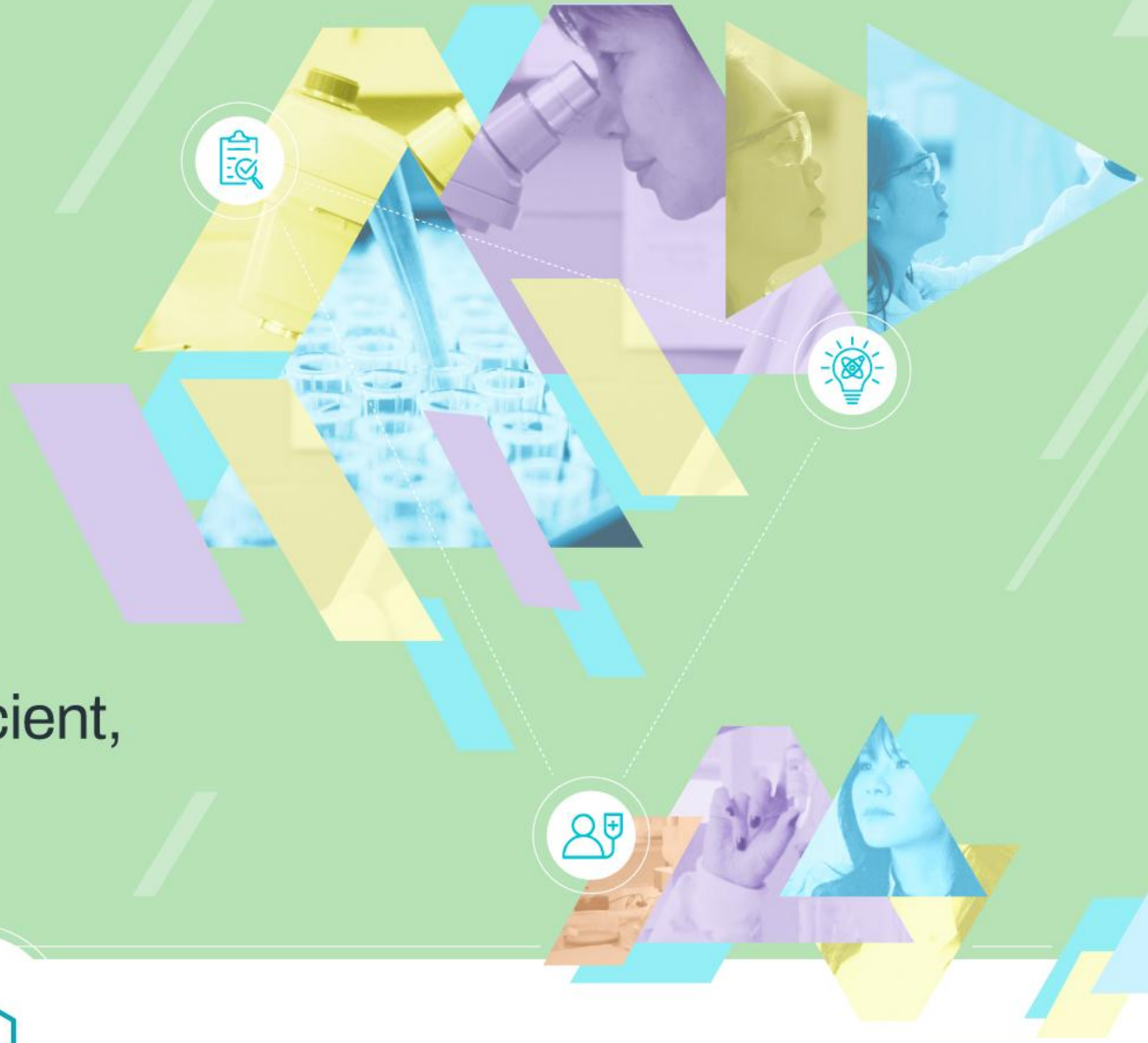
03-06 December 2024

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

03-06 December 2024

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EVOLVING LANDSCAPES

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

Welcome to Day 1

Collaboration and worksharing to bring innovation to patients

Organized by IFPMA

In partnership with Medicines Australia

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.

Empowering patient voices: integrating patient perspectives in regulatory affairs

ARC 2024
ASIA REGULATORY CONFERENCE

PANEL DISCUSSION

Edmund Lau
Committee Member
World Patients Alliance

Julie Cini
Director
Advocacy Beyond Borders

Karen Villanueva
President
Philippine Alliance of Patient Organizations (PAPO)

Paloma Tejada
Associate Director,
Alliance Building
IFPMA

Keynote Sessions

Moderator

ARC 2024
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Keynote: The Indo-Pacific Regulatory Strengthening Program (RSP)

Felicity Jameson

Director, Regulatory Strengthening Section, International Regulatory Branch, Medicines Regulation Division

Therapeutic Goods Administration

ARC 2024
ASIA REGULATORY CONFERENCE

The Indo-Pacific Regulatory Strengthening Program (RSP)

Dr Felicity Jameson
Therapeutic Goods Administration
3 December 2024
ARC2024

Australia's Indo-Pacific Health Security Initiative

In **October 2017,** the Australian Government launched a 5-year, AUD300 million Health Security Initiative.

To contribute to the avoidance and containment of infectious disease threats with the potential to cause social and economic harm on a national, regional or global scale.

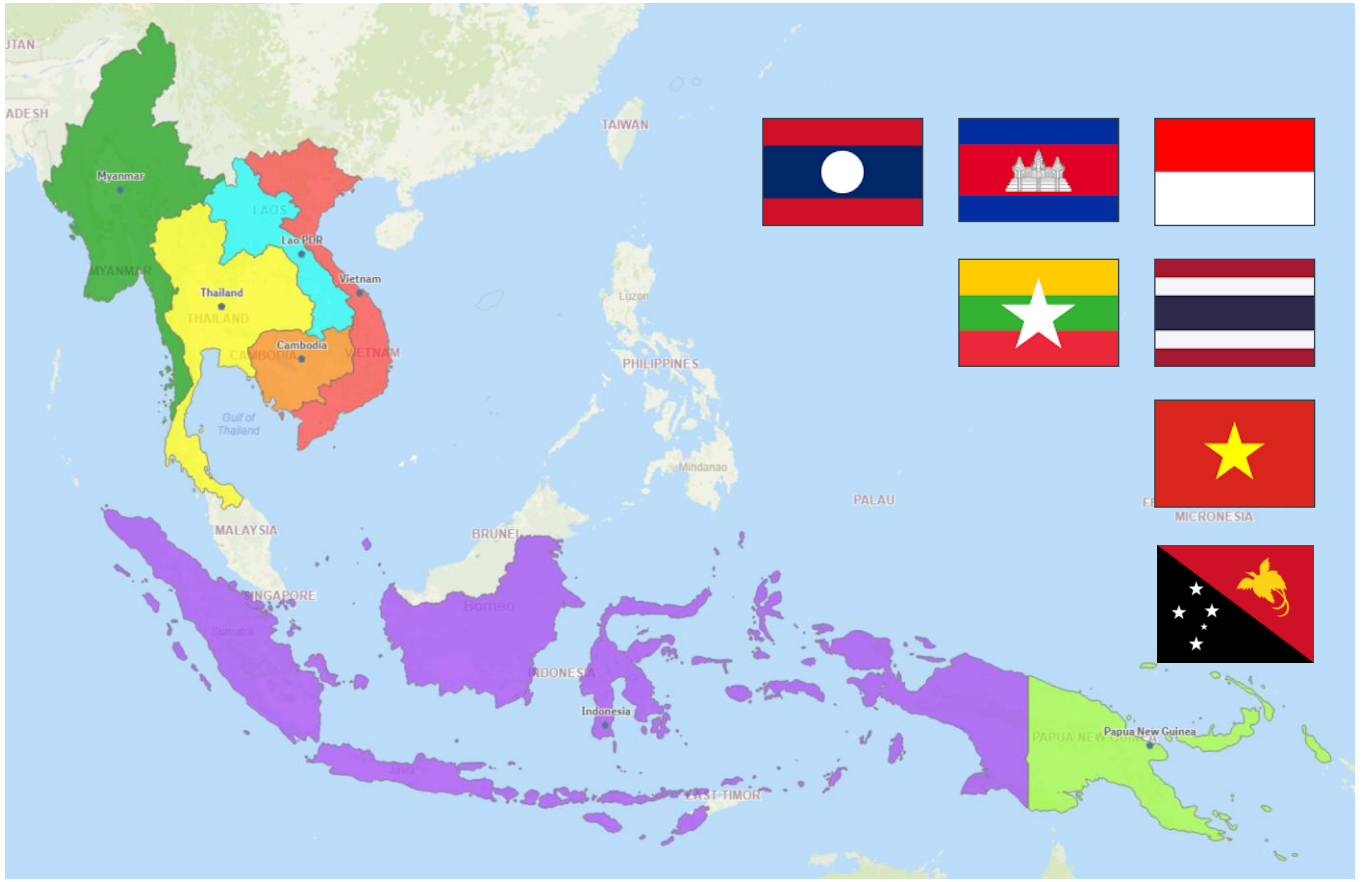
Indo-Pacific Regulatory Strengthening Program

The RSP was launched on **3 October 2018**, funded to June 2023.

Strengthening the capability of National Regulatory Agencies to increase the availability of safe and effective medicines and medical devices through improved regulatory practice and regional coordination.

Component 1 **-** Strengthening the capability of NRAs to increase the availability of safe and effective medical products

Component 2 **-** Enhancing stakeholder coordination to promote regional collaboration on regulatory practice



Vaccine Access and Health Security Initiative

Announced by the Foreign Minister on **30 October 2020**.

Support Pacific and Southeast Asian countries' efforts to deliver safe, effective and accessible COVID-19 immunisation programs, based on a health and regulatory systems strengthening approach and in line with best practice standards.

The funding will further help ensure that the countries of the Pacific and Timor-Leste are able to achieve full immunisation coverage, and will make a significant contribution toward meeting the needs of Southeast Asia.

The Pacific: ~ AUD200 million **Southeast Asia:** ~ AUD300 million

Total shared doses

52,192,670

Country	Doses	Country	Doses
Global	114,400	Solomon Islands	618,200
Cambodia	2,830,530	The Philippines	8,132,080
Fiji	1,651,100	Timor-Leste	1,190,040
Indonesia	8,395,000	Thailand	452,790
Laos	1,504,780	Tonga	76,190
Nauru	24,280	Tuvalu	20,500
Kiribati	50,500	Vanuatu	160,000
Papua New Guinea	335,270	Vietnam	26,461,860
Samoa	175,150		

Table: COVID-19 vaccine doses shared from Australia's supply, procured by Australia, for partner countries or distributed through the COVAX Facility as at 9 May 2023.

TGA’s COVID-19 Vaccine Program: 2021-2023

Support for the marketing authorisation or EUL of COVID-19 vaccines.

Support for ensuring the quality of vaccines procured, based on GMP standards.

Vaccine safety reporting systems and communications.

18 Countries in Southeast and the Pacific

Cambodia, Fiji, Kiribati, Indonesia, Lao PDR, Malaysia, Myanmar, Nauru, Papua New Guinea, The Philippines, Samoa, Solomon Islands, Thailand, Timor-Leste, Tonga, Tuvalu, Vanuatu and Vietnam

Delivery: Virtual engagement from May 2021 – June 2023

Staffing: Regulatory scientists, medical officers and program management based in Canberra with a regional advisor in Singapore.

Invested: Australia's SEA Economic Strategy to 2040

Regulatory collaboration to increase regional recognition, cooperation and reliance so products approved in one Southeast Asian market can access several markets.

Improve recognition arrangements for TGA-approved products by Southeast Asian national regulatory authorities to allow for earlier access to markets, supported by the exchange of information.

Expanding regulator-to-regulator cooperation, and promoting compatibility between Australian, Southeast Asian and global frameworks through the RSP, will support health outcomes in the region and its growing markets.

Recommendations

62. Expand the TGA regulatory strengthening program to build the capacity of regional regulators.
63. Support regional health policy agencies to build digital health capabilities and policy frameworks, led by CSIRO's Australian e-Health Research Centre.

Invested

Australia's International Development Policy

Australia's International Development Policy is centred on listening, respect and genuine partnership. It will guide how Australia's development program supports a peaceful, stable, and prosperous future for Australia and our region – ensuring it is fit for the challenges and opportunities of our times.

August 2023: First new policy in a decade.

[Australia's International Development Policy | Australian Government Department of Foreign Affairs and Trade (dfat.gov.au)]

22 of Australia's 26 nearest neighbours are developing countries, and some remain fragile.

In many countries, ***health systems*** *are struggling to provide universal care and combat disease... Harnessing opportunities and mitigating risks requires* ***effective institutions****, equitable services, and improving critical infrastructure.*

We will work closely with, and be guided by, our partners to ensure their needs are reflected... We will ensure diverse voices are heard and make sure women and girls are engaged in meaningful ways. We will start from a place of respect and an appreciation of the strengths and interests that all partners bring to the table. We have strong and enduring relationships in the region on which we will build.

Partnerships for a Healthy Region

Minister for Foreign Affairs, Senator the Hon Penny Wong

Improving the health and wellbeing of communities across the Pacific and Southeast Asia is critical to ensuring our region's security, prosperity and stability.

COVID-19 has reversed health and development gains in our region, and Australia is working with partners to restore their health systems and build on investments made during the acute phase of the pandemic.

Partnerships for a Healthy Region

5-year initiative announced by the Foreign Minister in a joint media release on **23 February 2023**.

Part of Australia's continued investment in the health of our region and an important contribution to the Pacific and Southeast Asia's recovery from COVID-19.

Expanding regional health assistance provided by key Australian Government agencies and organisations.

Extending partnerships with international agencies, supporting health systems in our region.

The RSP to continue with an expanded scope.

RSP Expanded Scope

- **Indonesia**
- **Lao PDR**
- **Cambodia**
- **Fiji**
- **Malaysia**
- **Papua New Guinea**
- **The Philippines**
- **Timor-Leste**
- **Thailand**
- **Vietnam**
- **Federated States of Micronesia**
- **Kiribati**
- **Nauru**
- **Niue**
- **Palau**
- **Republic of Marshall Islands**
- **Samoa**
- **Solomon Islands**
- **Tonga**
- **Tuvalu**
- **Vanuatu**
- **Myanmar***

Regulatory Strengthening Program Design

Targeted capacity building activity themes

Quality

- Pre-market assessment of quality and manufacturing controls
- Good Manufacturing Practice
- Laboratory testing
- Substandard and falsified medicines
- Lifecycle management of products (variations)

Safety and Efficacy

- Pre-market assessment of safety & efficacy and post-market surveillance
- Risk Management Plans
- Medicine defects (may also involve product quality)
- Adverse event reporting
- Causality assessments
- Recalls

Risk Communication

- Role of regulators in keeping external stakeholders appropriately informed
- Promotion of the Quality Use of Medicines

Cross Cutting

Tools required to perform regulatory functions effectively (i.e. the legal, policy, IT and operational framework).

Opportunities to engage in **Reliance and Cooperation** for the purpose of:

- saving resources
- avoiding unnecessary duplication
- building a knowledge base by learning from other agencies

Design of inclusive & participatory **GEDSI** approaches and systems, including incorporation of GEDSI considerations in legal, policy and operational frameworks.

Regulatory Systems Strengthening

Targeted health systems *strengthening*, capacity building activities for 11 countries

Indonesia, Laos, Cambodia, Fiji, Papua New Guinea, Timor-Leste, the Philippines, Thailand, Vietnam, Malaysia and Myanmar (on hold)

Responsive Regulatory Support

‘On call’ *support* will be offered to address specific regulatory needs at a point in time for 22 countries

Indonesia, Laos, Cambodia, Fiji, Papua New Guinea, Timor-Leste, the Philippines, Thailand, Vietnam, Malaysia, Federated States of Micronesia, Kiribati, Nauru, Niue, Palau, Republic of Marshall Islands, Samoa, Solomon Islands, Tonga, Tuvalu, Vanuatu and Myanmar (on hold)

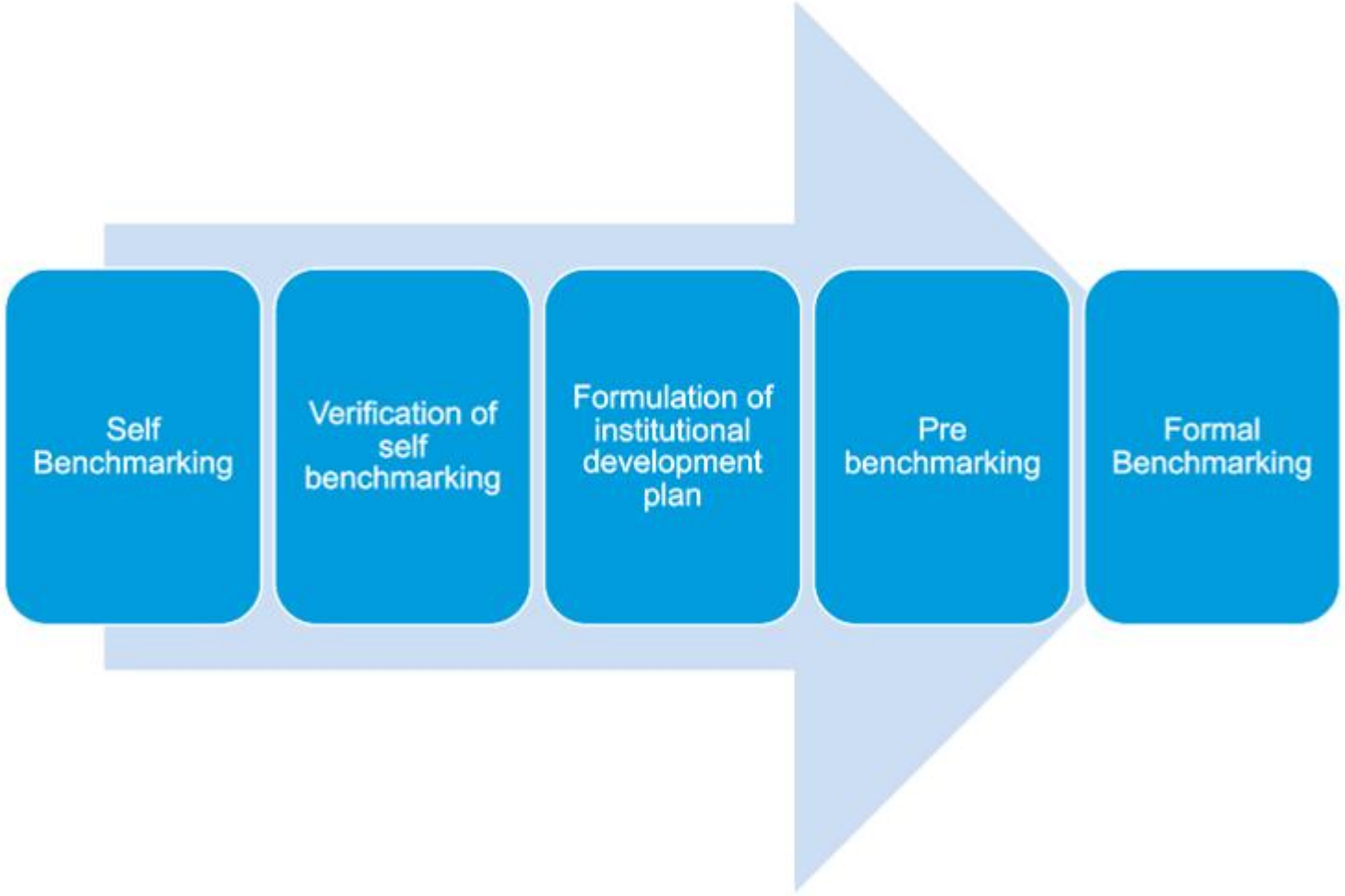
Support based on ‘regulatory maturity’

WHO Global Benchmarking Tool (GBT)

Used to determine maturity levels on a 1-4 ranking

WHO GBT Performance Maturity Levels				
ISO 9004	1	2	3	4
WHO GBT	**No formal apporoach** Some elements of regulatory system exist	**Reactive approach** Evolving national regulatory system that partially performs essential regulatory functions	**Stableformal system approach** Stable, well-functioning and integrated regulatory system	**Continual improvement emphasized** Regulatory system operating at advanced level of performance and continuous improvement
	Can ensure the quality of products if rely on ML 3/ ML 4 regulatory systems		Target of WHA Resolution 67.20	Advanced and well resourced regulatory systems

The GBT process



GBT Assessments

The TGA is historically a Stringent Regulatory Agency and hopes to achieve WHO Listed Authority (WLA) status to cement its international role in medical product regulation and to continue to be able to offer technical assistance to our regional colleagues as a trusted authority.

RSP staff have assisted with GBT-based exercises in PNG, Timor-Leste, the Philippines, Singapore and the Republic of Korea.

Pre-benchmarking exercise with PNG, September 2024.

Types of regulatory support

1) Product specific Market Authorisation
2) Capacity building
3) Responsive technical assistance

RSP is unique!

Existing pathways for Market Authorisation

- Requires open dialogue between applicants and NRAs
- Enabled by sharing information, e.g. filing strategies
- Objectively determine the value of current ‘work sharing’ initiatives and ‘reliance’ approaches

ACCESS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

ACCESS

Project Orbis

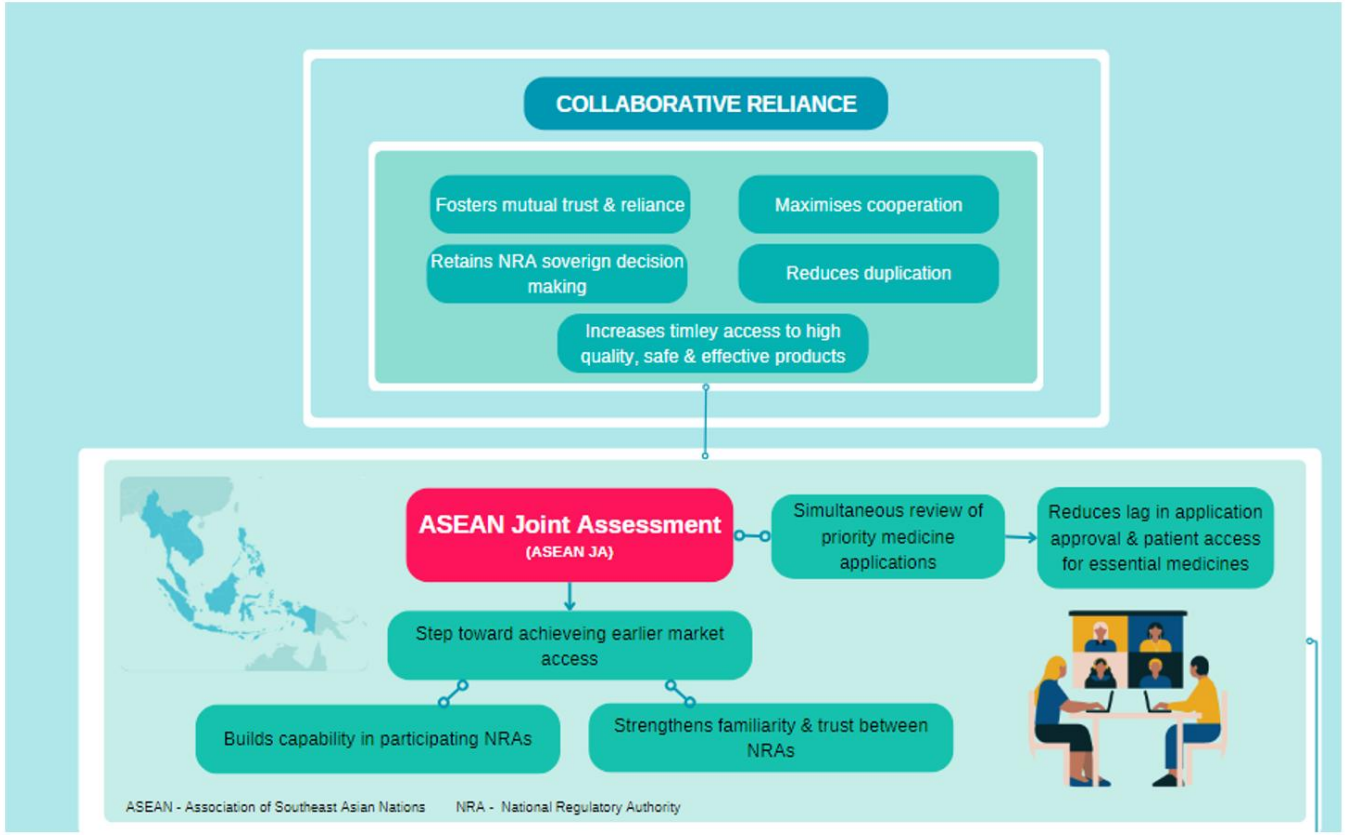
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

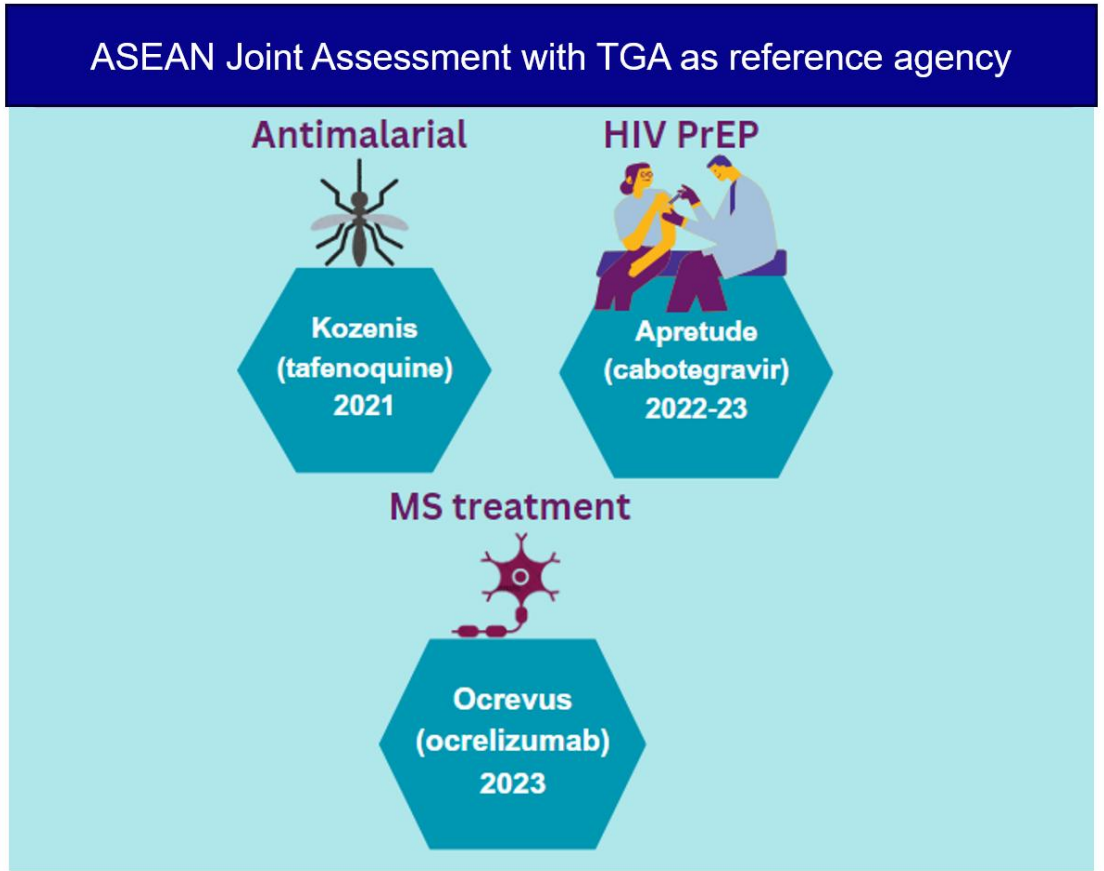
EUM4All OPEN

swissmedic
Marketing Authorisation
for Global Health Products
(MAGHP)

MAGHP

TGA support for ASEAN Joint Assessments





Product Specific: Tafenoquine

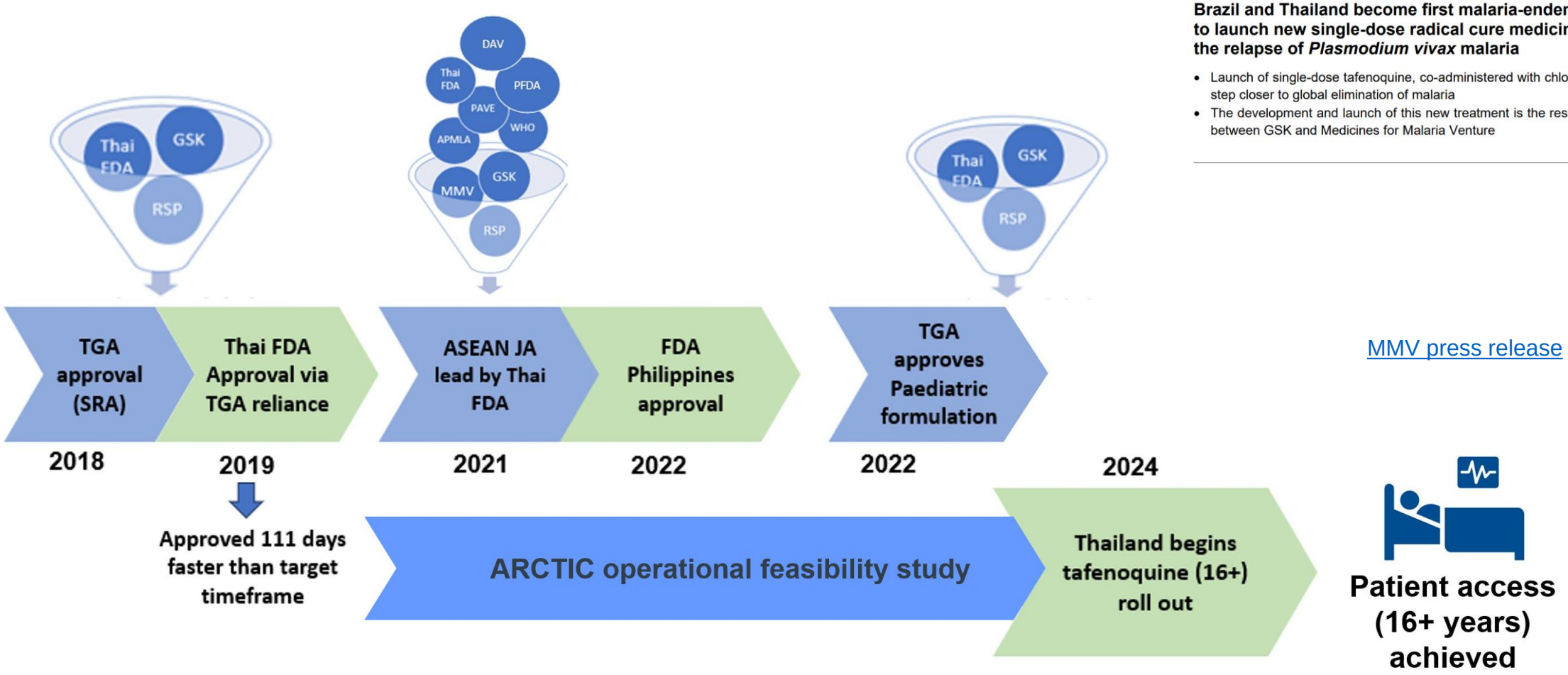
Press release
For media and investors only

Issued: 05 July 2024, London UK

Brazil and Thailand become first malaria-endemic countries to launch new single-dose radical cure medicine to prevent the relapse of *Plasmodium vivax* malaria

- Launch of single-dose tafenoquine, co-administered with chloroquine, is another step closer to global elimination of malaria
- The development and launch of this new treatment is the result of a partnership between GSK and Medicines for Malaria Venture

[MMV press release]



Bilateral Support Timeline

3 - 5 July 2019

WHO Workshop on Risk Management Plans and Periodic Safety Update Reports for tafenoquine with the Thai FDA

29 June – 6 July 2019

Mission to Thai FDA – CMC and Clinical aspects of the tafenoquine review

29 July – 2 Aug 2019

Thai FDA, Bureau of Drug Control visit the TGA

12 – 16 August 2019

Thai FDA, Health Products Vigilance Centre and WHO visit the TGA

4 – 6 September 2019

WHO Workshop on Signal Detection and Management and Benefit-Risk Assessment with the Thai FDA

Other Product Reviews

	KOZENIS	Anti-HIV products	ZOLGENSMA
Complexity	Small molecule, single active	Small molecule, FDC	Gene therapy
TGA registration	Sep-18	Feb-19	Mar-21
Partner NRA approval	Dec-19	Nov-22	Mar-23
Estimated review period*	< 1 year	~ 2 years	~ 1 year
Engagement	in-person	virtual	virtual
PDP	MMV	-	-

* Estimates based on period of engagement between TGA and partner NRAs

Capacity building in Fiji

- No requirement for products to be registered prior to importation
- Implementing medicine registration processes
- Links to procurement for public hospital system

2023: Listing products

- Visibility over products being imported
- Establish a database
- Provide importers time to submit applications

Mid-2024: Registration of products for import

Listing pathway open from Feb 2023 – Feb 2025

What is the minimum information Fiji should request to ensure the quality, safety and efficacy of imported products?

- RSP is working with Fiji's regulator to determine standards, develop guidelines, communicate changes to applicants and train staff
- Encourage the use of reliance, where practical

Responsive technical assistance

Urgent request received 31 January 2024.

First delivery 23 February 2024.

- IV antibiotics
- Glucose, saline and water for injection
- Zero stock of EML medicines and some essential supplies

Follow up in-country support through RSP team March 2024.

Medicine delivery 23 February 2024

Our Stakeholders

Australian Government
INDO-PACIFIC CENTRE FOR HEALTH SECURITY

Department of Foreign Affairs and Trade (DFAT)
Centre for Health Security

Incidents and Substandard/Falsified Medical Products (ISF)

Facilitated Product Introduction (FPI)

SEARO (and SEARN)

Coalition of Interested Parties (CIP) – GSG (Global Steering Group)

WPRO (and WPRA)

World Health Organization

Regulatory Systems Strengthening (RSS)

Pharmacovigilance

Coalition of Interested Parties (CIP) - SEARN

WHO country offices

UMC (Uppsala Monitoring Centre)

ASEAN

BADAN POM

Indonesian Food and Drug Authority, Badan POM/BPOM

NATIONAL PHARMACEUTICAL REGULATORY AGENCY
MINISTRY OF HEALTH MALAYSIA

Malaysia National Pharmaceutical Regulatory Agency (NPRA)

NCIRS National Centre for Immunisation Research and Surveillance Australia

NCIRS - National Centre for Immunisation Research and Surveillance

Ministry of Health, Lao PDR. Food and Drug Department (FDD)

Thai Food and Drug Administration (Thai FDA)

ADB ASIAN DEVELOPMENT BANK

Asian Development Bank (ADB)

MMV Medicines for Malaria Venture

MMV Medicines for Malaria Venture

Centre of Regulatory Excellence

CoRE

CEPI

CEPI - Coalition for Epidemic Preparedness Innovations

CLINTON HEALTH ACCESS INITIATIVE

CHAI - Clinton Health Access Initiative

ក្រសួងសុខាភិបាល
MINISTRY OF HEALTH
នាយកដ្ឋានឱសថ ចំណីអាហារ មធ្យោបាយ និងគ្រឿងសំអាង
DEPARTMENT OF DRUGS AND FOOD

Ministry of Health, Cambodia Department of Drugs and Food (DDF)

BILL & MELINDA GATES foundation

Bill & Melinda Gates Foundation (BMGF)

TB Alliance

TB Alliance

Drug Administration of Vietnam (DAV)

MINISTRY OF HEALTH & MEDICAL SERVICES

Fiji Medicines Regulatory Authority (Fiji MRA)

USP

mSupply

mSupply

PAPUA NEW GUINEA

Papua New Guinea National Department of Health (NDOH)

FDA Food and Drug Administration PHILIPPINES

Food and Drug Administration (FDA), Philippines

Ministério da Saúde

Ministry of HealthTimor-Leste, Direcção National da Farmacia e Medicamentos (DNFM) (National Directorate of Pharmacy and Medicine)

Pmda

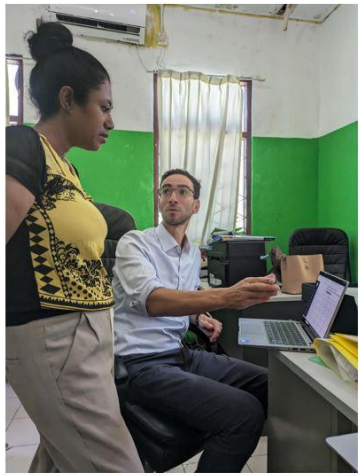
Pharmaceuticals and Medical Devices Agency (Japan)

Asia-Pacific Economic Cooperation - Regulatory Harmonization Steering Committee (APEC RHSC)

Unitaid

UNITAID

Who we work with…




World Health Organization


Western Pacific Region
World Health Organization
Ms Siti Naasirah Hj Aji
Brunei Darussalam
Dr Paul Huleatt
Australia
Ms Zanatul Aini Zainin
Brunei Darussalam


BỘ Y TẾ
CỤC QUẢN LÝ DƯỢC
DRUG ADMINISTRATION OF VIETNAM

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Keynote: Collaboration and work sharing to bring innovation to patients

Marie Valentin

Team Lead, Facilitated Product Introduction Regulation and Safety Unit [REG] Regulation and Prequalification Department [RPQ]

World Health Organization

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World Health Organization

Collaboration and work sharing to bring innovation to patients

Marie Valentin

Team Lead,

Facilitated Product Introduction

Regulation and Safety Unit, Regulation and Prequalification Department,

World Health Organization

IFPMA 12th Asian Regulatory Conference – Day 1 Tuesday 3rd December 2024 (virtual)

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

Medical products – instrument for public heath

SDG 3 – Target 3.8

Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and **access to safe, effective, quality and affordable essential medicines and vaccines for all**

World Health Organization

Access to medical products – global challenge

- Good health is impossible without access to medical products;
- An estimated **two billion people have no access to essential medicines**, effectively shutting them off from the benefits of advances in modern science and medicine.
- Reasons for limited/insufficient access are numerous – including insufficient/inadequate regulatory capacity and lack of collaboration and work sharing between countries in regulation of medical products.

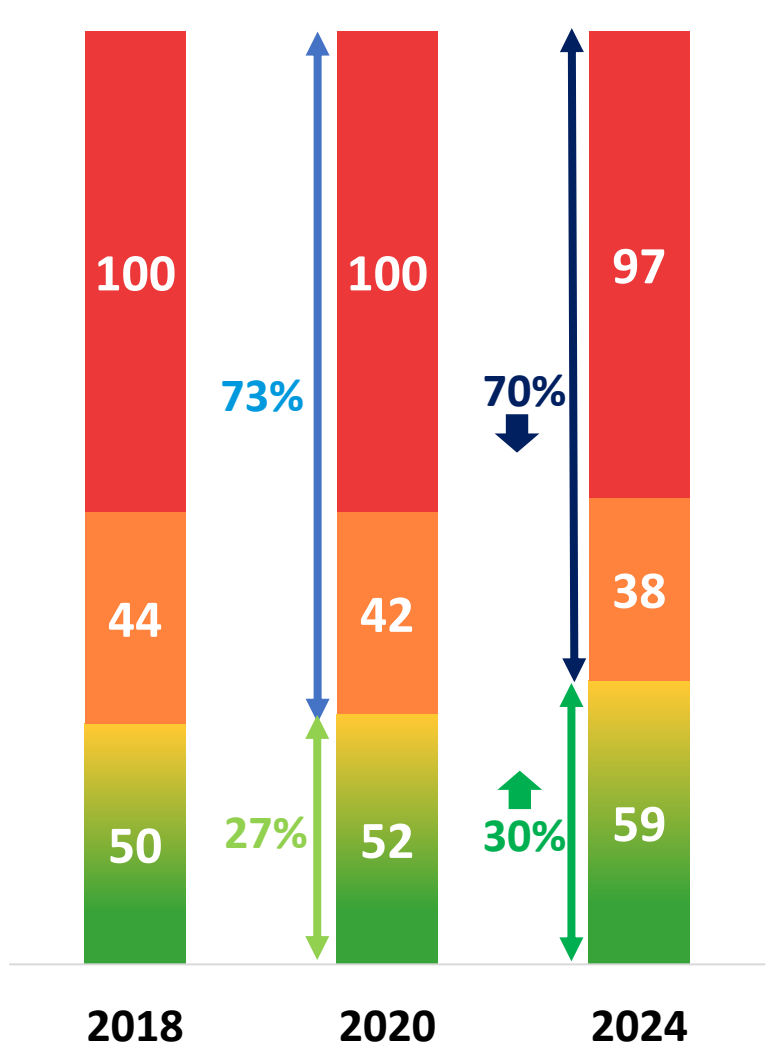
Objectives of the WHO regulatory system strengthening programme

Why reliance?

ML

- *With some elements of regulatory system* — 1
- *Evolving national regulatory system* — 2
- *Stable, well functioning and integrated* — 3
- *Advanced level of performance and continuous improvement* — 4

ML: *(regulatory system) maturity level*



1 - Build regulatory capacity in Member States consistent with good regulatory practices

Good regulatory practices, 2021

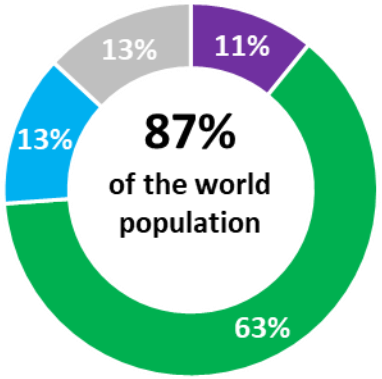
2 - Promote regulatory cooperation, convergence and transparency through networking, **work-sharing and reliance**

Good reliance practices, 2021

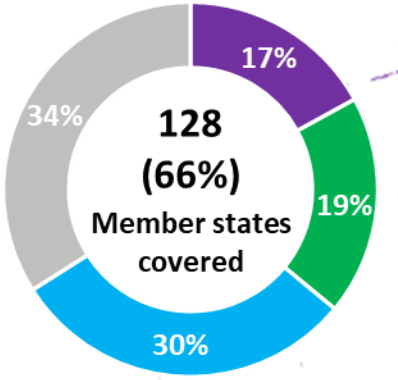
*Total Number of countries = **194***

Global status of benchmarking and performance evaluation of regulatory systems (2016 – September 2024)

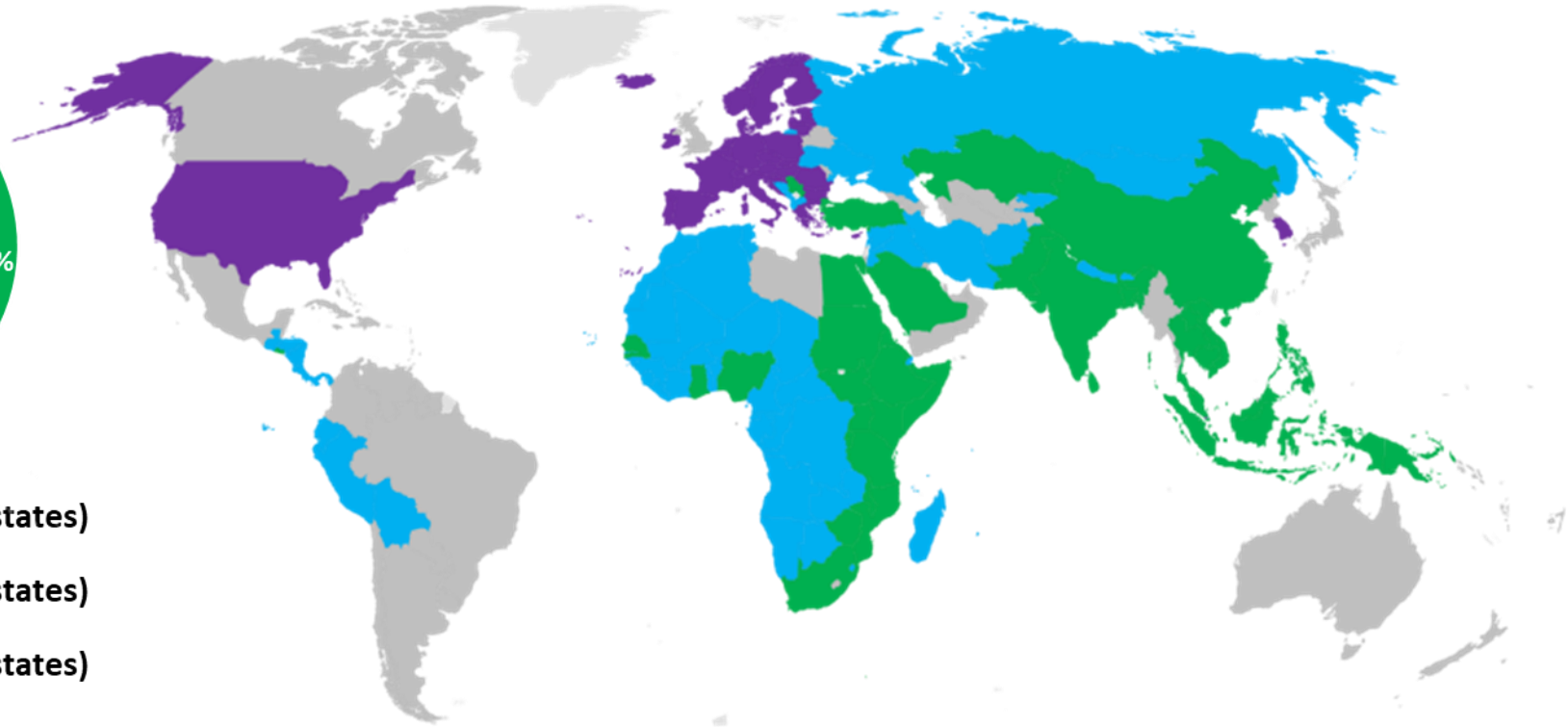
% of world population



% of member states



WHO Listed authority (WLA)	**(33 member states)**
Benchmarking	**(37 member states)**
Self-benchmarking	**(58 member states)**



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization (WHO) concerning the legal status of any country, territory, city or area of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on map represent approximate border lines for which there may be not yet be full agreement.

Powered by Bing

Source: WHO RSS database, Sep 2024

World Health Organization

Growing use of reliance

World Health Organization

Growing use of reliance

Long history of improving efficiency through reliance (e.g. CPP)

Reliance embedded in the WHO Global Benchmarking Tool

WHO Good Reliance Practices, March 2021

Promote “informed” reliance

Increase reliance for all regulatory functions & worksharing

Develop more guidance for practical implementation

PAST

COVID-19/emergency response as strong accelerator for reliance

Universality, regardless of maturity level or resources

PRESENT

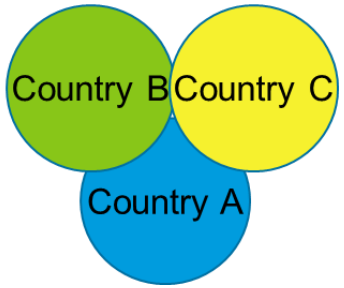
FUTURE

World Health Organization

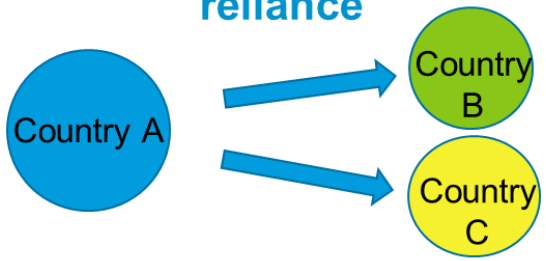
Reliance's many shapes and forms

"The act whereby the regulatory authority in one jurisdiction **takes into account and gives significant weight** to **assessments performed 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."

Work-sharing

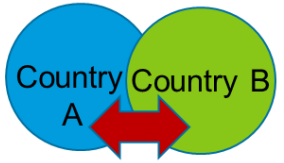


Abridged pathway using reliance



Recognition

Unilateral



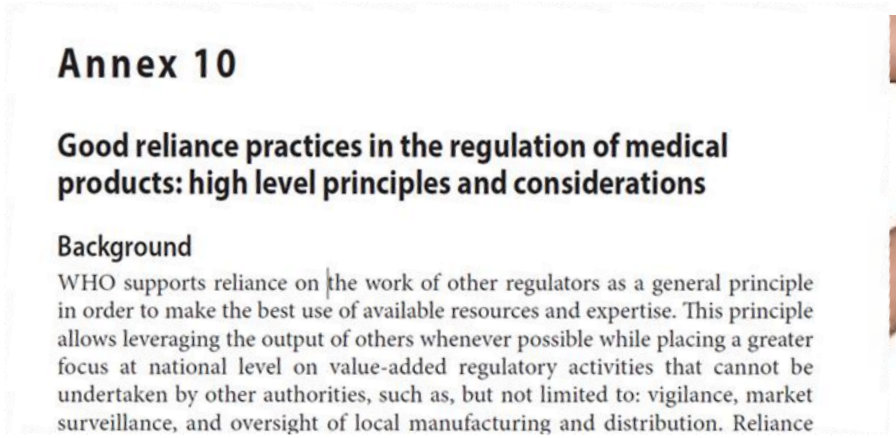
Mutual recognition

- Sovereignty maintained;
- More efficient use of global regulatory resources;
- Decrease duplication, increase trust and collaboration.

World Health Organization

Source of information on reliance

WHO Good Reliance Practices



Annex 10

Good reliance practices in the regulation of medical products: high level principles and considerations

Background

WHO supports reliance on the work of other regulators as a general principle in order to make the best use of available resources and expertise. This principle allows leveraging the output of others whenever possible while placing a greater focus at national level on value-added regulatory activities that cannot be undertaken by other authorities, such as, but not limited to: vigilance, market surveillance, and oversight of local manufacturing and distribution. Reliance

Adopted by WHO Expert Committee on Specification for Pharmaceutical Products in October 2020, published in March 2021 https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

Short eLearning Module of main principles and examples of reliance (Oct 2022) https://openwho.org/courses/good-reliance-practices

IPRP International Pharmaceutical Regulators Programme

IPRP Questions and Answers document[1] on Reliance
Version dated 30 September 2022

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2. What is "not" reliance ? 2
3. Why is reliance important for the regulatory oversight of medical products? 3
4. Do National Regulatory Authorities maintain their independence and sovereignty when using reliance? 3
5. What are the main principles of reliance? 4
6. What competences are required in applying reliance? 4
8. What type of reliance models exist? 5
10. How can an NRA start using reliance models? 6
11. What is the risk-based approach in reliance? 6
12. At which stages of the product life cycle can reliance be used? 7

International Pharmaceutical Regulators Programme
Questions & Answers on Reliance
https://admin.iprp.global/sites/default/files/2022-11/IPRP_RelianceQ%26As_2022_0930.pdf

World Health Organization

IPRP Good Reliance Practice Repository on current models and frameworks for reliance October 2024 - https://www.iprp.global/news/iprp-good-reliance-practices-repository-now-published

Examples of reliance in WHO Processes

WHO Prequalification (abridged, alternative etc.)

Good Practices Inspections

WHO Collaborative Registration Procedure

WHO Certificate of Pharmaceutical Products

Reliance key to facilitate access during pandemic response

Reliance is key to effective access and oversight of medical products in case of public health emergencies

Agnes Saint-Raymond, Marie Valentin, Nobumasa Nakashima, Nick Orphanos, Gustavo Santos, Georgios Balkamos & ...show all

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Expert Review of Clinical Pharmacology
https://www.tandfonline.com/doi/full/10.1080/17512433.2022.2088503

World Health Organization

Regulatory convergence and harmonization initiatives

Convergence and harmonization efforts should in theory diminish duplication, creating a "common language" for decision-making and facilitating cooperation, work-sharing and eventually reliance or recognition

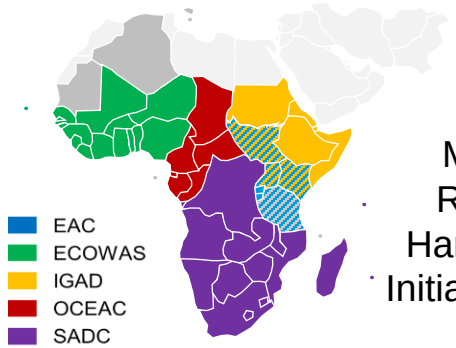
ICH harmonisation for better health

IPRP International Pharmaceutical Regulators Programme

ICMRA International Coalition of Medicines Regulatory Authorities

PIC/S

IMDRF International Medical Device Regulators Forum



African Medicines Regulatory Harmonization Initiative (AMRH)

ASEAN SIAHR Project

Caribbean Public Health Agency

CARPHA

SEARN SOUTH-EAST ASIA REGULATORY NETWORK

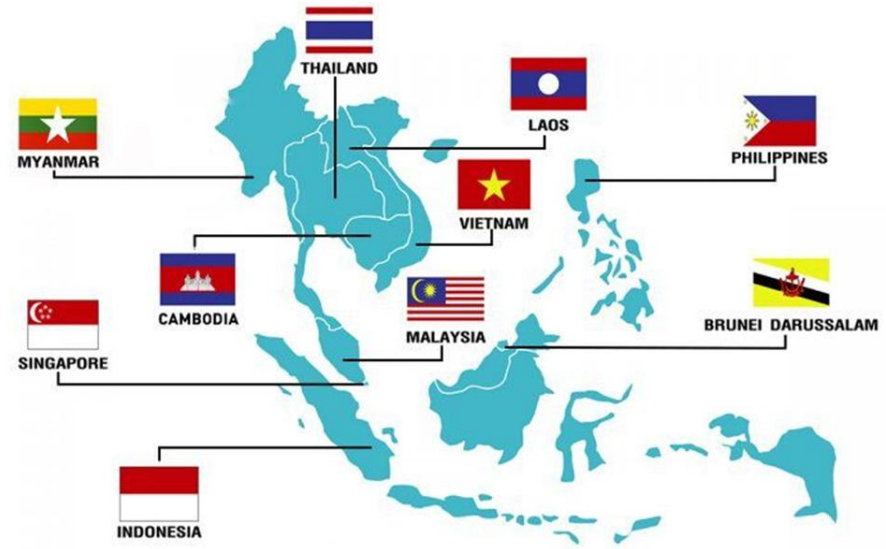
RED PANDRH PARF

PANDRH

African Vaccine Regulators Forum (AVAREF)

ASEAN Joint Assessment concept and principles

Same application



Technical assessment of modules (quality, safety and efficacy) **carried out jointly**

- Open to all 10 ASEAN NRAs on **a voluntary basis**
- **Minimum of 3 NRAs**
- Administrative/local submission/assessment is conducted by individual NRAs in parallel/before the technical assessment starts

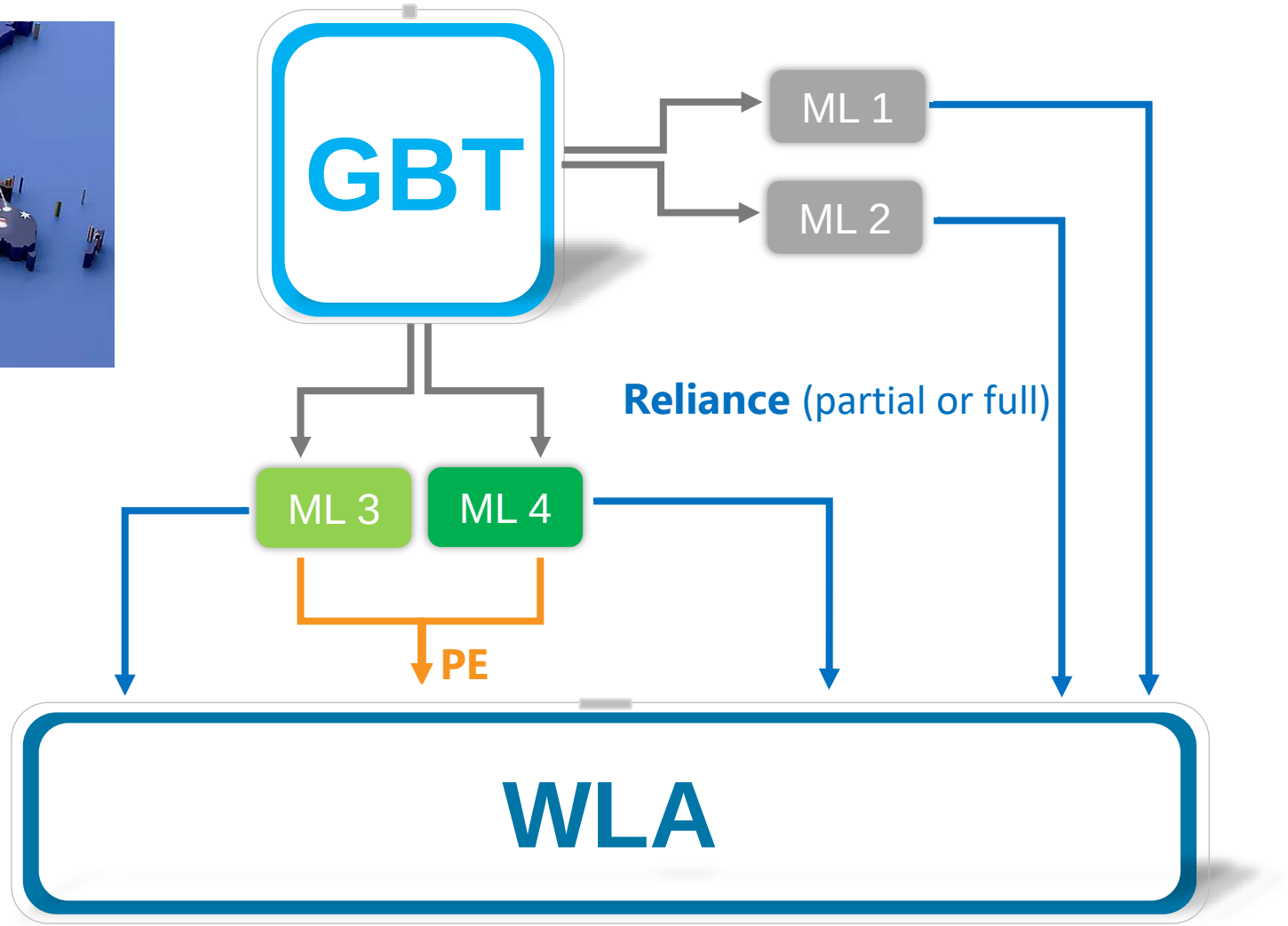
- **Final regulatory decision taken by each NRA** (according to national timelines) based on joint assessment report and national-relevant considerations if applicable (30 to 90 days)

ASEAN Joint Assessment*

* Can be used by other ASEAN non-participating NRAs

Fostering reliance through the WLA initiative

- Only ML3 and ML4 RAs are eligible for performance evaluation
- Reliance can be applied by all



First three WLAs

31st October 2023

SRA

Switzerland

Swissmedic

tWLA

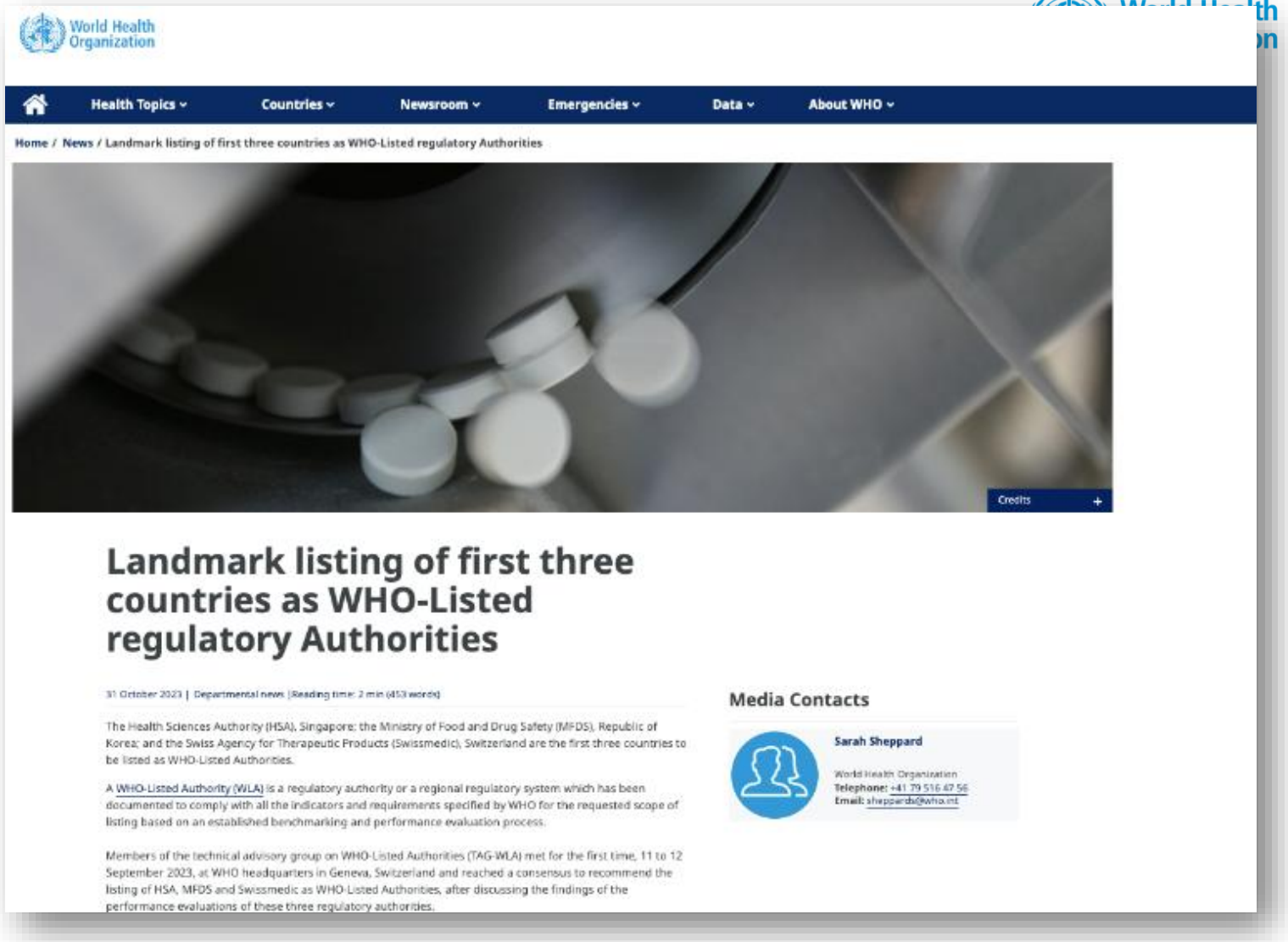
Republic of Korea

MFDS

ML4 NRA

Singapore

HSA



https://www.who.int/news/item/31-10-2023-landmark-listing-of-first-three-countries-as-who-listed-regulatory-authorities

33 new WLAs

20th May 2024

RRS

European Medicines Regulatory Network

EC/EMA

+30 NCAs

SRA

United States of America

US FDA

ML4 NRA

Singapore

HSA*

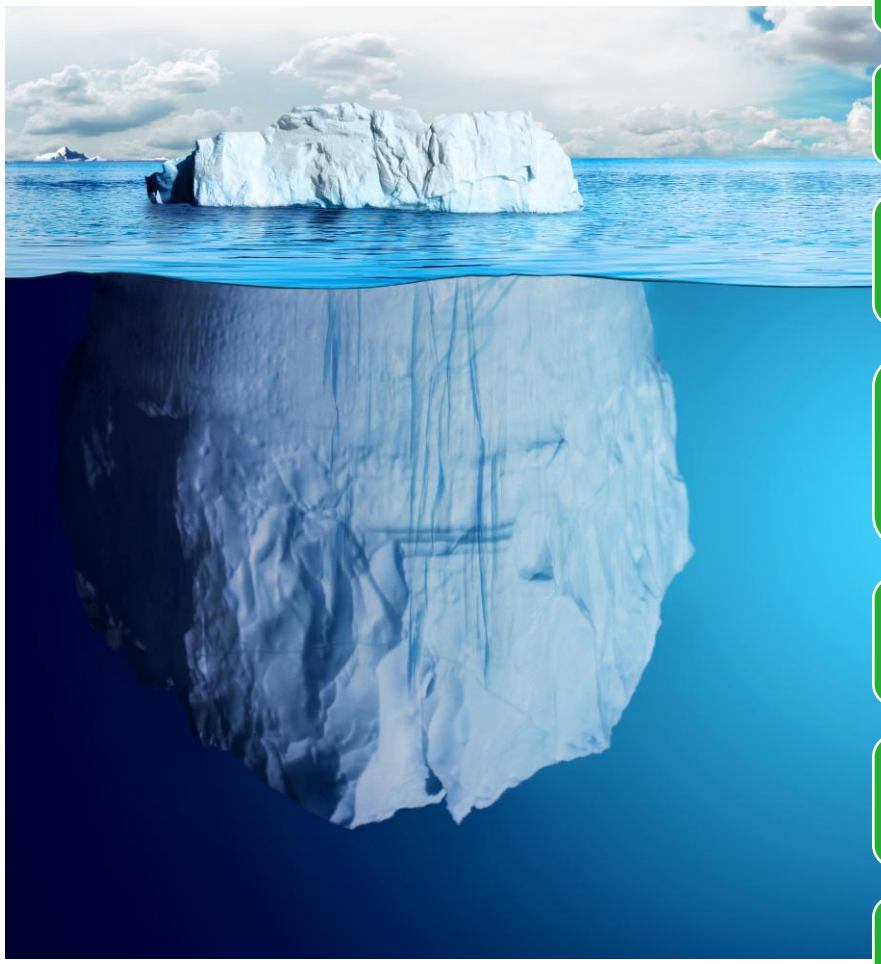
* MC function

https://www.who.int/news/item/20-05-2024-largest-number-of-regulatory-agencies-for-medical-products-approved-as-who-listed-authorities

How can we collectively better manage PAC?

Initial authorization

Post-authorization changes



- Pragmatic approach
- More recognition for (minor) variations?
- Increase transparency of PAC assessment
- Accommodate new concept for product lifecycle management (e.g. ICH Q12)
- Simplification of regulatory frameworks
- More reliance and ensuring product sameness
- Build trust between stakeholders

Key Messages on reliance going forward

- Essential for all regulators to accommodate/implement reliance in their regulatory functions.
- Colloboration & communication between all stakeholders is key.
- New opportunities for reliance with the WLA framework.
- Collectively define better model for PAC management.

www.who.int/medicines

Thank you for your attention!

Marie Valentin, Team Lead, Facilitated Product Introduction Team, World Health Organization

valentinm@who.int

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

ACCESS Consortium

Moderated Panel

ARC 2024
ASIA REGULATORY CONFERENCE

PANEL DISCUSSION

Leonard Both
Swissmedic

Michelle Cheng
Abbvie

Helen Critchley
Sanofi

Freddie Foo
Health Sciences Authority

Joel Raffel
Medicines and Healthcare products Regulatory Agency

Michael Wiseman
Therapeutic Goods Administration

Tham Vo
Medicines Australia

swissmedic

The Access Consortium

IFPMA, ARC Dec 2024, Virtual Conference

Leonard Both, PhD LLM

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Hallerstrasse 7, 3012 Bern
www.swissmedic.ch

Disclaimer

- The views and opinions expressed in the following PowerPoint slides are those of the individual presenter.

Background

- There is a growing awareness of the need for regulators to work together to maximise use of resources.
- Global collaboration is urgently needed. Working together allows patients earlier access to medicines, which is both an industry objective and a regulator's objective.
- The Access Consortium is actively exploring approaches to ensure deeper collaboration and ultimately facilitate timely patient availability of medicines across all Access regions.
- Our work has recently been expanded to ATMPs, inspections, advice to companies via Access *Pipeline meetings,* and clinical trials.
- This session will explore how Access Consortium agencies have been working together and how their collaboration could evolve in the future.

Our goal

Our main goal is to maximise international co-operation between partners in the Access consortium, reduce duplication, and increase each agency's capacity to ensure patients have timely access to high quality, safe and effective therapeutic products.

The trend towards globalisation of therapeutic products industries and the rapid emergence of new technologies in the last decade accompanied with shared global challenges have created an increased need for regulatory bodies to co-operate and communicate with each other routinely. To address this, we maximise the use of up-to-date technical expertise, and ensures a consistent, contemporary approach to assessing the benefits and risks associated with the use of therapeutic products.

Australian Government
Department of Health
Therapeutic Goods Administration

Health Canada
Santé Canada

HSA
Health Sciences Authority

swissmedic

MHRA

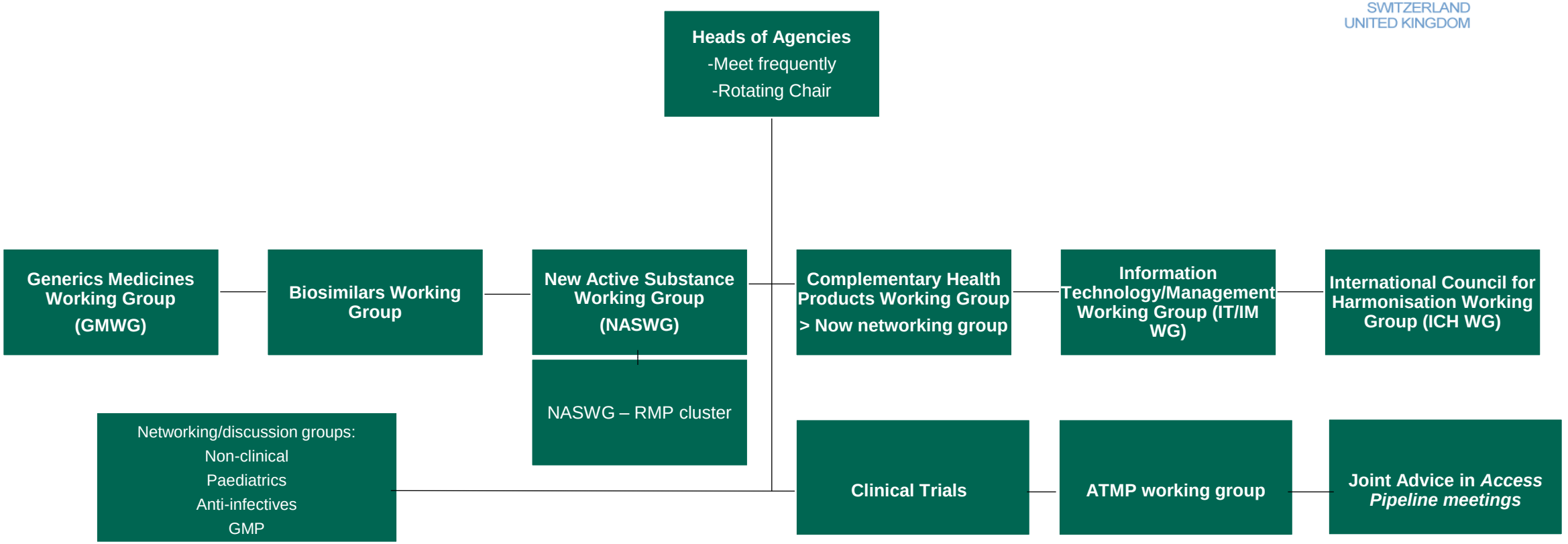
ACSS
CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND

2021

ACCESS
CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

Structure

ACCESS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM



ACCESS CONSORTIUM

AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

Access Consortium

Strategic Plan 2021-2024

Strategic Objectives

The following are the strategic objectives for 2021-2024 to guide the Access Consortium in achieving its vision and mission.

Strengthening Access work-sharing initiatives

Making Access a competitive and efficient submission pathway of choice for industry, supporte by regulators:

- Increase the number of applications assessed by Access work-sharing initiatives
- Increase the variety of health products assessed within Access
- Optimize work-sharing through greater alignment of regulatory approaches and technic and scientific requirements
- Strengthen collaboration by supporting Access participation in international initiatives
- Explore best practices with optimal use of resources for assessment collaboration
- Capture lessons learned from the COVID-19 experience to innovate together and improve work-sharing

Expanding lifecycle approach

Maximizing collaboration throughout the health product lifecycle:

- Consider collaboration on clinical trials design and/or sponsor advice
- Explore the use of real-world data and real-world evidence in clinical trial design and regulatory approaches
- Establish collaboration and scientific information sharing within Access on risk management, pharmacovigilance and post-market safety
- Explore the use of pharmacovigilance and real-world data to support early entry on the market of vaccines and therapeutics for COVID-19 and other diseases
- Consider further collaboration, including work-sharing, on global Good Practice (GxP) inspections complementary to existing international initiatives

Regulatory innovation that integrates a healthcare systems approach

Increasing regulatory capacity while collaborating with key national healthcare systems partners to facilitate uptake of innovative health products:

- Strengthening and leveraging regulatory scientific capacity within Access for emerging technologies and innovative products
- Explore collaboration with national health technology assessment organizations (and similar)
- Explore a more collaborative aligned “systems” approach to regulating innovative products by:
    - integrating national healthcare system partners throughout the lifecycle of innovative products, and
    - fostering links between healthcare system needs and regulatory oversight of innovative products

Indicators of Success

The Access goal to become regulators of choice will be measured by the following indicators of success:

- Increase in applications to Access at the same time or soon after filed with other major medicines regulators
- Increase in number of products made available to patients via Access
- Increase in diversity of products assessed via Access
- Decrease in average time to market for products assessed under Access
- Reduced effort and duplication for both regulators and industry
- Increased collaboration on the alignment of products made available to patients via Access with healthcare system needs
- Increased collaboration on global GxP inspections
- Increase in number of ICH guidelines implemented through Access collaboration

Example for successful Access collaboration

Research and analysis

ACCESS Consortium guidance on strain changes in authorised COVID-19 vaccines

A regulatory approach for updating authorised coronavirus vaccines should mutations at any time make them less efficacious due to insufficient cross-reactivity.

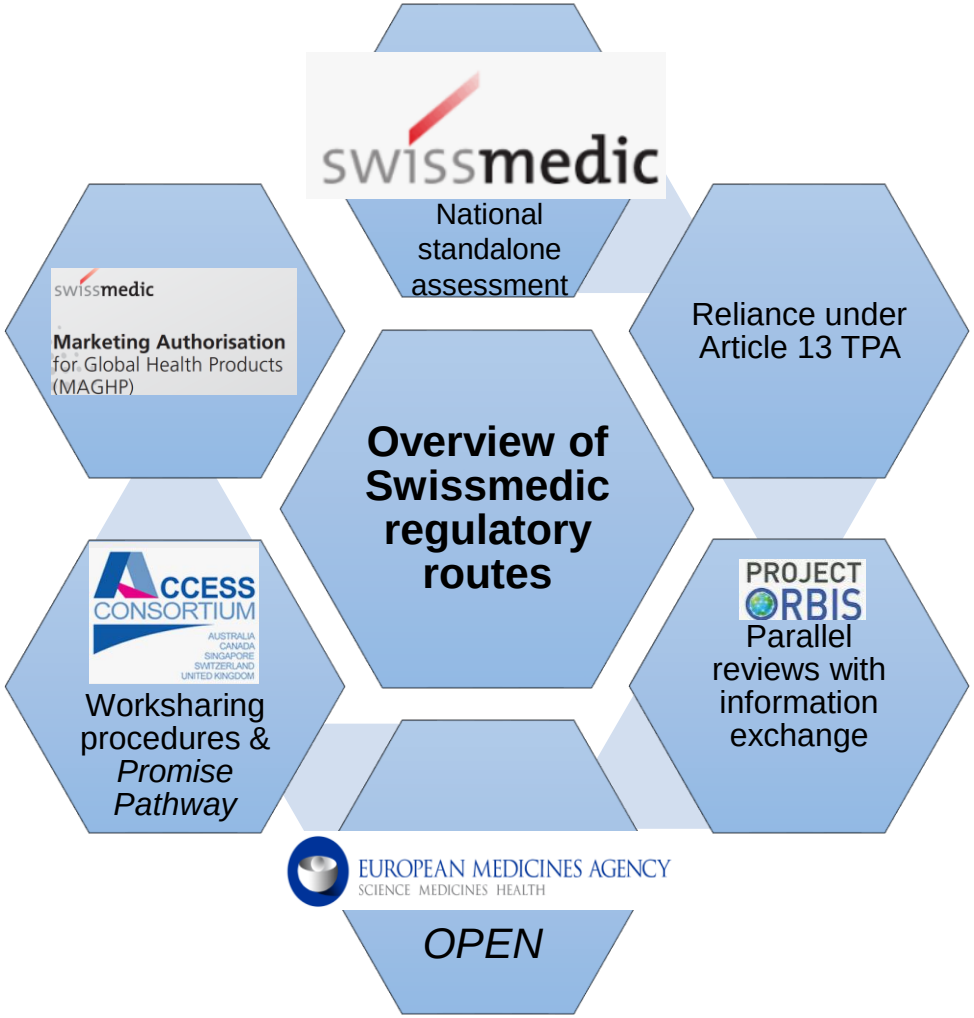
This document is only applicable to COVID-19 vaccines which have already been authorised, based on adequate data on pharmaceutical quality, safety and efficacy from pivotal clinical trials.

On public health and scientific considerations, Regulatory Authorities do not consider an updated coronavirus vaccine to be an entirely novel product with the resulting requirement for lengthy full-blown clinical studies.

Rather, a regulatory approach like for seasonal updates for influenza vaccines can be taken. Evidence gathered by the large pivotal clinical studies for initial authorisation and by mass vaccination campaigns is a strong foundation for this approach, as is ongoing research on the "correlate of protection" (i.e what immunological readouts correlate with clinical protection from COVID-19 disease).

Access Consortium worksharing is part of an agency's toolkit

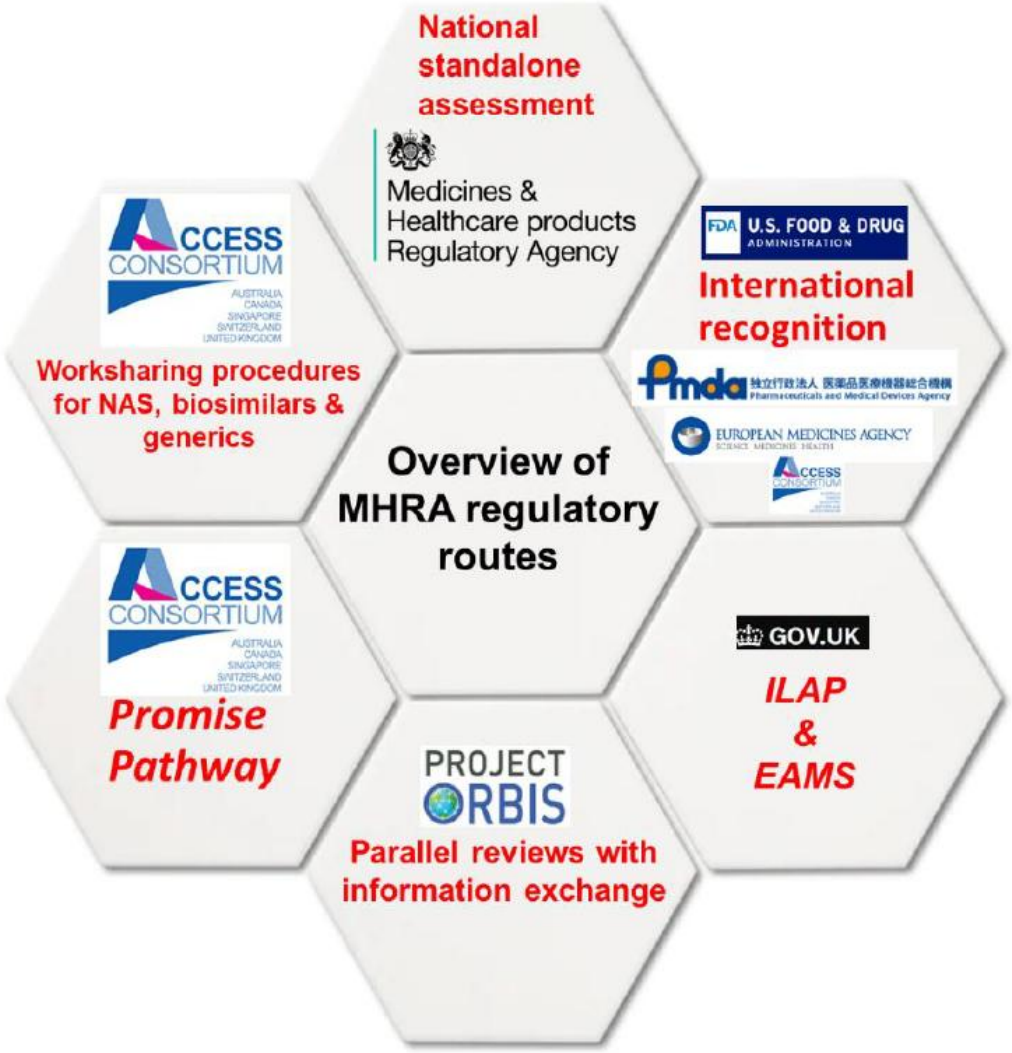
(Example Switzerland)



Agencies can benefit from a sustainable toolkit of regulatory pathways, including reliance, worksharing, info exchange, and independent national reviews.

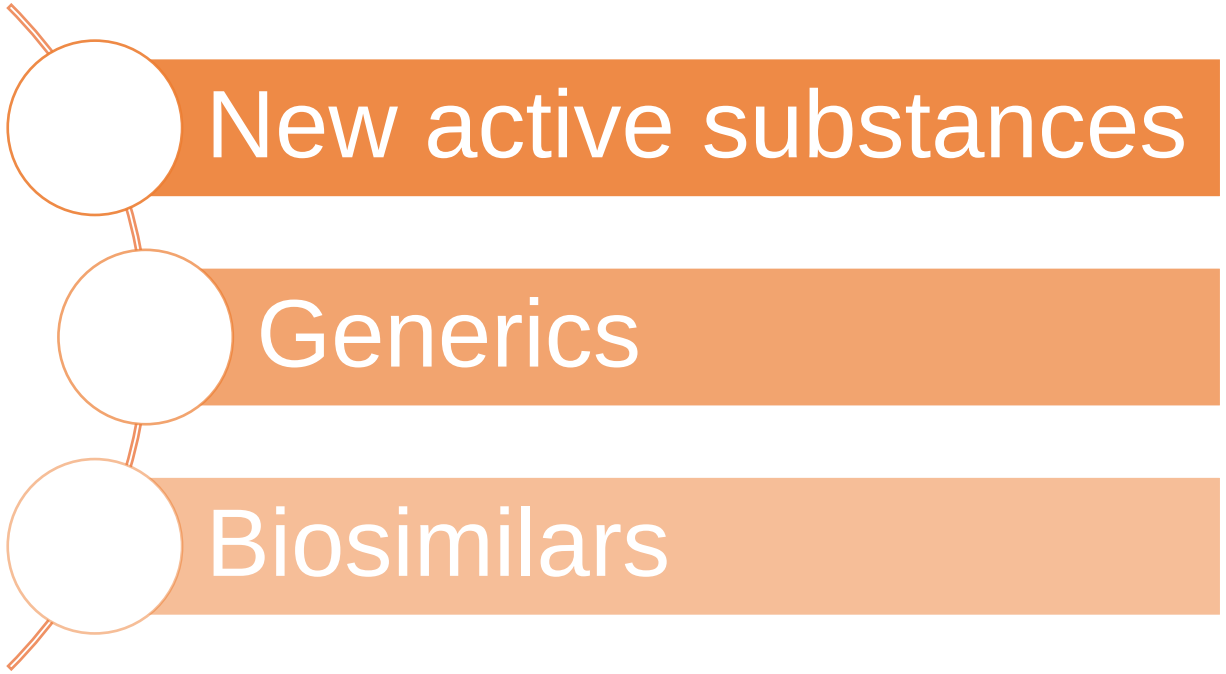
Access Consortium worksharing is part of an agency's toolkit

(Example UK)



Agencies can benefit from a sustainable toolkit of regulatory pathways, including reliance, worksharing, info exchange, and independent national reviews

3 Access Consortium initiatives for worksharing (WS):

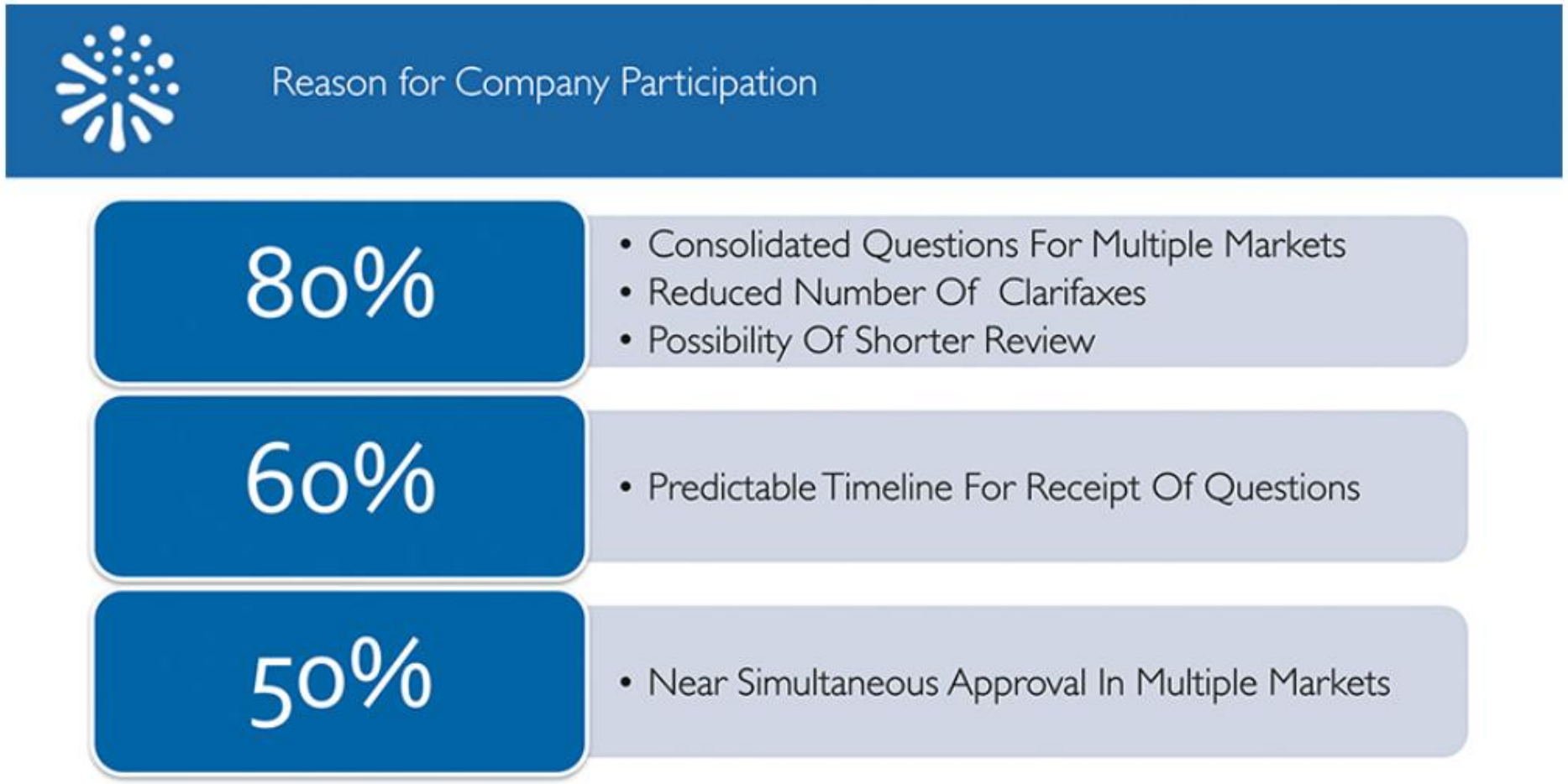


WS procedures are subject to sovereign decisions for each country.

The rules and operational procedures for WS procedures can be found on the agencies' websites.

Reasons for agencies to workshare

- Access members have equal status in terms of engagement and decision making and can opt out if they wish.
- For new drug applications, the workload is simply split by CTD modules
- Applicants (sponsors) can choose from two to five jurisdictions (Australia's TGA, Health Canada, Singapore's HSA, Swissmedic and MHRA).
- **1st wave** agency positioning with a large population - All five jurisdictions have a collective population base of ~160 million.



Graph from *Innovative Medicines Canada* survey conducted in June 2021

Work-sharing: Process

- Review under the Access Consortium is initiated by sponsors by submitting an “Expression of Interest” (EOI) application form outlining any differences foreseen in the dossiers to all applicable health authorities.

- Participating regulatory authorities and the sponsor may conduct a joint meeting to lay out a consolidated roadmap for the review cycle, including dates for the initial list of joint questions and the proposed decision date.

- At this point, the principal review activities are divided/assigned to different participating health authorities while country-specific CTD module 1 and the risk-management plan are independently reviewed by each authority.

Access Consortium work-sharing authorisations

Applications that have successfully received market approval through the Access Consortium "New Active Substance Work Sharing Initiative" (NASWSI) in Switzerland:

Medicinal product	Active substance	Partner agencies involved
Xofluza®	Baloxavir Marboxil	Australia's Therapeutic Goods Administration (TGA), Health Canada
Kesimpta®	Ofatumumab	TGA Australien, Health Canada, Health Sciences Authority (HSA) Singapore
VeraSeal®	Fibrinogen and Thrombin	Australia's Therapeutic Goods Administration (TGA), Health Canada
Verquvo®	Vericiguat	Australia's Therapeutic Goods Administration (TGA), Health Sciences Authority (HSA) Singapore
Kerendia®	Finerenone	Health Sciences Authority (HSA) Singapore, Australia's Therapeutic Goods Administration (TGA)
Nexviadyme®	Avalglucosidase alfa	Health Canada, Australia's Therapeutic Goods Administration (TGA)
Cibinqo®	Abrocitinib	Health Sciences Authority (HSA) Singapore
Vabysmo®	Faricimab	Australia's Therapeutic Goods Administration (TGA), Health Canada, Health Sciences Authority (HSA) Singapore, Medicines and Healthcare Products Regulatory Agency (MHRA)
Scemblix®	Asciminib	Australia's Therapeutic Goods Administration (TGA), Health Canada, Health Sciences Authority (HSA) Singapore, Medicines and Healthcare Products Regulatory Agency (MHRA)
Kapruvia®	Difelikefalin	Australia's Therapeutic Goods Administration (TGA), Health Canada
Mounjaro®	Tirzepatid	Australia's Therapeutic Goods Administration (TGA), Health Canada, Health Sciences Authority (HSA) Singapore
Tavneos®	Avacopan	Health Canada
Vafseo®	Vadadustat	Australia's Therapeutic Goods Administration (TGA), Medicines and Healthcare Products Regulatory Agency (MHRA)
Alhemo®	Concizumab	Australia's Therapeutic Goods Administration (TGA), Health Canada
Omvoh®	Mirikizumab	Australia's Therapeutic Goods Administration (TGA)
Veoza®	Fezolinetant	Australia's Therapeutic Goods Administration (TGA)
Awiqli®	Insulin icodec	Health Canada, Australia's Therapeutic Goods Administration (TGA)
Fruzaqla®	Fruquintinib	Australia's Therapeutic Goods Administration (TGA), Health Canada, Health Sciences Authority (HSA) Singapore, Medicines and Healthcare Products Regulatory Agency (MHRA)
Velsipity®	Etrasimod	Health Sciences Authority (HSA) Singapore
Winrevair®	Sotatercept	Australia's Therapeutic Goods Administration (TGA), Health Canada, Health Sciences Authority (HSA) Singapore

Applications that have successfully received market approval through the Access Consortium "Generic Medicines Work Sharing Initiative" (GMWSI) in Switzerland:

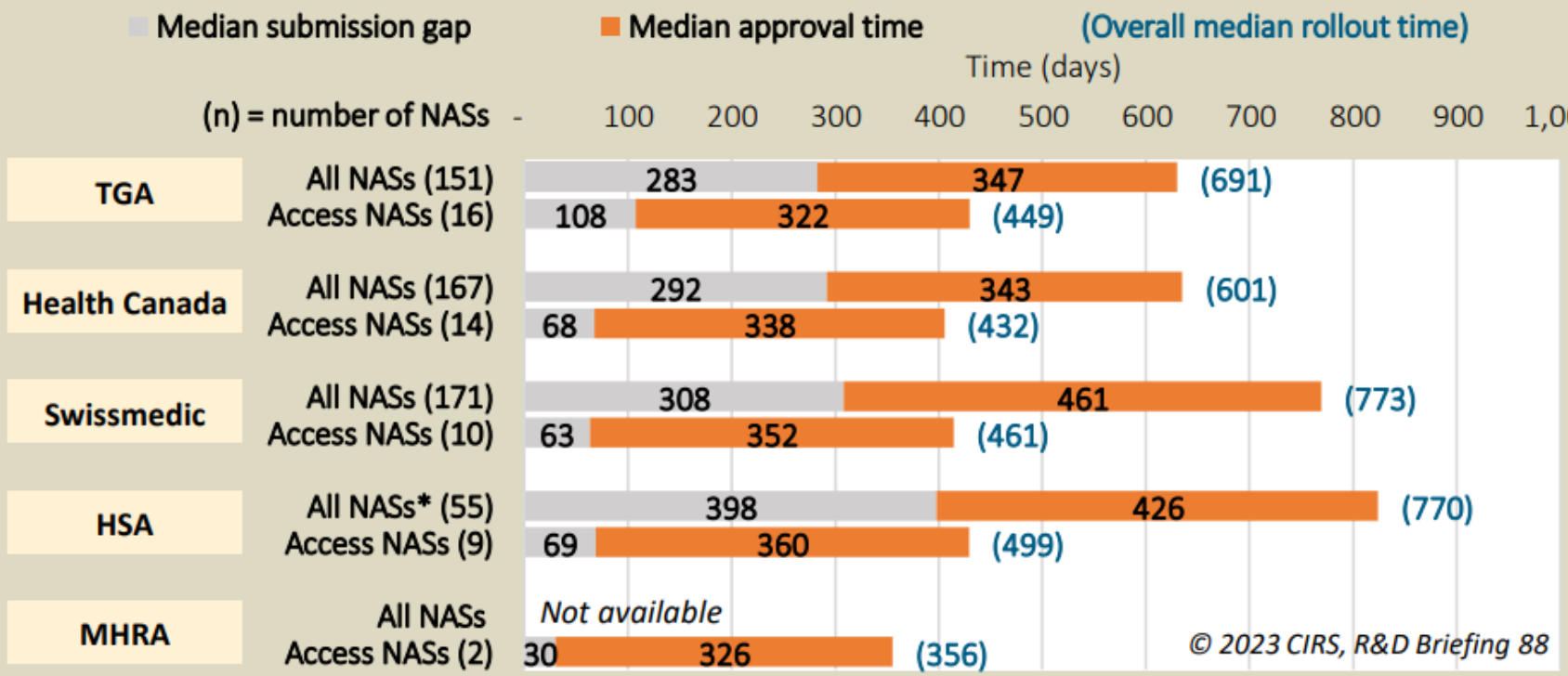
Generic Medicines	Active substance	Partner agencies involved	Links
Everolimus Teva®	Everolimus	Australia's Therapeutic Goods Administration (TGA), Health Canada	
Dabigatran Sandoz®	Dabigatran	Australia's Therapeutic Goods Administration (TGA)	
Agilus®	Dantrolen	Medicines and Healthcare Products Regulatory Agency (MHRA)	
Enzalutamid Sandoz®	Enzalutamid	Medicines and Healthcare Products Regulatory Agency (MHRA)	

Last modification 02.10.2024

NAS Work-sharing Initiative

Metrics published in CIRS R&D Briefing 88 confirm reduced submission gaps, as well as competitive approval times.

Figure 13: Median submission gap and median approval time for all NASs approved compared to those approved via the Access Consortium between 2018-2022



Submission gap is calculated as the time from the date of submission at the first regulatory agency (out of EMA, FDA, PMDA, Health Canada, Swissmedic and TGA) to the date of regulatory submission to the target agency. Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. Rollout time is calculated from the date of submission at the first regulatory agency to the date of regulatory approval at the target agency.
**The timelines for other NASs were obtained from Industry via the CIRS Growth and Emerging Markets Programme.*

Access collaboration

- Shortened submission gaps, improved use of available resources and competitive approval times usually outweigh coordination efforts between Access partners.

- A common challenge is conducting a peer review based on something another agency has assessed. Trust must be built between parties, including direct interactions and dialogue.

- Access collaboration goes beyond the assessment of MAA modules, extending into post-marketing and inspection activities, spanning from small to large molecules, and more recently, also covering ATMPs.

- In addition, to make Access submissions more attractive to companies, a new fast-track assessment called the *Promise Pathway* has recently been introduced.

Pilot: Access Consortium Promise Pathway

New Access Work-Sharing Pathway for Priority Procedures

Promise Pilot Pathway

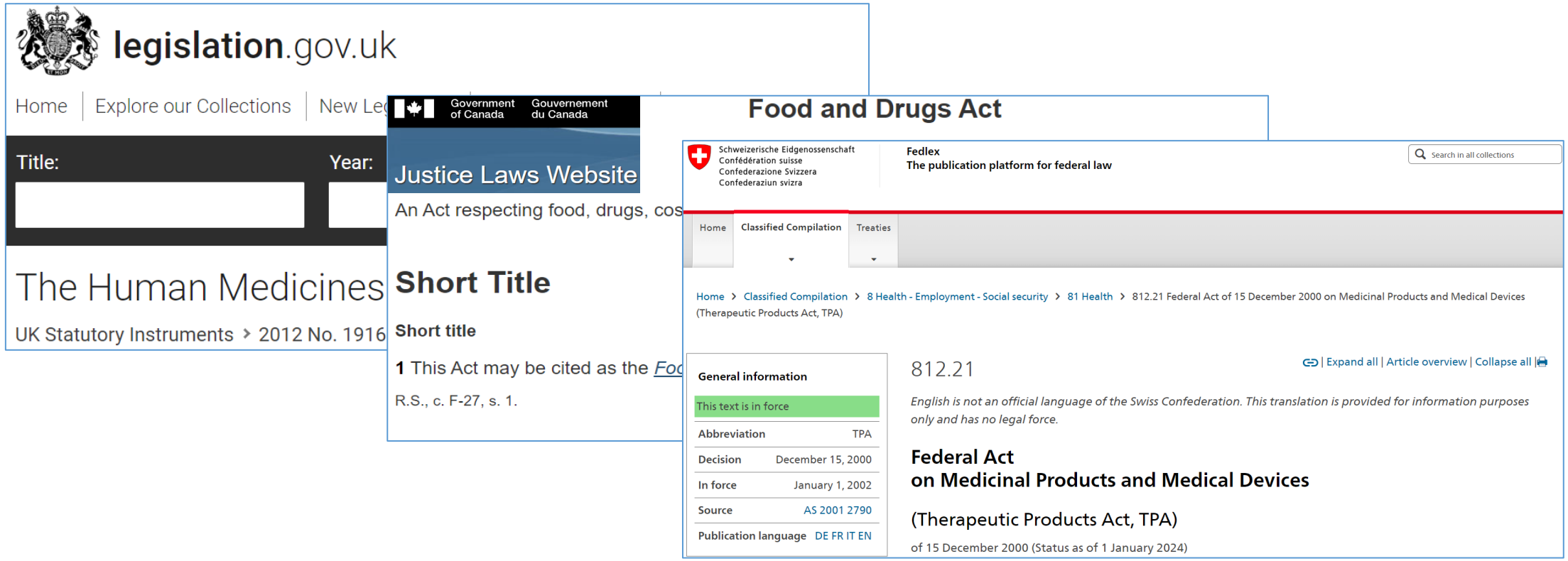
13.12.2023

The Access Consortium working group for new active substances has established an aligned process for priority review, which includes the decision on priority status. In order to facilitate the process for applicants, common timelines for the priority review request have been established, and the request is evaluated in a collaborative way, seeking a consensus decision.

In creating the Promise Pilot Pathway, the Access partners sought commonality in their respective criteria for priority review. Applications for new active substances fulfilling the following criteria are eligible for the Promise Pilot Pathway:

- diagnoses, treats or prevents a condition that is serious, life-threatening or severely debilitating and
- for which no other treatment is currently registered and marketed in participating jurisdictions for the proposed indication

Legal framework in various Access countries



- The differences in legislation may lead to a different terminology, product classification, or statutory procedural timelines between Access countries
- In addition, there are differences in local regulations and guidelines between Access countries (e.g. biosimilars)
- Overall, there is still a long way to go for Access, but working together will lead to increased international harmonisation and regulatory convergence over time.

Thank you for listening!

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.

KEY TAKEAWAYS AND INSIGHTS

- Australia’s regulatory system program is aimed at strengthening capability and enhancing stakeholder collaboration in the Indo-Pacific region.
- For WHO, reliance, collaboration and worksharing exist in several forms and can help to address the access gap for patients.
- Growing awareness that national regulatory authorities need to maximize use of resources.
- ACCESS Consortium designed to maximize international co-operation and reduce duplication.

Thank you

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03-06 December 2024

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

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Reliance: case studies, lessons learned & across the product life cycle - PACs & GMPs

07:30-10.30 CET/ 17:30-20.30 AEDT

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