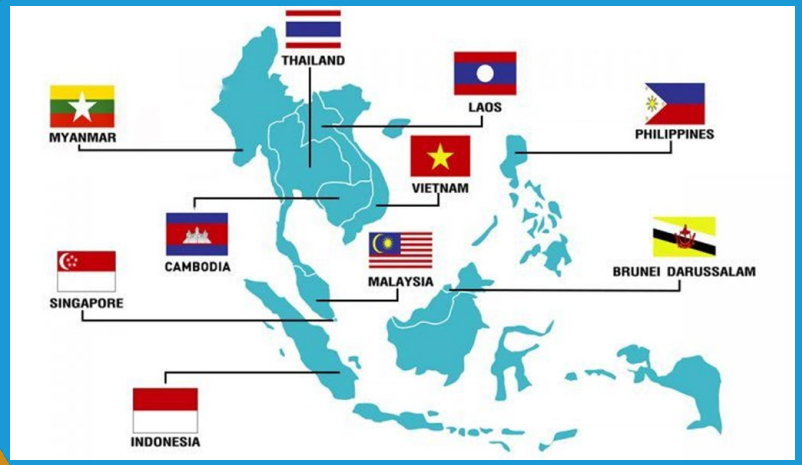
WHO Good Reliance Practices and support to ASEAN joint assessment procedures



Asia Partnership Conference of Pharmaceutical Associations Conference

Tokyo, Tuesday 23rd April 2024

Marie Valentin
Team Lead, Facilitated Product Introduction
WHO Regulation and Prequalification Department

World Health Organization

Reliance at the core of a more efficient use of global resources

>70% of countries have weak national regulatory systems
Need to facilitate access to quality-assured medical products and to build capacity

Reliance to promote better use of limited resources and to strengthen global regulatory oversight

Apply a risk-based approach, avoid duplication where possible, full range of reliance options (work sharing, abridged pathways, etc.)

Implementation
Voluntary participation, change mindset, start small, learning by doing, harmonization facilitator but not pre-requisite

WHO Listed Authorities
Transparent, evidence-based system to define trusted authorities

Source of information on reliance

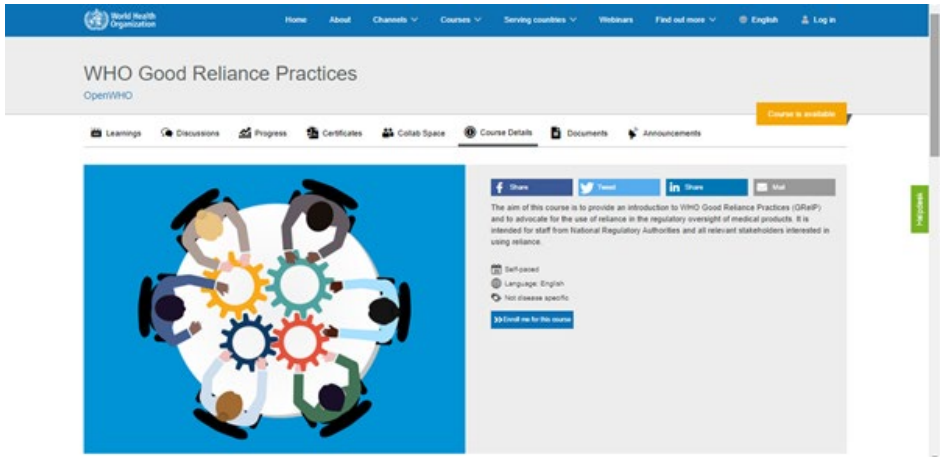
WHO Good Reliance Practices

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

Table of Contents

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

WHO Support to ASEAN Joint Assessment Coordinating Group

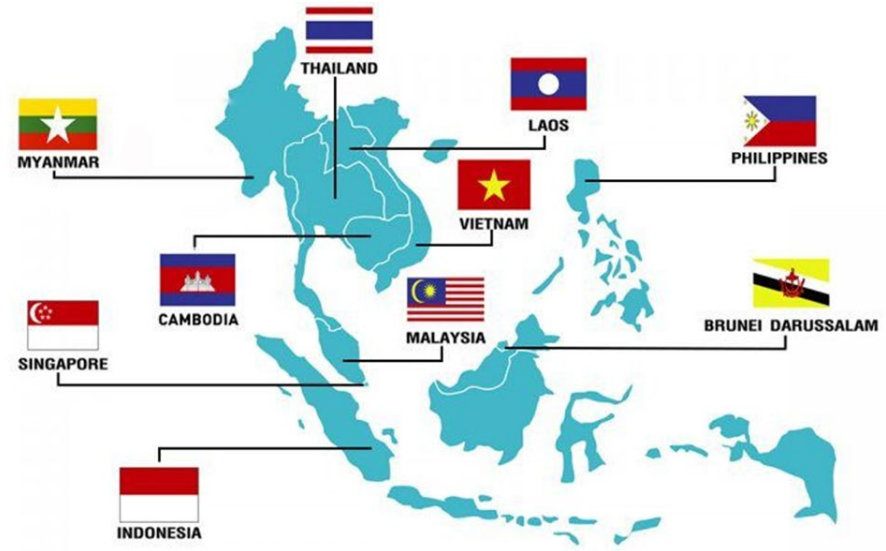
Support and facilitation of Pharmaceutical Product Working Group (PPWG) since inception, 2000

Establishment of a Joint Assessment Coordination Group (JAGG) in 2017 (PPWG + WHO)

- Development/maintenance of **ASEAN JA procedures** (procedural documents, FAQ, list of priority products)
- Coordination facilitation of **ASEAN joint assessment**
- Development of a dedicated **IT platform** (Joint Assessment Information Management System JAIMS)
- **Advocacy** to NRA and companies
- Coordination of **exchange of administrative tools and agreements**

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

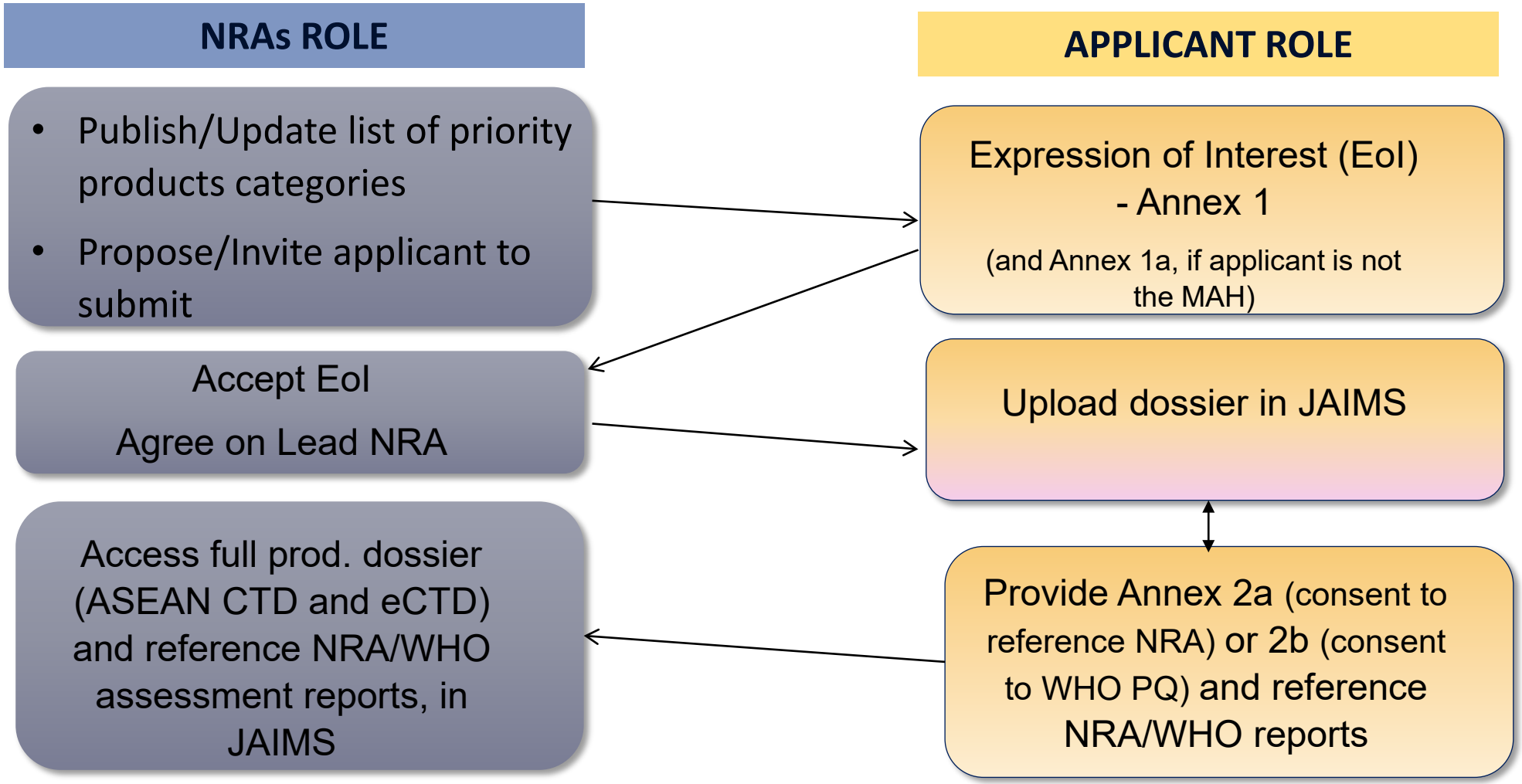
ASEAN Joint Assessment - Achievements

Five completed joint assessments

Product	Therapeutic area	NRAs	Technical support	Timelines	Year (JA)
Pyronaridine-artesunate	Malaria	**10 NRAs** **Lead Malaysia**	WHO &EMA (Art. 58)	Longer as pilot	2019
Tafenoquine succinate	Malaria	**4 NRAs**: Myanmar, Philippines, Vietnam, **Thailand**	WHO & TGA	< 5 months	2021
Two cabotegravir formulations (tablets and injectable)	HIV	**5 NRAs**: Malaysia, Myanmar, **Philippines**, Vietnam, Thailand	WHO & TGA	~ 6 months	2023
Ocrelizumab (first biological product)	Multiple sclerosis	**6 NRAs:** Thailand, Indonesia, Lao PDR, Cambodia, Indonesia and The Philippines	WHO & TGA	< 6 months	2023

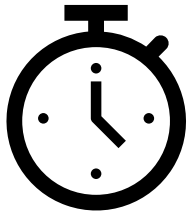
- Technical support of Australia TGA (unredacted assessment reports, TGA experts)
- JA reports can be used by other ASEAN NRAs that did not participate but may receive same application
- ASEAN successfully revised in 2022. Second revision starting in 2024.
- ASEAN JA information management system (JAIMS) developed to support applications process and provide a centralized platform for ASEAN joint assessment procedures.

ASEAN Joint Assessment – Application process



Reference NRAs are drawn from those defined by WHO as 'stringent' NRAs (SRAs): https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs
Occasionally, ASEAN NRAs may decide to rely on a different NRA if this is needed and justified.

ASEAN Joint Assessment – Timelines



Clock stop

Assessment up to **90 days**

Lead NRA shares **List of questions** with applicant

Applicants responses

NRA review up to **40 days**

10 days → New List of Questions

10 days → JA Meeting

10 days → JA Report

10 days → JA Report

ASEAN Full JA process up to **150 calendar days**, 140 if JA meeting
ASEAN Expedited JA process **< 140 calendar days**

Duration of national Decision-making Process: Number of working days:
Brunei Darussalam 60 – Cambodia 90 – Indonesia 45 - Lao PDR 45 – Malaysia 30 – Myanmar 90 (standard)/60 (urgent) – Philippines 30 – Singapore 30 – Thailand 30 – Viet Nam 60

ASEAN Joint Assessment – Published information

ASEAN's Joint Assessments Coordinating Group periodically publishes a list of priority product categories eligible for the Joint Assessment Procedure, as referred in the document "Information for Applicants" available on this website.

No	**Pharmaceutical and Biological Products** (as applicable)
1	Products for the treatment of hepatitis B
2	Products for the treatment of hepatitis C
3	Products for the treatment of cancer[1]
4	Products for the treatment of HIV/AIDS
5	Products for the treatment of TB
6	Products for the treatment of Malaria
7	Products for the treatment of treatment-resistant depression
8	Products for the treatment of interstitial lung disease
9	Products for the treatment of chronic kidney disease
10	Products for the treatment of autoimmune diseases such as Crohn's disease, rheumatoid arthritis, psoriatic arthritis, generalized pustular psoriasis
11	Products for the treatment of Alzheimer's disease
12	Products containing new anti-infective substances
13	Products for Maternal and Reproductive Health
14	Products for the treatment of rare diseases (orphan drugs)
15	Vaccines

ASSOCIATION OF SOUTHEAST ASIAN NATIONS | **Standard and Conformance** | POLICY & GUIDELINES

https://asean.org/our-communities/economic-community/standard-and-conformance/key-documents-publications/

8. Pharmaceutical Product Working Group (PPWG)

- ASEAN Pharmaceutical Regulatory Policy
- Guidelines for Implementation of Harmonised Accreditation in ASEAN
- Glossary for ACTD & ACTR
- ASEAN Common Technical Documents (ACTD)
- ASEAN Common Technical Dossier (ACTD) Revision 1
  - Part I Organisation of Dossier
  - Part II Quality
  - Part III Nonclinical Document
  - Part IV Clinical Document
- ASEAN Common Technical Requirements (ACTR)
  - ACTR Quality
  - ACTR Safety and Efficacy
  - ASEAN Guidelines for Validation of Analytical Procedure for Vaccine
  - ASEAN Guideline on Stability Study of Drug Product Revision 2
- Labelling
- ASEAN Variation Guideline for Pharmaceutical Product Revision 1
- ASEAN Variation Guideline for Pharmaceutical Product Revision 2
- Question and Answer (Q&A)
  - Q&A on ASEAN Stability Guideline
  - Q&A for Stability Guideline on Vaccine
- Joint Assessment Coordinating Group (JACG)
  - List of Priority Product Types/Categories for ASEAN Joint Assessment Procedure
  - Frequently Asked Questions (FAQ) on the ASEAN Joint Assessment (JA) Procedure
  - ASEAN Joint Assessment Procedure for Pharmaceutical Products Information for applicants
  - Joint Assessments Information Management System (JAIMS) demo link: https://youtu.be/IAwtK2iV-UQ
  - Open Q & A Session between Industry Association Representatives with WHO on Joint Assessment Activities
- **Joint Sectoral Committee on ASEAN MRA for Bioequivalence Study Report (JSC MRA BE)**
  - Technical Documents for Implementation ASEAN MRA for Bioequivalence Study Report
    - Procedures and Manual of Joint Sectoral Committee (JSC) and Annexes
    - Operation Manual of the Panel of Experts (PoE) and Annexes
    - Manual for Application of Bioequivalence (BE) Centre to be listed under ASEAN MRA BE and Annexes

Chair: NPRA, Malaysia
Co-Chair: FDA, Thailand

1. List of priority product categories eligible for joint assessment:
https://www.npra.gov.my/media/attachments/2022/04/11/proposed-list-of-priority-products_22mar2022.pdf
2. Detailed information about the procedure and submitting an application:
https://www.npra.gov.my/media/attachments/2022/04/20/information-for-the-applicants.pdf
3. Questions and Answers document on the JA procedure:
https://www.npra.gov.my/media/attachments/2022/04/20/frequently-asked-questions.pdf
4. JAIMS demo link:
https://youtu.be/IAwtK2iV-UQ

ASEAN Joint Assessment - Key messages going forward

1. Overwhelming for NRAs at all maturity levels to fulfil all regulatory work alone and independently from other regulators;

2. **Many reliance tools available to NRAs and Industry** to facilitate the regulatory decisions, such as ASEAN JA and WHO Collaborative Registration Procedure;

3. One JA is starting and **healthy pipeline for future JA**;

4. **Best use of global regulatory resources and time**.

Acknowledgement

Equitable access to affordable quality medicines and other health products requires **an integrated approach** with all stakeholders

World Health Organization

WORKING TOGETHER

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Team Lead, Facilitated Product Introduction
WHO Regulation and Prequalification Department