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Strong Ties of Japan with Asia and the World for Delivering
'Tomorrow's Normal'

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Session Title: DIAMond S01

Promotion of ASEAN Joint Assessment (AJA) and Abridged regulatory pathways in Malaysia

National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health, MALAYSIA

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This presentation is incomplete without accompanying verbal commentary.

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• ASEAN JA: Product Eligibility Criteria & Process Flow

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• Abridge Regulatory Pathways in Malaysia – FRP (reliance)

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• Key Takeaways



INTRODUCTION

ASEAN Joint Assessment Coordinating Group (JACG)

BACKGROUND

- ASEAN JACG was formed under the ASEAN PPWG with the support of WHO.
- The latest initiative to strengthen the implementation of ASEAN harmonized regulatory requirements, with a vision to ensure access to good quality, effective medicines for ALL ASEAN citizens.
- July 2017: The first ASEAN Joint Assessment was conducted.
- Malaysia and Thailand were re-elected as Chair and Co-Chair by the JACG and endorsed by the PPWG in 2022 for another three-year term.

OBJECTIVES



To strengthen NRAs technical capacity



To foster mutual trust and reliance among AMS



To ensure regulatory work is conducted in a timely and efficient manner



To facilitate the review of priority medicines throughout ASEAN while respecting national decision-making processes

About ASEAN Joint Assessment (AJA)

Joint Assessments - a formal procedure, the same application is simultaneously submitted to a number of participating NRAs

Assessment work is carried out together by staff of participating NRAs and a joint assessment report is produced

The final decision on the application is taken by each individual NRA through their normal decision-making process

Note:

1. Same application refers to the technical content of the application; national administrative parts remain different
2. Simultaneously refers to the fact that JA process will not start until applications are received (via JAIMS) by all participating NRAs



ASEAN JA: PRODUCT ELIGIBILITY CRITERIA & PROCESS FLOW

AJA Procedures



Priority therapeutic areas

Initial (2017)

Priority diseases in ASEAN region: Hepatitis B & C, HIV/AIDS, TB, Malaria

2021

expanded to include category of products under **maternal & reproductive health, rare disease, autoimmune diseases and oncology**

Current

Open to products
Outside priority areas

**NCEs
Biologics
Generics**

2020

expanded to include
biologics

AJA Procedures

Products eligibility criteria

- Products already **approved by a reference NRA (WHO Listed Authorities)**, prequalified by WHO-PQP, or **assessed through special regulatory pathways such as EU Article 58 or US-FDA tentative approval.**
- Products manufactured in a **PIC/S-GMP compliant site.**

Submission of dossier

- Full application dossier is uploaded by the applicant to the dedicated **IT platform developed by WHO – JAIMS.**
- The applicant provides access to detailed assessment reports generated by a reference NRA or WHO.

Product Assessment

- Each joint assessment requires a **minimum of three (3) NRAs.**
- Abbreviated JA procedure (Reliance).



Next?

New Registration Application

- NCE ✓
- Biologics ✓
- Generics ✓

New Registration Application

- product that has never been approved by any reference NRA nor approved by WHO PQ nor EU article 58 nor US FDA tentative approval?
- 1st wave?
- Line extension?
- PAC including new indication, addition of manufacturing sites?

Participation in the AJA

- Voluntary participation - NRAs may decide whether to participate for each product.
- Applicants shall indicate the countries they wish to nominate for the JA.
- The nominated NRAs will then determine their participation but their participation is not mandatory

ASEAN JA Process Flow– 1. Selection Process

A. ASEAN Joint Assessment Selection Process

RESPONSIBILITY

PROCEDURE

Chair, Co-Chair &
WHO

Lead NRA

Lead NRA

Start

- Applicants send to JACG Chair and Co-Chair via the WHO - Expression of Interest (EOI)
- Chair/Co-Chair/WHO seeks concurrence of participating NRAs for accepting EOI
- Selection of Lead NRA

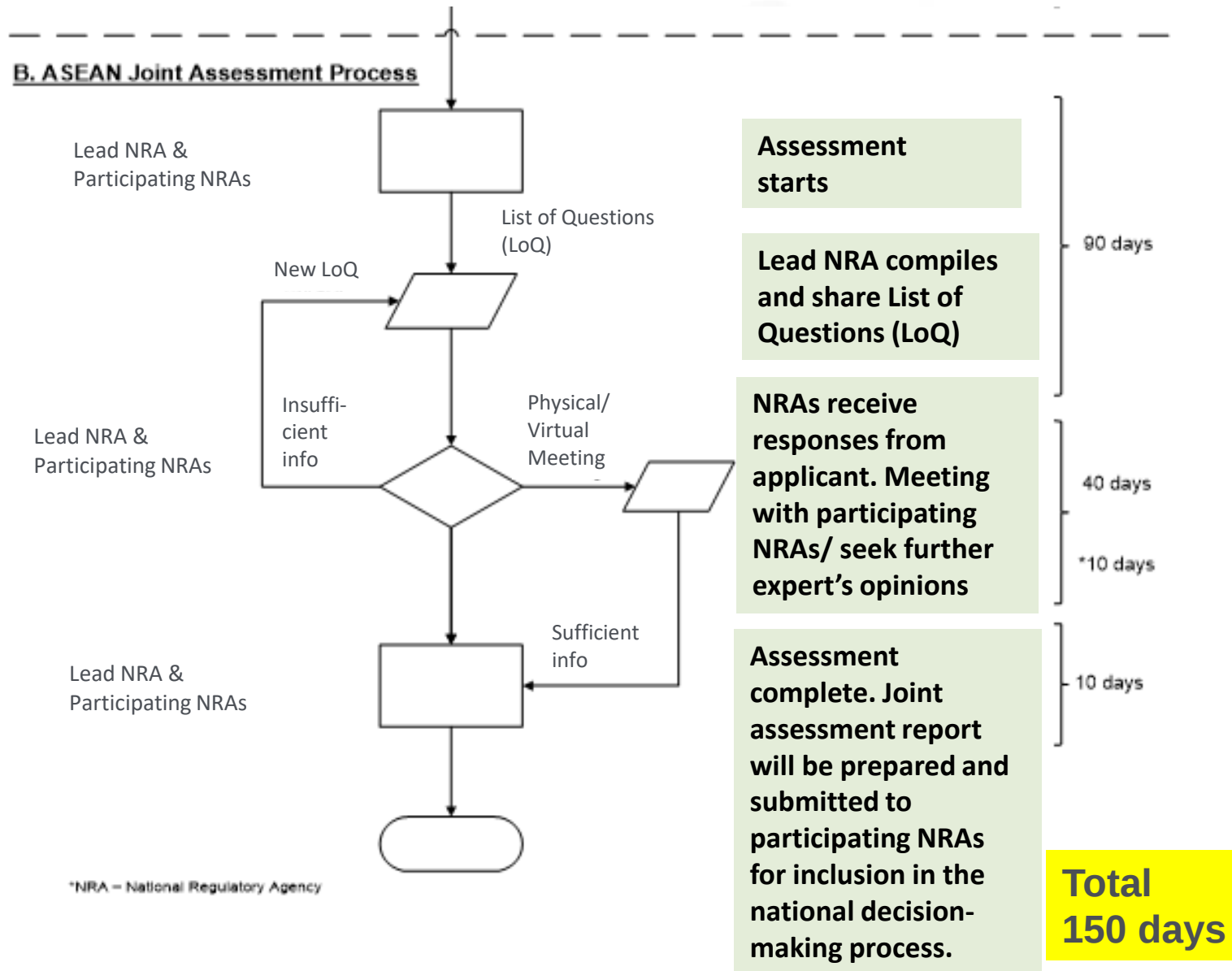
30 days

Lead NRA exchange letters with **Reference NRA** and obtain **assessment report**

30 days

Lead NRA requests applicant to submit or upload required documentation

ASEAN JA Process Flow – 2. Assessment Process



REQUIREMENTS

- ACTD or ICH-CTD format shall be provided in electronic form to be uploaded to Joint Assessments Information Management System (JAIMS) – **all parts except administrative (country specific requirements)**
- Administrative part of dossier specific to each participating NRA requirements will be submitted directly to each participating country (full submission depends on each country requirements (before or after AJA – e.g. Msia))

FEE

- **No fee for AJA**, fee as required by each participating NRA will be paid according to normal national procedures.



Information for
applicants

[Learn More](#) 



Priority Products

[Learn More](#) 



Frequently Asked
Questions

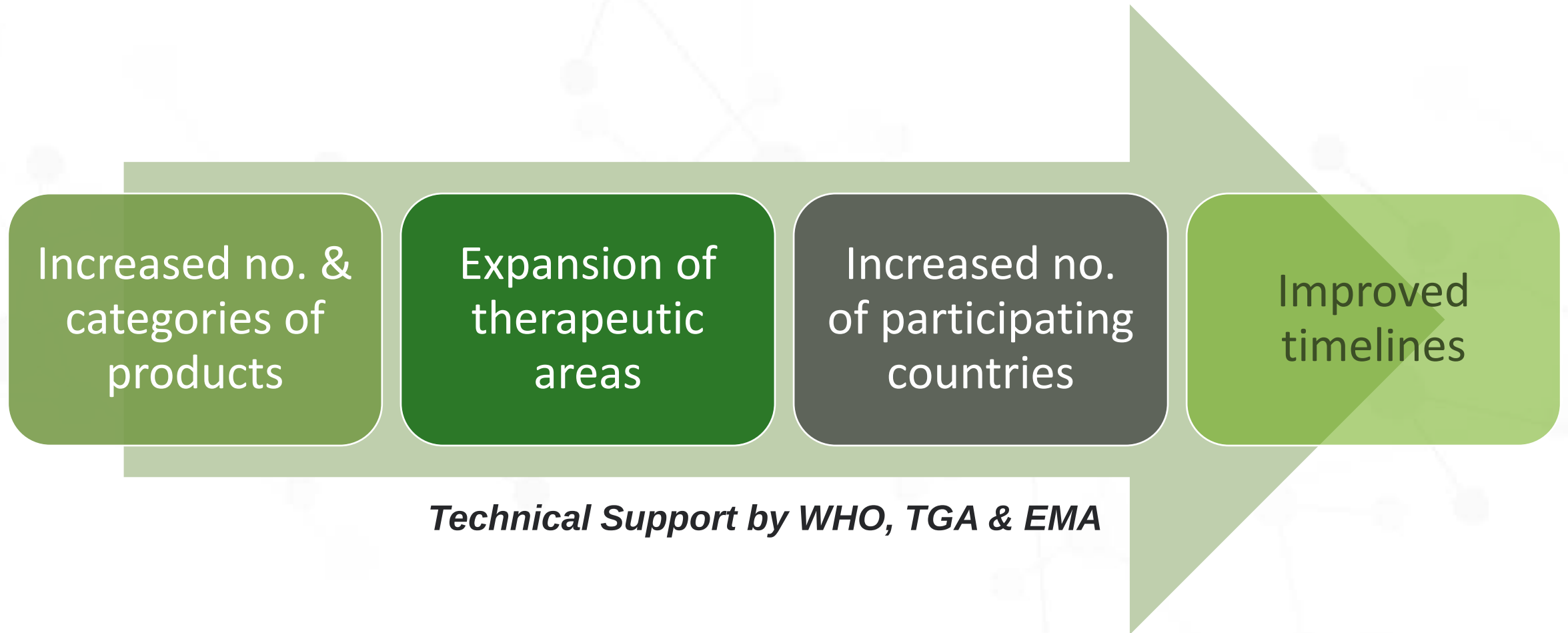
[Learn More](#) 

Guidance Available on the NPRA website

For further information, kindly contact: jacgppwg@npra.gov.my

PRODUCTS EVALUATED UNDER AJA

ASEAN JA Products – From pilot (2017) to current (2025)



ASEAN JA Products

	2017	2020	2022	2023	2024	2025	2025
Active Ingredient	Pyronaridine + Artesunate	Tafenoquine succinate	Cabotegravir in tablet and injectable form	Monoclonal Antibody	Dapagliflozin	Vildagliptin	Aztreonam-Avibactam
Disease	Malaria	Malaria	Pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection	Multiple Sclerosis	Type 2 Diabetes Mellitus, Heart Failure and Chronic Kidney Disease	Type 2 Diabetes Mellitus	Treatment of infections
Participation	Brunei Darussalam, Cambodia, Indonesia, Malaysia (lead), Myanmar, Singapore and Thailand	Myanmar, Philippines, Vietnam and Thailand (lead)	Malaysia, Myanmar, Vietnam, Thailand and Philippines (lead)	Malaysia (lead), Cambodia, Lao PDR, Indonesia, Thailand and Philippines	Brunei Darussalam, Cambodia, Lao PDR, Malaysia (lead) and Myanmar	Brunei, Cambodia, Indonesia, Laos, Malaysia (lead), Myanmar, and the Philippines	Brunei, Indonesia, Malaysia, the Philippines, Singapore (lead), Thailand, Vietnam, Laos and Cambodia.
Technical Support	WHO & EMA	WHO & Australian TGA	WHO & Australian TGA	WHO & Australian TGA	WHO & Australian TGA	WHO & Australian TGA	WHO & EMA
Timeline (Including time taken by applicant for correspondence)	≈2 years by (July 2017 – Aug 2019)	< 1 year (Dec 2020 – Feb 2021)	≈1 year (June 2022 – May 2023)	≈7 months (March 2023 – Oct 2023)	≈9 months (May 2024 – Feb 2025)	On-going (June 2025-kick-off meeting)	On-going (May 2025-kick-off meeting)