Forthcoming Strategies of the ASEAN Joint Assessment

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Azuana Ramli, PhD
Chair of ASEAN Joint Assessment Coordinating Group (JACG)
Deputy Director, National Pharmaceutical Regulatory Agency (NPRA), Malaysia

Presentation Outline

1. **Introduction:**
   - ASEAN Pharmaceutical Product Working Group (PPWG)
   - ASEAN Joint Assessment Coordinating Group (JACG)

2. **ASEAN Joint Assessment:**
   - ASEAN JACG
   - JA Procedure and Processes
   - Joint Assessments Information Management System (JAIMS)
   - Products

3. **ASEAN JA Benefits and Challenges**

4. **Ongoing and Forthcoming Strategies for ASEAN JA**

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Harmonization of ASEAN Pharmaceutical Regulations

1992

Establishment of the ASEAN Consultative Committee for Standards and Quality (ACCSQ)

1999

ACCSQ established a Pharmaceutical Product Working Group (PPWG)

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Objective of PPWG

To develop harmonization of pharmaceutical regulations of the ASEAN member countries to complement and facilitate the objective of ASEAN Free Trade Area (AFTA)

Initiatives to Support Harmonization and Regional Cooperation

- ASEAN Common Technical Dossier (ACTD)
- ASEAN Common Technical Requirements (ACTR)
- ASEAN Sectoral Mutual Recognition Arrangement for GMP Inspection of Manufacturers of Medicinal Products (GMP MRA)
- ASEAN Post Market Alert System (PMAS)
- ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products (BE MRA)
- ASEAN Guidelines on stability study bioequivalence and bioavailability studies, manufacturing process validation, validation of analytical procedures and variations
- **ASEAN Joint Assessments Coordinating Group (JACG)**

ASEAN Joint Assessment Coordinating Group (JACG)

- A project under the ASEAN PPWG with the support of WHO.
- To strengthen the implementation of ASEAN harmonized regulatory requirements (SIAHR), with a vision to ensure access to good quality, effective medicines for ALL ASEAN citizens.
- Malaysia and Thailand have been re-elected as Chair and Co-Chair by the JACG and endorsed by PPWG in 2022 for another term of 3 years.

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ASEAN JACG

Purposes

1. To strengthen NRAs technical capacity
2. To foster mutual trust and reliance among AMS
3. To ensure regulatory work is conducted in a timely and efficient manner
4. To facilitate the review of priority medicines throughout ASEAN while respecting national decision-making processes

ASEAN JA

Procedures

Application routes available:

1. The responsive application
   - applicants propose products **that are included i**n the priority list
2. The proposed application
   - applicants propose products **that are not included** in the priority list
3. The invited application
   - applicants are approached by ASEAN NRAs or WHO

Priority therapeutic areas:

- Medicines for the treatment of priority diseases in ASEAN region. In 2020, the list has been expanded to include the biological products.
- In 2021, the list further expanded to include category of products under maternal & reproductive health, rare disease, autoimmune diseases and oncology.
- Although there is preference for products within the priority areas, applicants can now submit applications for other products - outside priority areas for consideration by ASEAN NRAs (but have been approved by a reference NRA).

ASEAN JA

Procedures

Products eligibility criteria

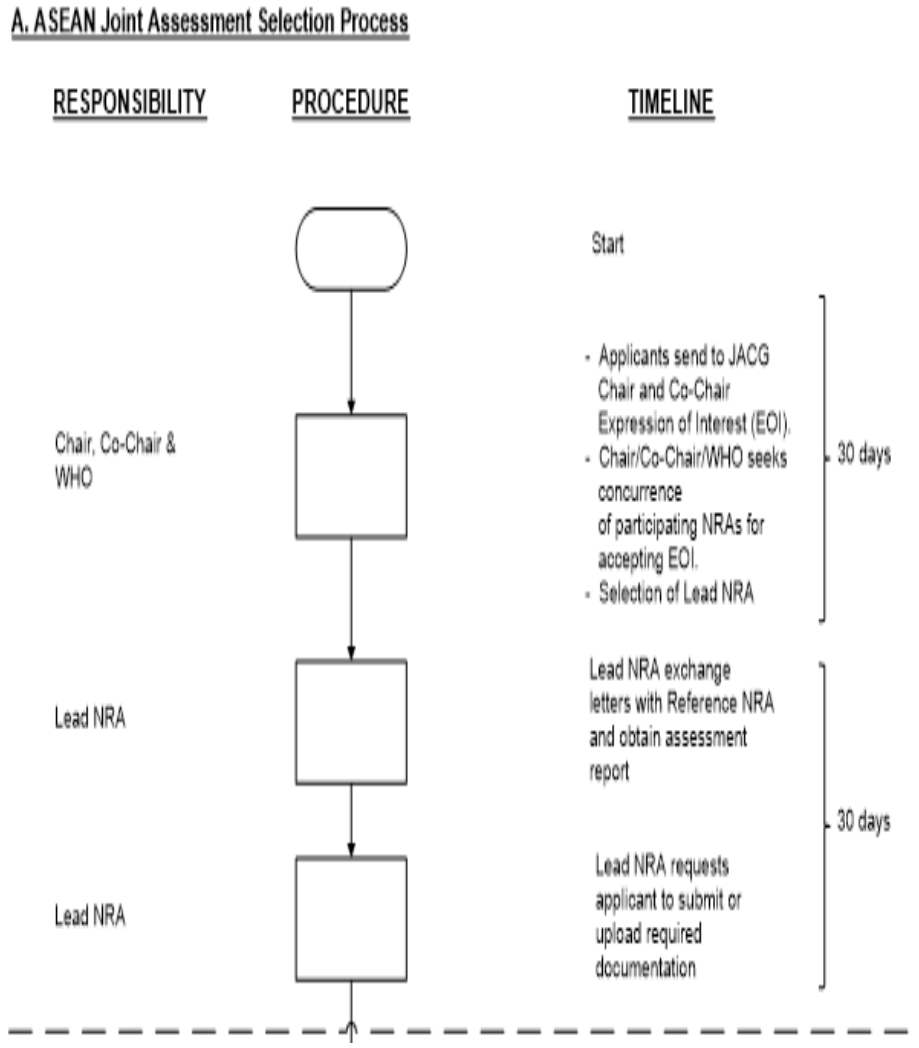
- Products already approved by a reference NRA, prequalified by WHO-PQP, or assessed through special regulatory pathways such as EU Article 58 or US-FDA tentative approval.
- Products manufactured in a PIC/S-GMP compliant.

Submission of dossier

- Full application dossier is uploaded by the applicant to the dedicated IT platform developed by WHO.
- The applicant provides all participating NRAs with access to detailed assessment reports of the product (scientific evaluation and inspections reports) generated by a reference NRA or WHO.

Product Assessment

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



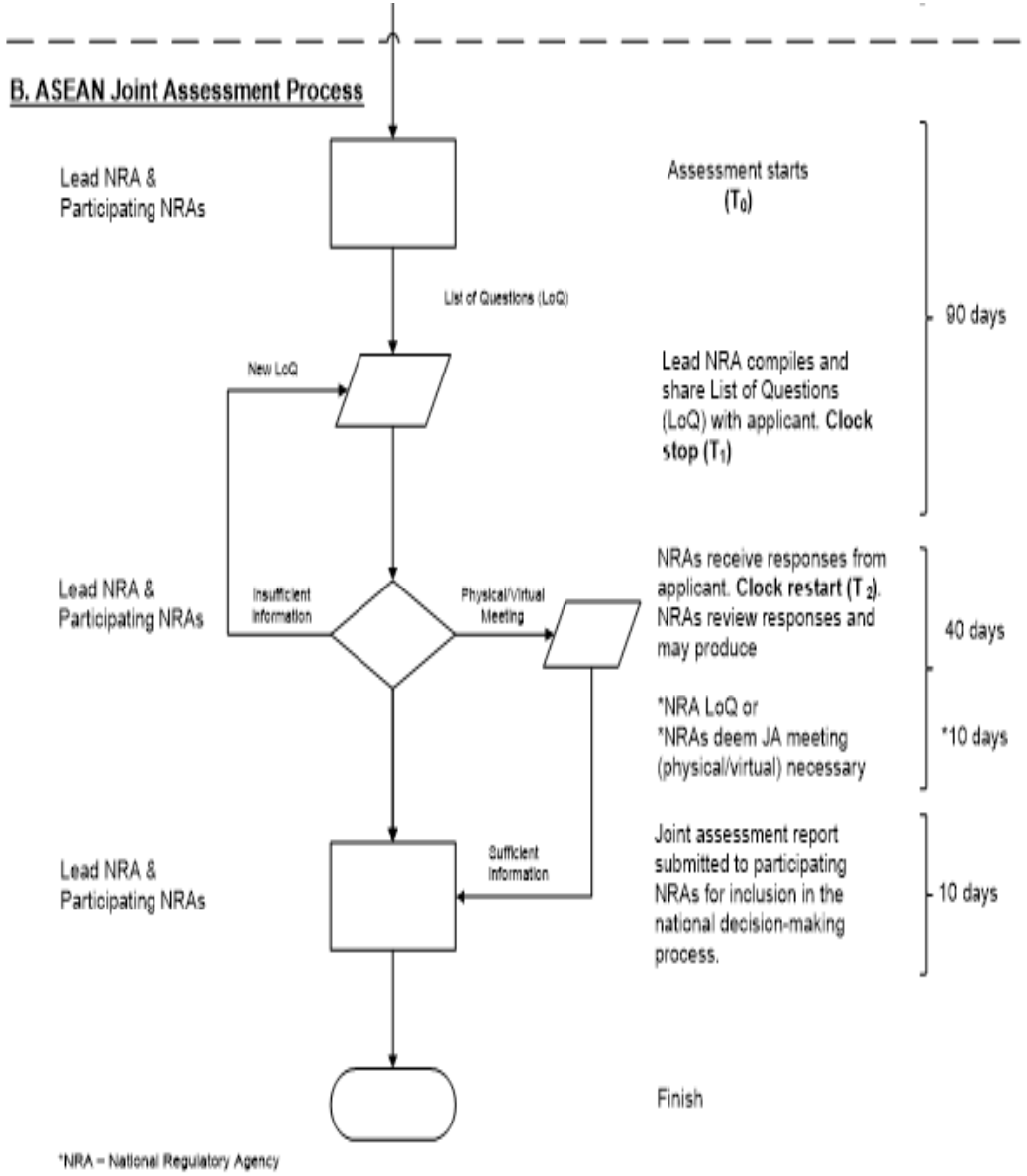
Joint Assessments Information Management System (JAIMS)

- An operational mechanism consisting of appropriate administrative tools and an IT platform
- Established in August 2021 by WHO, to be used in the JA

- Involves :
  - ✓ Uploading application dossiers
  - ✓ Reviewing dossier online/observations/questions post to applicant
  - ✓ Facilitate lead NRA to manage/coordinate assessment

*Access to confidential data within the JAIMS is restricted to authorized personnel only

ASEAN JA Assessment Process



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The Lead NRA coordinates and facilitates the assessment process

Participating NRAs confirm their access to the application and reference documentation from reference NRA or WHO, assess the application using JAIMS platform

JA meeting is to review and discuss all aspects of the application, clarify technical issues, address diverging opinions, and prepare a joint assessment report

Timeline: 150 calendar days; 140 calendar days if JA meeting unnecessary

ASEAN JA Products

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	2017	2020	2022	2023
Active Ingredient	Pyronaridine + Artesunate	Tafenoquine succinate	Cabotegravir in tablet and injectable form	Monoclonal Antibody
Disease	Malaria	Malaria	Pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection	Multiple Sclerosis
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
Technical Support	WHO & EMA	WHO & Australian TGA	WHO & Australian TGA	WHO & Australian TGA
Timeline (Including time taken for correspondence)	≈2 years (July 2017 – Aug 2019)	< 1 year (Dec 2020 – Feb 2021)	≈1 year (June 2022 – May 2023)	≈7 months (March 2023 – Oct 2023)

ASEAN Joint Assessment

Benefits

REGULATOR

- Collaboration and understanding among AMS regulators is enhanced.
- Reliance concept and mechanisms learnt and better understood by participating AMS.
- Improved capacities in the assessment of pharmaceutical products through experience sharing and learnings among AMS.
- Improvement in MA timelines.
- Timely market access of essential products to patients.

APPLICANT

- Concurrent submission and registration in multiple countries leading to access to various markets at the same time.
- Potential cost efficiencies for industry (Sharing of resources, expertise, and assessment processes across multiple jurisdictions can reduce duplication of effort/ work).
- Foster closer collaboration and engagement between industry & regulatory authorities.
- Opportunities for innovation and improving services to meet regional standards and requirements: driving competitiveness and market growth.

ASEAN JA: Challenges

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Resource constraints

- Limited resources such as time and personnel

Limitations in centralized submission system

- Require separate submission in each NRA for registration purpose. Different format of submission in each NRA result a delay in registration process

Complexity in coordination and communication among AMS

- Coordinating schedules and logistics for joint assessments can be challenging

Lengthy timeline to achieve national marketing authorization following JA

- National administrative issues during national submission (e.g country specific requirements: CPP, additional sample testing prior registration, additional stability testing data on top of zone IVB)

Diverse regulatory frameworks

- Different in laws, standards and procedures
- Some NRAs requiring full national submission before engaging in a JA. This will delay JA

Lack of capacity & understanding in reliance for some countries

Forthcoming Strategies for ASEAN JA

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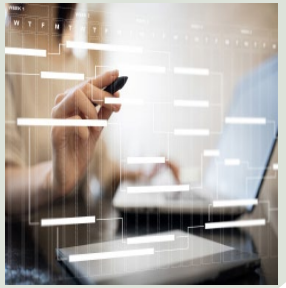
1) Continuous Improvement of ASEAN Joint Assessment (JA) procedure and processes

Streamlined Process

- Optimizing procedures
- Reduce redundancies
- Improving efficiency to facilitate assessment process
- Adopt risk-based approaches



Transparency & Predictability

- Increase transparency in the ASEAN JA process with stakeholders engagement
- Feedback mechanisms will enhance confidence and foster trust among industry stakeholders

Shorter Timeline

- Shorter timelines for approval of medicinal products, resulting in quicker access and increased availability of medicines and vaccines for patients in the region

Enhanced Coordination

- Strengthen coordination / communication among AMS

Forthcoming Strategies for ASEAN JA

1) Continuous Improvement of ASEAN Joint Assessment (JA) procedure, cont'd

Capacity Building

- Enhance the expertise and capabilities of regulatory authorities involved in the ASEAN JA procedure via training programs, technical assistance & knowledge sharing.

IT Platform (JAIMS) Improvement

- Improving the information management system for Joint Assessments within ASEAN requires a comprehensive approach to ensure efficient data collection, analysis, communication and dissemination of findings.
- An evaluation session was conducted after the completion of each JA activity for purposes of improving the JAIMS platform.

Forthcoming Strategies for ASEAN JA

2) Formalizing the JA procedure as an additional pathway at country levels

- Involves establishing a structured framework or guidance within each AMS to guide the conduct of joint assessments
- Lao PDR, Malaysia, the Philippines and Thailand have established a national procedure to accommodate ASEAN JA while Singapore's regulatory system provides for flexibility that enables applicants to choose their preferred registration pathway, including for applications to be evaluated via ASEAN JA
- Other ASEAN NRAs confirmed that there is a plan to review the current national regulatory pathways and continue to explore the feasibility of incorporating ASEAN JA as an additional facilitated registration pathway

Advantages of recognizing JA procedure as an additional pathway at national level

Promote Standardization

Ensure transparency and accountability

Improve the efficiency of regulatory processes

Promotion of trust and confidence among AMS and stakeholders

Forthcoming Strategies for ASEAN JA

3) Harmonization of Regulatory Requirements / Standards

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Comprehensive assessment of regulatory frameworks and practices in AMS

To identify priority areas for harmonization (e.g Adoption of Common Technical Dossiers)

To engage with relevant stakeholders

Negotiation and Agreement

Implementation planning for adoption of harmonized regulation

4) Continuous & Stronger Advocacy Work to Promote ASEAN JA

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Advocacy efforts help raise awareness, generate support, and foster adoption of the ASEAN JA pathway and ultimately contributing to greater regulatory harmonization

- ***Policy Advocacy***: Engage with regulatory authorities, policy makers in ASEAN member states to advocate for supportive policies, regulations, and institutional frameworks that facilitate JA. Highlight the potential benefits of JA in terms of trade facilitation, regulatory convergence.

- ***Engagement with Industry Associations****:* Collaborate with industry associations and professional organizations to disseminate information about the ASEAN JA pathway to their members.

- ***Partnerships and Alliances:*** Build coalitions and alliances with like-minded organizations, industry partners to amplify the message on ASEAN JA. Collaborating with a diverse range of stakeholders will help to mobilize support for the ASEAN JA pathway and increase its visibility and impact.

- ***Provide Technical Assistance***: Offer technical assistance and support to companies interested in participating in the ASEAN JA process with the assistance from WHO. This include guidance on preparing regulatory submissions, navigating the assessment process, addressing regulatory requirements, and complying with quality standards.

5) Further Enhancement of ASEAN Joint Assessment

Collaboration with Reference NRAs

- ASEAN member states to adopt and adapt best practices, improving the effectiveness and efficiency of joint assessments
- To facilitate knowledge exchange and capacity building among ASEAN member states. Training and technical assistance provided by reference NRAs can enhance the skills and expertise of regulatory authorities and industry stakeholders involved in joint assessments
- To facilitates technology transfer and innovation diffusion, enabling ASEAN member states to adopt advanced methodologies, tools, and techniques for conducting joint assessments
- To explore opportunity to have an early involvement in the assessment of the product together with reference countries (e.g ‘first wave’ products that are essential to the region)

Upcoming Product for ASEAN JA

1. Dapagliflozin Tablets 5 mg and 10 mg

Participating countries:

•Brunei Darussalam Department of Pharmaceutical Services
•Cambodia Department of Drug and Food
•Indonesia National Agency of Drug and Food Control
•Lao PDR Food and Drug Department
•National Pharmaceutical Regulatory Agency, Malaysia

2. Vildagliptin Tablets 50 mg

Participating countries:

•Cambodia Department of Drug and Food
•Indonesia National Agency of Drug and Food Control
•Lao PDR Food and Drug Department
•National Pharmaceutical Regulatory Agency, Malaysia

3. Nebivolol Tablets 2.5/5/10 mg

Participating countries:

•Cambodia Department of Drug and Food
•Lao PDR Food and Drug Department
•Myanmar Department of Food and Drug Administration

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