The 22nd DIA Japan Annual Meeting 2025

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

October 19-21, 2025 | Tokyo Big Sight

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

ABRIDGED REGULATORY PATHWAYS IN MALAYSIA: FACILITATED REGISTRATION PATHWAY - FRP (RELIANCE)

Facilitating Approval to innovative medicines (NCEs, biologics) / generics / biosimilars in Malaysia

1 Full Evaluation (Standard Pathway)

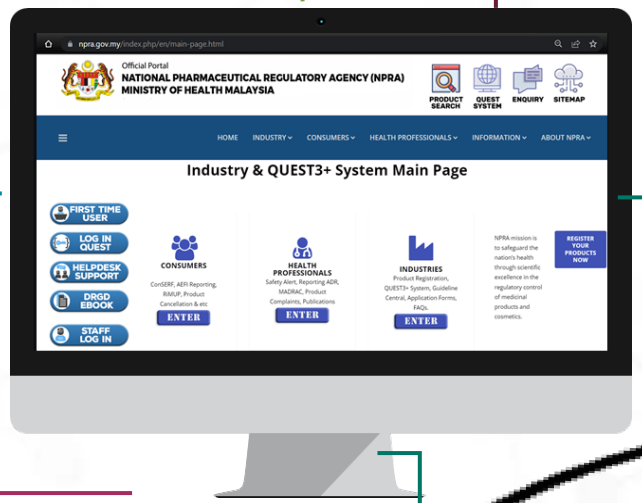
- 245 WD* (NCE & Biologics)
- 210 WD (Generic)
- Validity: 5 years

2 Full Evaluation (Conditional Registration (CR))

- Registered by at least 1 DCA reference agency
- 245 WD (NCE & Biologics)
- Upon request based on early clinical data (i.e. Phase II data)
- Confirmatory trials (Phase III) can be submitted when available
- Validity: 2 years

3 Conditional Registration of Pharmaceutical Products During Disaster

- Fulfills the pre-defined criteria
- Priority Review is automatically granted
- 70 WD
- Validity: 1 year



4 Orphan Medicines (For Rare Diseases)

- Designated as orphan medicine based on the list of rare diseases in the Malaysian Orphan Medicines Guideline
- 120 WD
- Validity: 5 years

5 Priority Review

Unmet medical needs, life-saving medicine, interest of public health, emergency supply, first generic/first biosimilar/first local generics/biosimilars

- ~~120 WD (NCE & Biologics)~~
- 100 WD (Generic)
- Validity: 5 years

6 Facilitated Registration Pathway (FRP)

- Approved by the DCA reference agencies: such as EMA, US FDA, TGA, UK MHRA, Health Canada, PMDA, SwissMedic/WHO CRP/ASEAN Joint Assessment
- Abbreviated: 90 WD
- Verification: 30 WD (ASEAN Joint Assessment)
- Assessment reports and list of Q&As to be provided
- Validity: 5 years
- NCE, Biologic, Generics

AJA is part of FRP

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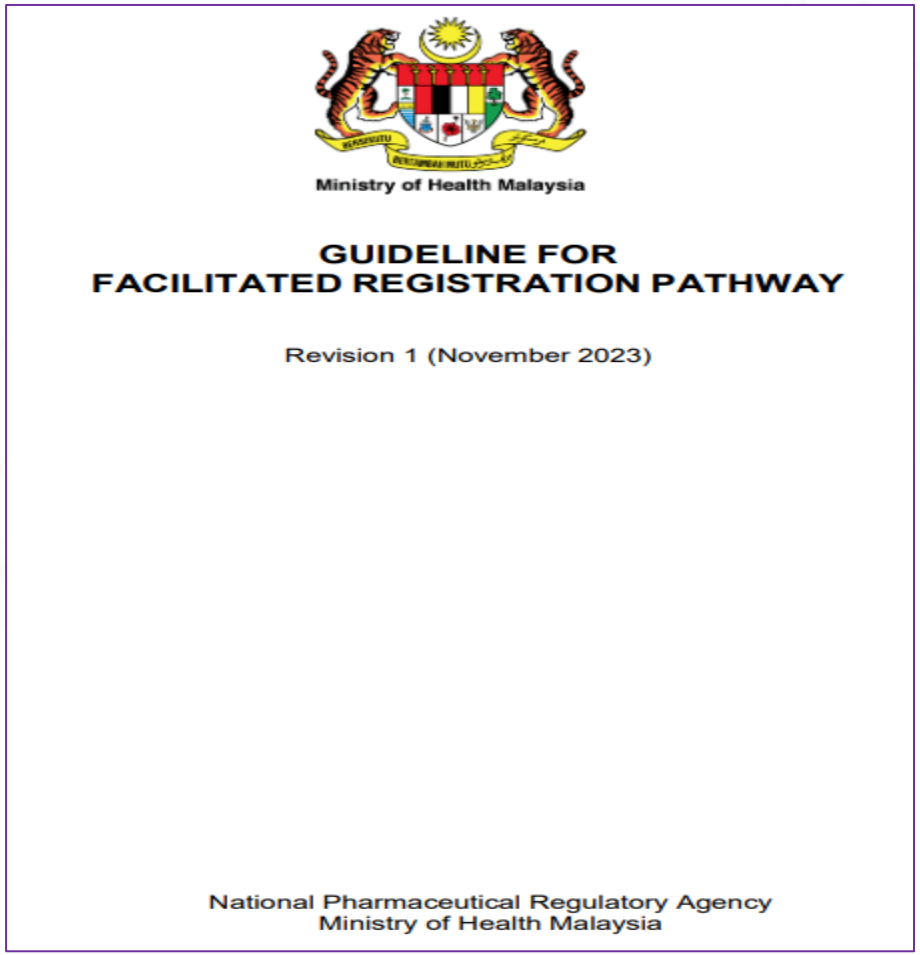
Updates and Improvements of the Revised FRP Guidelines


Ministry of Health Malaysia

GUIDELINE FOR
FACILITATED REGISTRATION PATHWAY

Revision 1 (November 2023)

National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia

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

Expansion : Category of products & reference Agencies/ procedures

Increased number of products eligible for participation under the FRP

Clearer Procedures and requirements

Enhanced guidelines - provide unambiguous eligibility criteria and procedural steps (flow chart) and tools

Faster Timelines

Reduction in approval times, with NPRA aiming for median approval times under FRP significantly shorter than standard pathways.

FRP guideline, Revision 1 (November 2023) – key features

Scope of products

Expansion

- New drug products (NCEs)
- **Generic medicines**
- Biologics including **cell and gene therapy products**

Reference agencies & Procedures

Addition

- EMA, US FDA, **Health Canada, PMDA, Swiss Medic, TGA, UK MHRA**
- **WHO Collaborative Registration Procedure (CRP)- SRA & PreQ**
- **ASEAN Joint Assessment (JA)**

Routes & timelines

Shorter timeline

- 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

Introduction of Regulator Tools:
Dossier Checklist – applicant to highlight differences
Evaluators' Guide/SOP

Introduction of Regulator & Applicant Tools:
Flow chart (FRP process)
FAQ (NPRA website)

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Regulatory requirements & 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 applicant 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*

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)

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Regulator Tools

Dossier Checklist

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 Manufacturer B	1) Name & address of Manufacturer A 2) Name & address of Manufacturer B	
Specification **S4.1**	Document (specific filename), version, and page number	Document (specific filename), version, and page number	Same as reference agency
Drug Product			
Stability Data **P8**	Stability data according to Zone III Document (specific filename), version, and page number	Stability data according to Zone IVb Document (specific filename), version, and page number	To comply with the ASEAN stability requirements

Evaluators' Guide / SOP

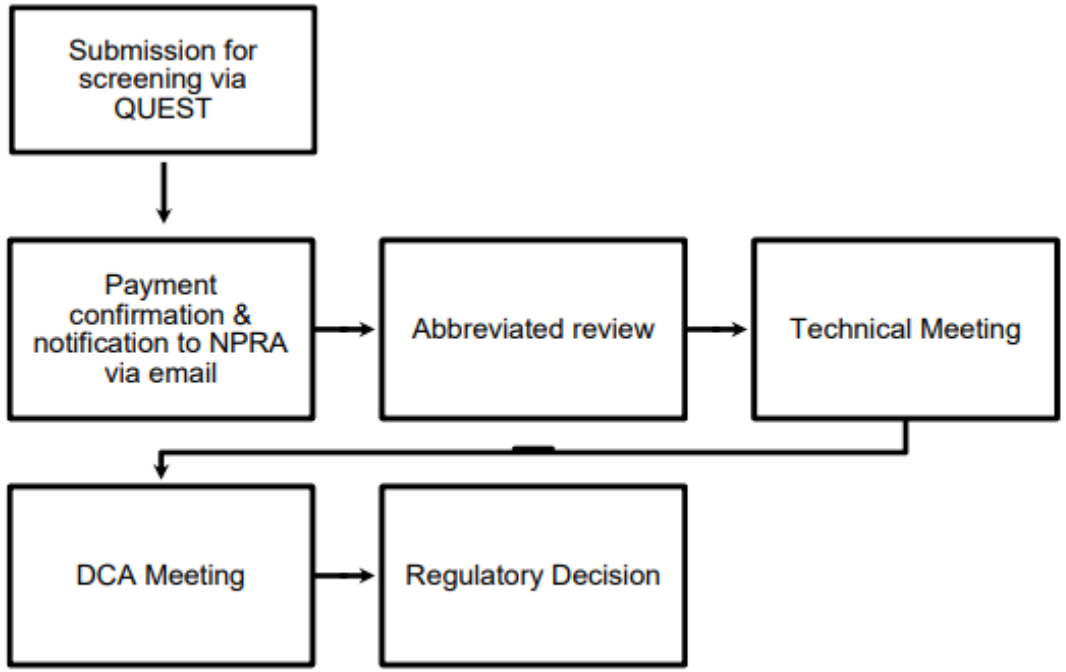
EVALUATORS' GUIDE FOR PRODUCTS SUBMITTED VIA A FACILITATED REGISTRATION PATHWAY

Version 1 2024

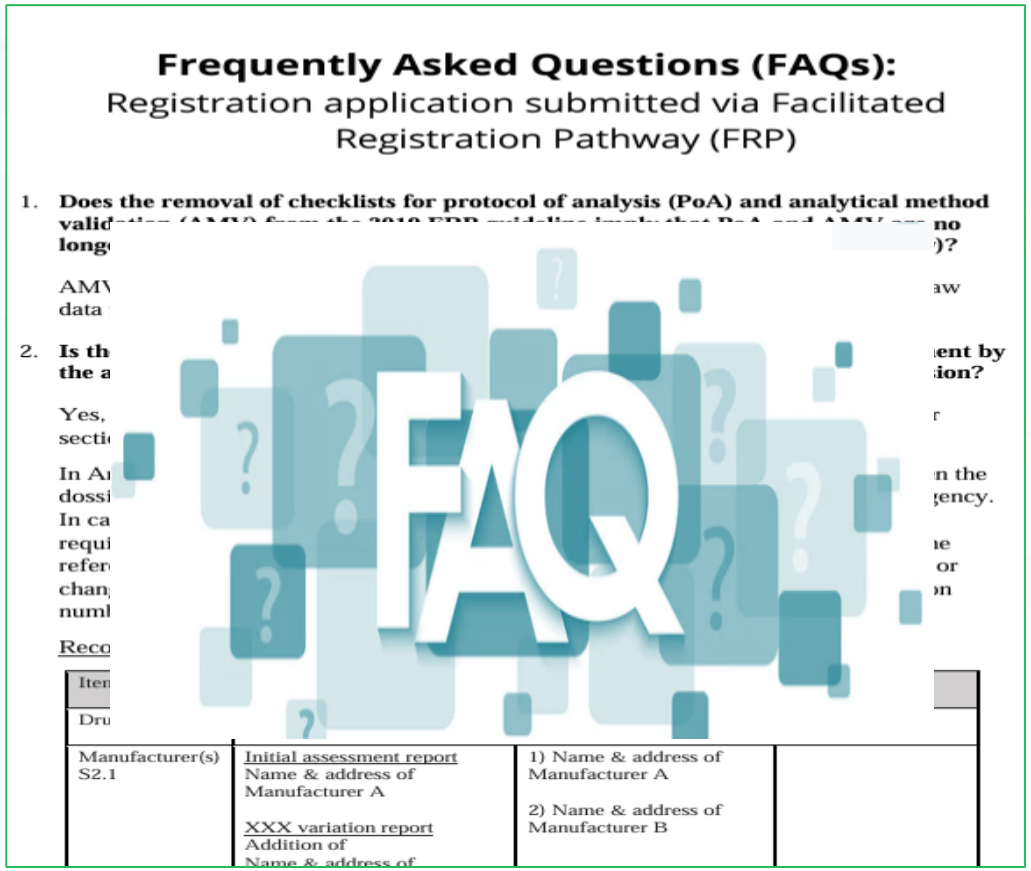
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia

Other Tools for Regulator & Industry

Flow chart
e.g. Product approved by reference agencies



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**

Manufacturer(s) S2.1	Initial assessment report Name & address of Manufacturer A XXX variation report Addition of	1) Name & address of Manufacturer A 2) Name & address of Manufacturer B	

KEY TAKEAWAYS

Key Takeaways

AJA: A Market Enabler

Facilitates entry into multiple ASEAN markets

Collaborate & Share

Continued collaboration is crucial for success.

Stay Informed

Monitor updates on AJA initiatives.

Leverage Reliance Pathways

Use Malaysia's FRP to accelerate approvals by relying on trusted reference agencies and ASEAN initiatives.

The ASEAN Joint Assessment Procedure marks a significant stride towards regulatory regulatory harmonisation. Continued collaboration among member states and active active engagement from stakeholders are essential for its sustained success and development. development.

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Thank you for your kind attention

Questions?