



Collaboration on Streamlining Review for Pharmaceuticals

The 11th Thailand – Japan Symposium

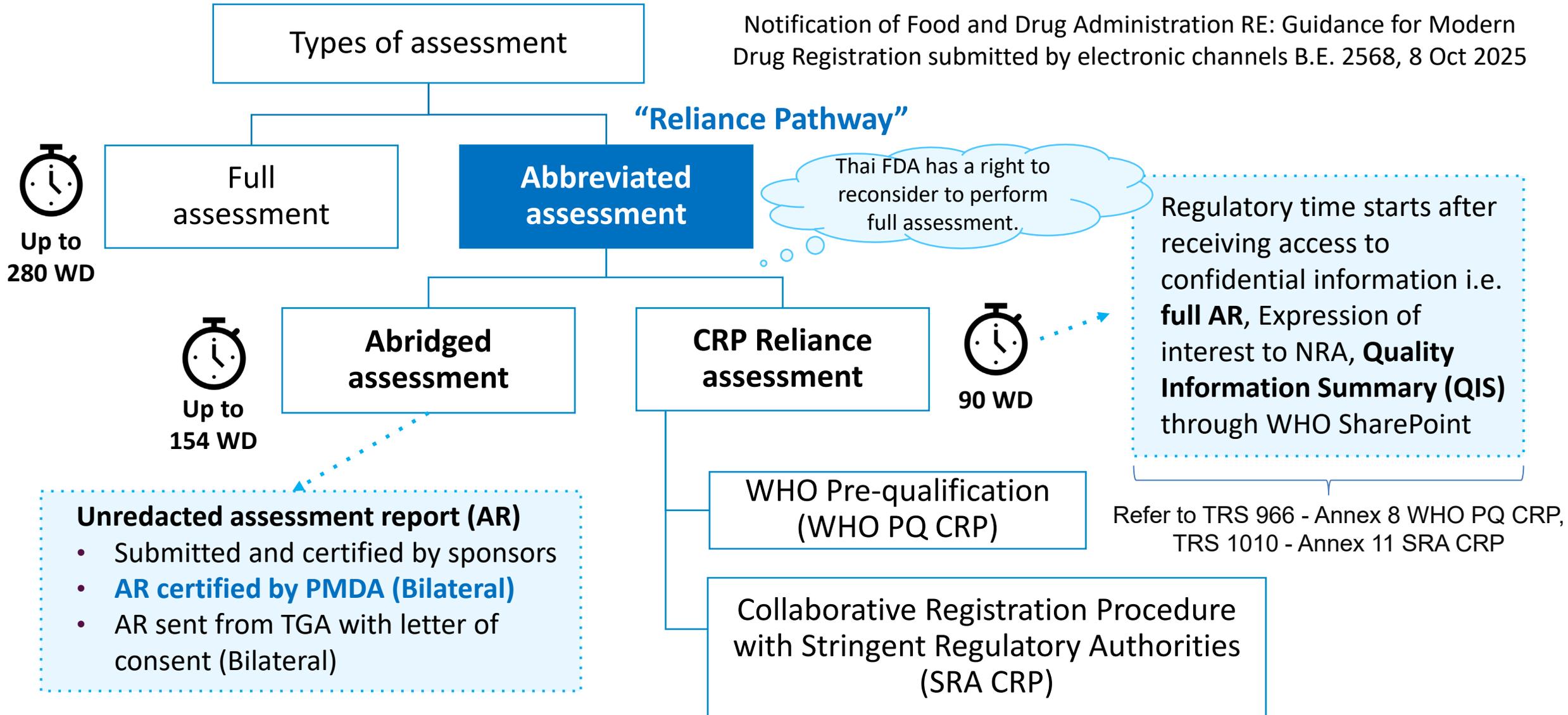
Food and Drug Administration
Ministry of Public Health, Thailand

Agenda

1. Registration Procedures of Pharmaceuticals in Thailand
2. Registration timeline of Pharmaceuticals in Thailand
3. Reliance: review and regulatory decision making
4. Case study in 2025 (utilizing abridged review pathway)
5. Benefits of the Reliance Pathway
6. Key Lessons learned

Registration Procedures of Pharmaceuticals in Thailand

Notification of Food and Drug Administration RE: Guidance for Modern Drug Registration submitted by electronic channels B.E. 2568, 8 Oct 2025



Registration timeline of Pharmaceuticals in Thailand

According to **Public Manual** for Modern drug registration submitted by electronic channels, 1 Sep 2025

Product Type	Registration Procedures & Timeline (working days)			
	Full Assessment	Abridged Assessment	WHO CRP#	SRA CRP#
Vaccines	280	154	90*	90*
New Drugs/ New Biologics	220	154	90*	90*
Biological products	160	110	90*	90*
New Generics/ Generics	135	115	90*	90*

Regulatory time starts after a valid application for registration according to the Procedure has been received and access to the confidential information has been granted (whichever is the later).

* If any deviations or difference from the application submission with WHO/SRA, deviations must be notified, and the timeline will be reduced by 30% from standard review.

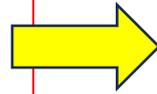
Public Manual Revision (1 Sep 2025)

Key changes include:

- **Process:** Added **pre-submission** and **pre-review meeting** steps for abridged reviews.
- **Timeline:** No changes to the abridged review timeline.

Reliance: review and regulatory decision making

#1 step Evaluate the **sameness**



For this Procedure, the same medicine is characterized by:

- the same qualitative and quantitative formulation;
- the same manufacturing site(s)⁶ for API and FPP including specific block(s)/unit(s), chain, processes, control of materials and final product, and in the case of vaccines also by the same batch release scheme;
- the same specifications for excipient, API and FPP;
- the same essential elements of product information.⁷



Any deviations from data approved by reference SRA, it should be clearly indicated and notified Thai FDA.



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TRS 1010 - Annex 11: Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products approved by stringent regulatory authorities

TRS 1010 - Annex 11: Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities

Annex 11, WHO Technical Report Series, No. 1010, 2018

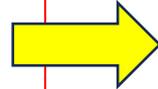
10 October 2018 | Technical document

Refer to Annex 11, WHO Technical Report Series, No. 1010, 2018.

Reliance: review and regulatory decision making

#2 step

Consider to factors affect the **benefit–risk profile** relevant to the use of product in **Thailand**



- Different **target population** e.g., ethnicity, gender, age group.
- **Epidemiology** and disease pattern.
- Feasibility of **diagnostic** modalities, monitoring and precautionary measures e.g., **specific gene testing** prior to initiation of treatment, resistant testing.
- Potential **interactions** with food and medications e.g., traditional **herbal** medicines, **Asian fruits**.
- Recommendation in the **clinical practice guideline**.
- **Quality aspects** e.g., stability studies under **ASEAN zone IVb** condition, storage conditions.



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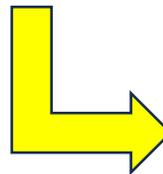
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3.3.3. Discussion on clinical efficacy and safety

Context consideration for difference

Table 6 Context consideration for abbreviated/review

No.	Aspects	Risk of difference	Explanation
1	Etiology		
2	Ethnicity		
3	Facility or capacity		
4	Clinical practice		
5	Epidemiology		
6	Others		

Case study for unmet medical need in 2025 – Alzheimer’s disease

The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Lecanemab in Early Alzheimer’s Disease

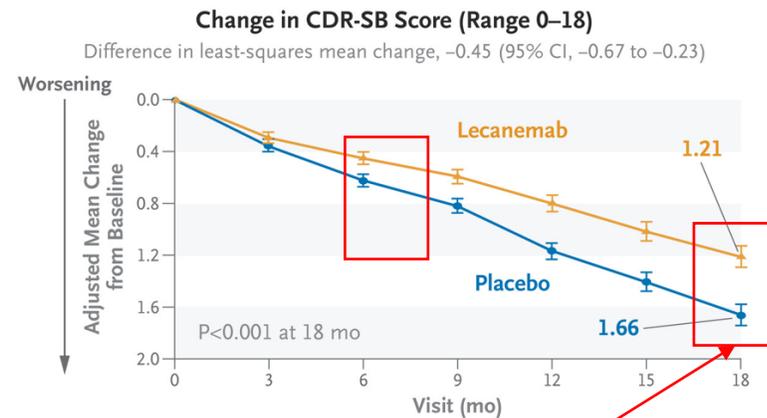
van Dyck CH et al. DOI: 10.1056/NEJMoa2212948

CLINICAL PROBLEM

Some evidence suggests that amyloid removal slows the progression of Alzheimer’s disease. Lecanemab, an anti-amyloid monoclonal antibody with high affinity for soluble amyloid protofibrils, is being tested in early Alzheimer’s disease.

CLINICAL TRIAL

Design: A phase 3, multicenter, double-blind, randomized, placebo-controlled trial assessed the efficacy and safety of lecanemab in patients 50 to 90 years of age with early Alzheimer’s disease.



27%

significant slowing disease progression on CDR-SB at 18 months

A **breakthrough** therapy for Alzheimer’s disease was accelerated reviewed through **bilateral cooperation with PMDA** and the Subcommittee on Development of Drug Regulatory Science and Innovation.

Approval timeline

“**179 working days**”

(reduced from standard review, 220 working days)

Benefits of the Reliance Pathway

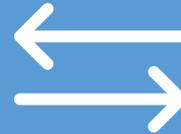
Faster patients access to quality-assured products through health authority collaboration by sharing of detailed assessment generated by reference SRA.



**Streamline
Registration
Process**



**Facilitate
Regulatory
Decisions**



**Reduce
Duplication**



**Foster
Capacity
Building**

The number of experts required and the overall registration timeline will be **reduced** compared to a full assessment pathway.

Key Lessons Learned

- **Deviations** from reference SRA approval and differences in quality parameters (e.g., drug product specification) lead to longer approval timelines and may necessitate a full assessment.
- Multiple **Post-Approval Changes**, such as a proposed new indication, could complicate ongoing assessments.
- **Differences in regulatory definitions** leading to the insufficient technical detail in the full Assessment Report (AR) for comprehensive review.
- We prefer **English AR translated by reference country**. In case AR translated by 3rd parties, certificate of translation is required.
- **Direct communication** with reference SRA is very important.