

# Best Practice for Predictability & Transparency to Facilitate Reliance Scheme in Thailand

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# Registration Procedures - Thailand

Notification of Food and Drug Administration RE: Guidance for Modern Drug Registration submitted by electronic channels, 23 Jun 2023

## Types of assessment

Full  
assessment

Abbreviated  
assessment

Abridged  
assessment

CRP Reliance  
assessment

WHO Pre-qualification  
(WHO PQ CRP)

Collaborative Registration Procedure with  
Stringent Regulatory Authorities (SRA CRP)

Thai FDA has a right to  
reconsider to perform full  
assessment.

Regulatory time starts after  
receiving access to  
confidential information i.e.  
**full AR**, Expression of  
interest to NRA, **Quality  
Information Summary (QIS)**  
through WHO SharePoint

Refer to TRS 966 - Annex 8 WHO PQ CRP,  
TRS 1010 - Annex 11 SRA CRP

### Unredacted assessment report (AR)

- Submitted and certified by sponsors
- AR certified by PMDA (Bilateral)
- AR sent from TGA with letter of consent (Bilateral)

  
Up to  
280 WD

  
Up to  
154 WD

  
90 WD

# Registration Timeline - Thailand

According to [Public Manual](#) for Modern drug registration submitted by electronic channels

Product Type	Registration Procedures & Timeline (working days)			
	Full Assessment	Abridged Assessment	WHO PQ 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.

# Reliance Journey: Faster Access to Pharmaceutical Products

## Cohort 1: WHO PQ CRP (2017 – 2022)

- Unestablished **Post-Approval Changes (PAC)** process.
- **Insufficient information** from abbreviated assessment report.



## Cohort 2: WHO PQ/SRA CRP year 1 + Abridged Review year 1 (2023)

- CRP is an efficient tool for **clearing previous backlogs** and streamline the review process.
- Industries need a year to create **internal process for SRA CRP**.
- Need to prepare **internal process** and understanding of reviewer team as well as mechanism to rely on the reference country.
- Need to understand and learn about the **system requirement and guideline** of WHO PQ and reference SRAs.

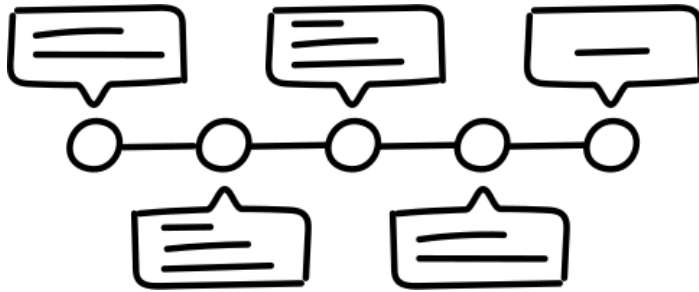
# Reliance Journey: Faster Access to Pharmaceutical Products

## Cohort 3: WHO PQ/SRA CRP year 2 + Abridged Review year 2 (2024)

- Effective communication and collaboration among NRAs, industries, and WHO.
- The corrective action to **timely access to the WHO Shared Platform**.
- **Expanding the scope** of CRP to include **SRA CRP and Abridged Review**.
- **Build trust** and understanding of **WHO PQ** and reference SRA's regulatory framework.
- The expectation of the **comprehensive assessment report of Generics** particularly for quality aspects.
- Leveraging **QIS** endorsed by SRA can facilitate a better understanding of quality part.
- Digital process can create transparency and efficiency for product licensing.



# Predictability and Transparency to facilitate Reliance Scheme



- **Public Manual establishment**

- Actively involve industry to ensure understanding of the requirements.
- Breakdown of process and identify the details and timeline of each step.

- **Consultation**

- Site-specific stability requirement aligned with ASEAN perspective
- GMP Inspection: No formal Mutual Recognition Agreement (MRA) among PIC/S members
  - GMP Clearance: Implemented through document review, with on-site inspections required for emerging countries when concerns arise



- **E-Tracking system**

- **Real-time tracking** of all application status on a single page and provide target regulatory approval to applicants for accurate business planning.
- **Implementation:** Accessible on Thai FDA website starting January 2, 2025



# Reliance Scheme



- **Factors:** Consider ICH regions (US, EU, Japan) and emerging R&D countries (India, China, Korea).
- **Reliance:** Employ a risk-based approach to balance consumer protection with the acceleration of innovative medicines
- **DCT:** Enhance efficiency by leveraging smartphone technology, providing an option for volunteers who are comfortable with technology.
  - DCT is beneficial for the ecosystem and can support Reliance by providing real-time data and remote monitoring, allowing for more informed and timely decisions.

Thank you