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

Up to 280 WD

Abbreviated assessment

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

Abridged assessment

Up to 154 WD

Unredacted assessment report (AR)

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

CRP Reliance assessment

90 WD

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

WHO Pre-qualification (WHO PQ CRP)

Collaborative Registration Procedure with Stringent Regulatory Authorities (SRA CRP)

Registration Timeline - Thailand

Asia Partnership Conference of Pharmaceutical Associations

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

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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

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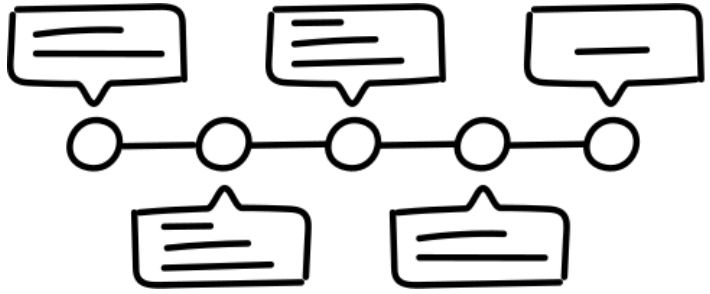
Cohort 3:
WHO PQ/SRA CRP year 2 + Abridged Review year 2 (2024)

- 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.

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Thank you