New Drug Review Cooperation Next Step

~ From Japanese views ~

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What do we seek “New Drug Review Scheme”??

- Taiwan FDA and MHLW/PMDA explored to **adopt (either) approved new drugs efficiently (2017)**
  - *Regulator has big burden to review alone.*
  - *Utilization of prior review experience is beneficial for both regulators*

- **Start “pilot”** at first (asked through both industries)

[Remarkable points]

- Start the process from **the applicant’s request** to PMDA and TFDA at first
- Submit **unmasked Review Report (English)** **<u>at the application</u>**
- Utilize **signed consent form** amongst Taiwan FDA, PMDA and applicant

-> Applicant; response the data and fact

-> Regulator; response the evaluation thought from the review report

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Accumulation of experience (1)

- After review of pilots product, Taiwan FDA and MHLW/PMDA **exchanged "Position Paper" in 2019**.

  Name: Position paper on New Drug Review Cooperation between Japan and Taiwan

"Position paper" is positioned complement of Pharmaceutical Regulatory Cooperation MOU from the technical aspect

-> After this success, several Position Papers have been considered under the MOU

- Taiwan FDA and MHLW/PMDA have been **communicating the review experience** at the application under Position Paper

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Accumulation of experience (2)

- Taiwan FDA and MHLW/PMDA summarized **"Q&A for the New Drug Review Scheme"** in Oct., 2022 to deliver detailed procedure.
  - *Transparency to applicant*
  - *Promotion of understanding for the procedure*
  - *Increase to the number to utilize this scheme*

- Taiwan FDA and MHLW/PMDA **further enhance Q&A contents** from the accumulation of review experience

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Items of Questions (1) version of Oct. 2022

General
What is the main purpose for the New Drug Review Scheme?
What are the benefits for industries joining the Scheme?
What are the criteria for joining the Scheme?
If the drug product was designated as orphan drugs, will it be applicable for the Scheme?
Application
How to join the Scheme?
Are there any additional requirement when submit for new drug registration under the Scheme?
How to request for the full unmasked review report?
As to unmasked review report which is necessary to be submitted under the New Drug Review Scheme, is it possible for applicant to submit company translation?
For applications utilizing the New Drug Review Scheme, is it necessary to submit safety information after marketing approval by the referred regulatory authority?

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Items of Questions (2) version of Oct. 2022

Workflow
Will there be special review timeline for the applications utilizing the Scheme?
How does the reviewers between both sides communicate?
If the inquiries have been responded by the applicant to the Approval side, will the Reviewing side raise the same inquiries again?
There are differences in the definition of orphan drugs and requirements for clinical trials according to the country/region. Which points should applicants take into consideration?
Which points should applicants take into consideration when the applicant submits a response to an inquiry from the regulatory authority?
Others
What points should be considered for the review to be finished within the standard review time?

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Our perspective

1. Every regulator needs **to introduce innovative pharmaceuticals in own country globally**

2. Also, currently, **industry select country** which to apply the product

3. Regulator needs to **adopt its situation efficiently**
   – **"Reliance"** is tool to accept other regulator's decision and thought

4. "New Drug Review Cooperation Scheme" is just its activity and contributes to **enhance practical collaboration** between Taiwan FDA and MHLW/PMDA

5. Further this collaboration scheme would be **a basis to progress review collaboration with other regulators**

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Reliance

- "The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to **assessments performed by another regulatory authority** or trusted institution, or to any other authoritative information, **in reaching its own decision**.

- Part of WHO's goal of strengthening regulatory capacity

IPRP Questions and Answers document on Reliance Version dated 13 June 2023
https://www.iprp.global/news/iprp-questions-and-answers-document-reliance-now-published

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Consideration For more enhancement

- Current scheme is **generally applicable** to the application of approved product **within 1 year.**
  -> It would be necessary to **make balance to expand approved product beyond 1 year for valuable innovative pharmaceuticals**.

- Cope with **the post-marketing safety issues** and **post-approval change after approved status**
  -> How to obtain most updated information

- In case that submission data would not be same, review report is to be utilized as only reference of evaluation and review thought.

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Towards next step

1. Expansion of **subject company**??
   From Taiwan/Japanese company to further??

2. Expansion of **scope of review cooperation**??
   From NCE to addition of indication??
   Focus on more specific cases??

3. **Enhancement of Q&A** from the experience??

4. Industry/company's **more participation** and input their experience to regulators??

5. Expansion to this activity **to other countries as model**??

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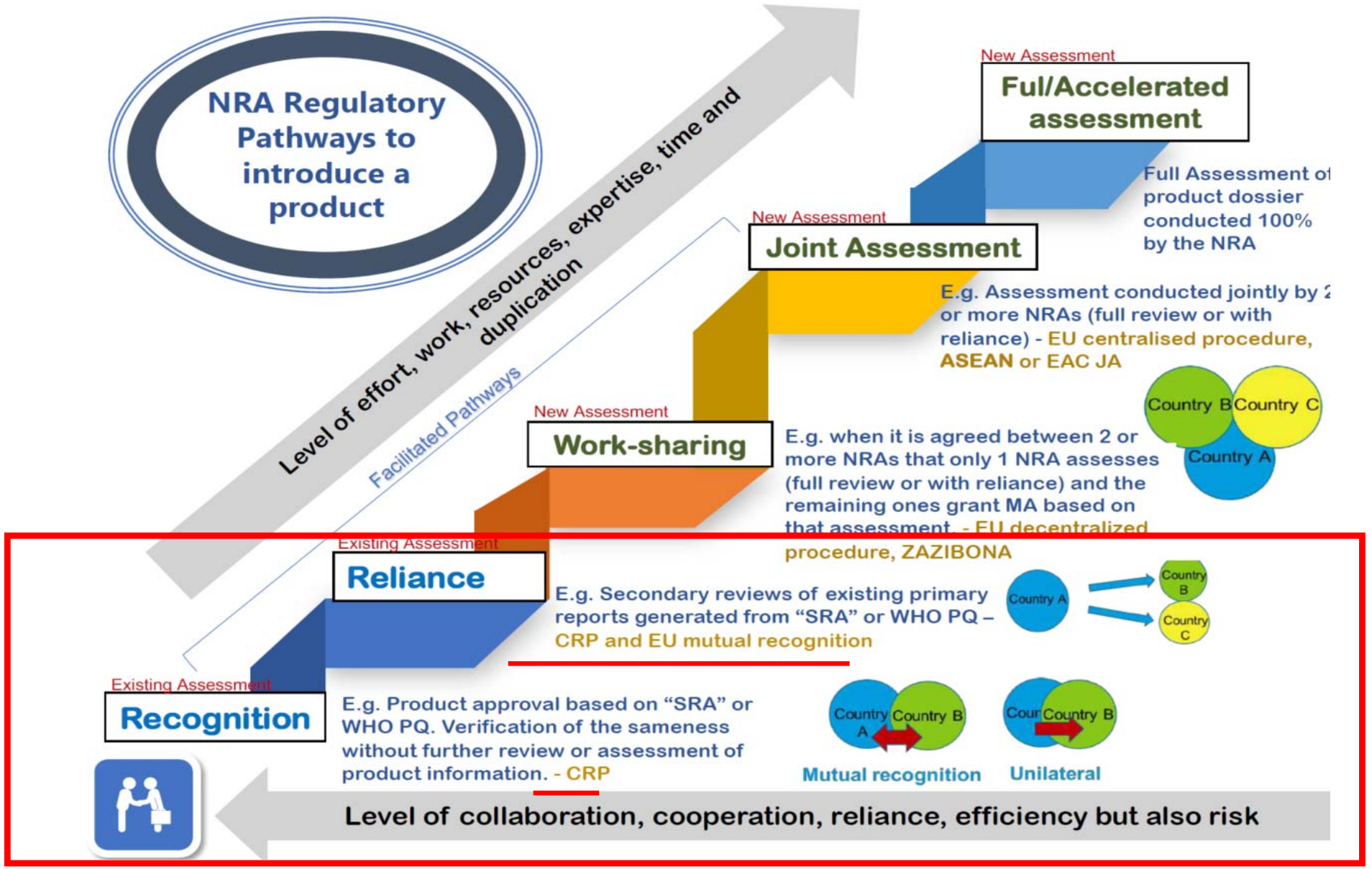
Decision Making by Regulatory Authority



WHO Good Reliance Practices
https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf

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Thank you very much!!

Please come to

http://www.pmda.go.jp

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