

# **Panel Discussion [NADFC-INDONESIA]**

**in APAC 2019**

To encourage scientific and risk based approach to stability study for post approval change (PAC) in “INDONESIA” at the present status,

**Question 1:** Do you accept “stability commitment”\* at the PAC review if the scientific and risk based approach can assure the shelf-life and storage conditions (Yes or No) ? **Yes**

\* “Stability commitment” is to initiate or complete ongoing, long-term stability testing on post-change batches.

**If Yes, What guideline, justification or methodology of scientific and risk based approach based do you accept it now?**

The current requirement for post approval changes in Indonesia allows to accept stability commitment for both minor and major changes with conditions.

The condition for stability commitment for minor changes is to have minimum 3 month real time stability data at submission.

The condition for stability commitment for major changes is to have minimum 6 month real time stability data at submission.

The shelf life would be determined by considering:

- the comparability stability profiles (accelerated and real condition stability data) of the previous approval with the proposed changes.
- The decision tree approach in ICH Q1 stability data.

*The requirement for post approval changes in Indonesia (Annex XVI of the Regulation of the Head of NADFC No.24 in 2017) is referring to the ASEAN Variation Guideline. In addition to it, we also consider EMA variation guideline. For Biological products, the requirement for post approval changes is referring to the WHO guidelines. Those guidelines allows stability commitment for post approval changes.*

To encourage scientific and risk based approach to stability study for post approval change (PAC) in “INDONESIA” in the future,

**Question 2:** Will you accept “*stability commitment*”\* at the PAC review if the scientific and risk based approach can assure the shelf-life and storage conditions in the future (Yes or No) ?

If Yes, What are required/changed if you can accept **it** in the future?

The current practice for post approval change (PAC) in Indonesia have already accepted the stability commitment for reviewing the PAC.

Any other comments regarding the future requirements for stability commitment (if any)

To encourage scientific and risk based approach to stability study for post approval change (PAC) in “INDONESIA”,

**Question 3:** *Do you have any concerns or discussion points to accept a “stability commitment” with scientific and risk based approach?*

#### Challenges for stability commitment

- The industry does not fulfill the minimum condition/data for having the stability commitment. E.g.: the real time stability data at submission is less than 3 months for minor changes, or less than 6 months for major changes.
- Difference of comparability stability profiles of the previous approval and the proposed PAC.
- The difference of condition in the stability studies.