Malaysia

Panel Discussion [Template]

in APAC 2019

To encourage scientific and risk based approach to stability study for post approval change (PAC) in "your Country/ Region" 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) ?***

** "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?
1	- ASEAN Guideline on Stability Study of Drug Product (R1) - Malaysian Variation Guideline for Pharmaceutical Products, 2013 - ICHQ5C: Stability Testing of Biotechnological/Biological Products (biologic product only) - Malaysian Variation Guidelines for Biologics (MVG) Not Applicable - We accept : • pharmaceutical : 3 – 6 months of long-term stability data with no commitment for PAC • biologic : 6 months of long-term stability data with no commitment for PAC

To encourage scientific and risk based approach to stability study for post approval change (PAC) in "your Country/ Region" 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) ?***

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

If No,	What guideline, justification or methodology based do you not accept it now?
Obs. 1	(for example) Asean Variation GL, Asean Variation GL modified by our own country , Variation GL determined by our own country or Local guideline required (Name of the Local guideline) etc.
Obs. 2	(for example) Lack of knowledge for risk-based approach process
Obs. 3	(for example) Depend on the PAC reviewer etc
Obs. 4	…

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

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To encourage scientific and risk based approach to stability study for post approval change (PAC) in "your Country/ Region" 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?
1	(for example) Change the local rule, Define the process with scientific and risk based approach, Feasibility of change the local rule etc.

If No,	What obstructions will you not accept it in the future?
Obs. 1	Not for now. Any acceptability of 'stability commitment' at the PAC review will be based on the ASEAN Guideline on Stability Study of Drug Product. We need to get consensus from ASEAN member state before implementation.
Obs. 2	For biologic products, it will be depending on case to case and the sound justification.
Obs. 3	

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

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To encourage scientific and risk based approach to stability study for post approval change (PAC) in "your Country/ Region",

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

According to ASEAN Guideline on Stability Study of Drug Product (R1), Malaysian Variation Guideline for Pharmaceutical Products, 2013, ICHQ5C: Stability Testing of Biotechnological/ Biological Products (biologic product only)

We do accept scientific and risk based approach which can provide opportunities for more flexible approaches but does not change the regulatory requirements .

1) Reduce the number of selection of batches and minimum time period covered for stability study for PAC compared to new drug product submission requirement based on the dosage form and the drug substance (API) stability.

   New product requirement

   - 3 batches with minimum of 12 months (new chemical entity) or 6 months (biologic) of long-term stability data and 6 months accelerated stability data at the time of new product application submission

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

Post approval change requirement

Major Variation (MaV)

Study	Storage Condition	Minimum Time Period Covered by Data at Submission	Number of Batches
Long term	30°C ± 2°C/75% RH ± 5% RH	6 months	Min. 2 For conventional dosage form and stable drug substances
			Min.3 For critical dosage form or unstable drug substances
Accelerated	40°C ± 2°C/75% RH ± 5% RH	6 months	Min. 2 For conventional dosage form and stable drug substances
			Min.3 For critical dosage form or unstable drug substances

Minor Variaton (MiV)

Study	Storage Condition	Minimum Time Period Covered by Data at Submission	Number of Batches
Long term	30°C ± 2°C/75% RH ± 5% RH	3 months*	Min. 2 For conventional dosage form and stable drug substances
		6 months	Min.3 For critical dosage form or unstable drug substances
Accelerated	40°C ± 2°C/75% RH ± 5% RH	3 months*	Min. 2 For conventional dosage form and stable drug substances
		6 months	Min.3 For critical dosage form or unstable drug substances

* Unless otherwise specified in ASEAN Variation Guideline

To encourage scientific and risk based approach to stability study for post approval change (PAC) in "your Country/ Region",

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

2) Allow PAC application with reduced design approach for stability study in which samples for every factor combination are not all tested at all time points such as bracketing and matrixing design.

3) Allow recommended labelling statements for the drug products to 'Do not store above 25°C' or 'Store below 25°C' when the stability of the drug product has been demonstrated at 25 °C/60% RH (long term) and 40 °C/75% RH (accelerated)

Other conditions to be consider:

a) If the product cannot meet the specifications during storage condition of long-term stability study on 30□C/75% RH for less than 18 months.

b) Consideration to choose 18 months as it is the minimum feasible duration for distribution of the product.

c) Applicant shall include scientific justification covering all aspects of the product as appropriate, e.g. drug substance, drug product, formulation, container closure, etc.