ATIM task force team

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3. Deliverables from EWGs and TFs

ATIM TF

2020 APAC ATIM Theme:

Consideration of ICH M9 BCS for the BE (Bioequivalence) waiver for the new drug application and post-approval changes

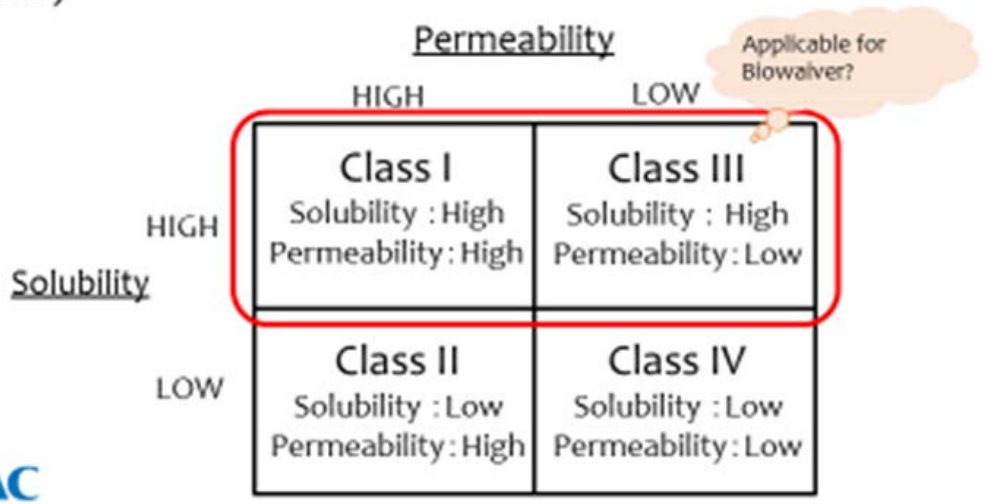
In 2019, JPMA issued a **position paper** for the continuing activities in pursuance of APAC missions and decided to pursue the following 4 points;

- Introduce science- and risk-based approach for change review process for efficient use of resources such in WHO guideline
- Seek an opportunity to adopt ICH Q1A stability approach to enhance and promote continuous improvement of the product and lower the level of introducing new innovative medicine to the patient
- Consider to implement mutual understanding and commitment approach, to conduct efficient stability and change management, using the tools such as Post-Approval Change Management Protocol (PACMP)
- **Examine Support Biopharmaceutics Classification System (BCS) of medicinal products and provide recommendation to support waiver of bioequivalence studies**

- ATIM TF considered to uptake merging ICH guideline, ICH M9, on the BE waiver using Biopharmaceutical Classification System (BCS).
- This new ICH guideline discusses technical and criteria for the determination of immediate release solid dosage form using Class I and III API.

Biopharmaceutics Classification System（BCS）

- BCS：Classification of compound based on solubility and permeability (membrane)



APAC

TF compared the difference between ICH guideline and other guidelines such as ASEAN guideline and discussed for the future harmonization.

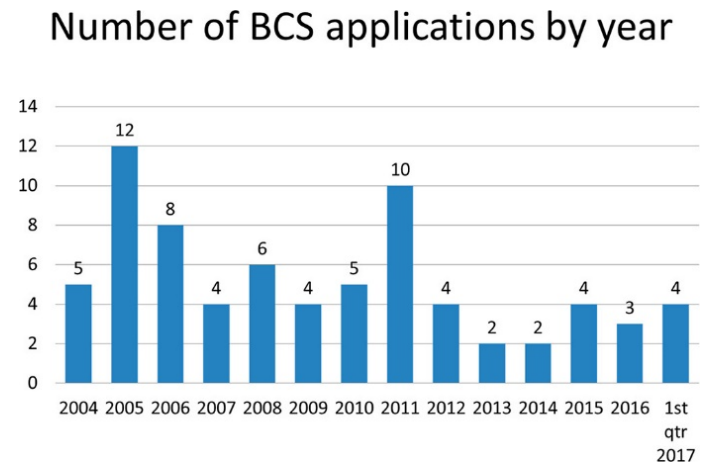
TF was enhancing the following points;

- Introduction of harmonized BE biowaiver will reduce **unnecessary clinical study** and may proceed efficient change control procedure based on in vitro
- Conducting unique BE study will **bring additional time and cost of the drug**, which will be reflected to the pricing of the product that may not be beneficial for the patients [1)]
- Implement and promote biowaiver by **science-based approach.**

1) Impact of the US FDA BCS guideline on global drug development.

These findings indicate a robust utilization of the BCS approach toward reducing unnecessary in vivo BE studies and speeding up availability of high quality pharmaceutical products.

On cost, the guidance has **saved the industry in excess of $100 million**.



IND, NDA, and original ANDA number of applications received/year.

Table 1. BCS Class 1 Applications Received and Approved for New and Generic Drugs from 2004 to March 2017

type of application	new drug		generic drug
# applications	48		25
# approved (% of total)	28 (58%)		23 (92%)
	IND stage	NDA stage	
# applications	18	30	
# approved (% of total)	12 (67%)	16 (53%)	

Asia Partnership Conference of Pharmaceutical Associations

Published in: Mehul U. Mehta; Ramana S. Uppoor; Dale P Conner; Paul Seo; Jayabharathi Vaidyanathan; Donna A. Volpe; Ethan Stier; Dakshina Chilukuri; Angelica Dorantes; Tapash Ghosh; Haritha Mandula; Kimberly Raines; Pariban Dhanormchitphong; Janet Woodcock; Lawrence X Yu;
Mol. Pharmaceutics **2017,** 14, 4334-4338.
DOI: 10.1021/acs.molpharmaceut.7b00687

For the 9th APAC meeting, TF was planning to introduce Dr. Ryosuke Kuribayashi (PMDA) as a Chair and hold a panel discussion with other authorities with this topic. Additionally, Dr. Kuribayashi to explain the new BE Guideline in Japan.

ATIM TF has provided Activity Report and will share it with APAC members.

Recommendation and Proposals

There are several points to consider the benefit of applying new ICH guideline;

- BE biowaiver based on BCS can contribute the **faster development, avoid unnecessary exposure of healthy patient during BE**, and efficient review of formulation change in pre- and post- submission
- Adaptation of the concept and risk based approach, this may also reduce the financial impact of the drug development by the industry, consequently the region may benefit from the faster introduction on the innovative drug with less pricing burden.
- With development ICH guideline, how can we adopt new BCS and its method, to harmonize the procedure to adopt BCS approvals

Next Step

For the proposal from ATIM TF, it is recommended that we need further discussion for better understanding of the how BCS could be used and benefit for the faster delivery of innovative drug and also how to implement this concept without reaching a consensus to adopt the agreement.
Further information sharing and discussion to prepare for the next APAC meeting may have an answer to resolve these points.