

MQS Session

The 12th APAC

Current Status and Future Plan of PACMP in Taiwan

Wan-Yu Chao
Specialist

Division of Medicinal Products

Taiwan Food and Drug Administration (TFDA)

18 April, 2023



衛生福利部
食品藥物管理署
Taiwan Food and Drug Administration

<http://www.fda.gov.tw/>

Current Measures for Post-Approval Change



Regulations Regarding Post-Approval Change in Taiwan

- ✓ Pharmaceutical Affairs Act
- ✓ Regulations for Registration of Medicinal Products

Post-Approval Change Category (Depends on the impact on drug product quality)

- ✓ **Prior Approval**

API sources, Dosage form, Excipients, Manufacturers, Specifications and Analytical methods, Container closure system, Storage condition

- ✓ **Self-management**

For changes that do not affect control and manufacturing process of drug product, such as expiration period extension, the record can be kept at manufacturing sites.

Drug licenses are renewed every 5 years. We take the chance of renewal to check if the DS/DP specifications are up-to-date.



Current Status Regarding Introduction of PACMP

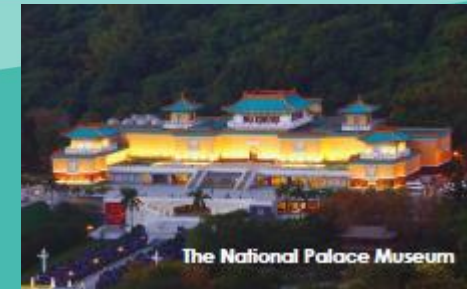
Implementation Status

- ✓ TFDA can accept prior approval or PACMP, as long as the scientific data and justification are sufficient to support post-approval changes.
- ✓ Until now, **TFDA has approved 8 cases of PACMP**. They are imported vaccine products for introduction new working cell bank/new reference standard.

Future Plan



- ✓ **Education**: This is our priority. We have been working hard on promoting the concepts of ICH Q12 both for regulators and for industry.
- ✓ **Accumulate more experience**: We have accepted some pilot cases from global pharma. We encourage companies to send PACMP as pilot cases and share experience.
- ✓ **Regulations**: We plan to publish guidance and QA documents in Chinese for industry to understand our review considerations. Besides, we will go back to check if it is necessary to revise our regulatory requirements.



Thank You For Your Listening!

For more information, please refer to
<http://www.fda.gov.tw>



Jadeite
Cabbage



Meat-Shaped Stone



衛生福利部
食品藥物管理署
Taiwan Food and Drug Administration

<http://www.fda.gov.tw/>