EFFECTIVE USE OF PHARMACOPOEIAS

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NPRA MALAYSIA

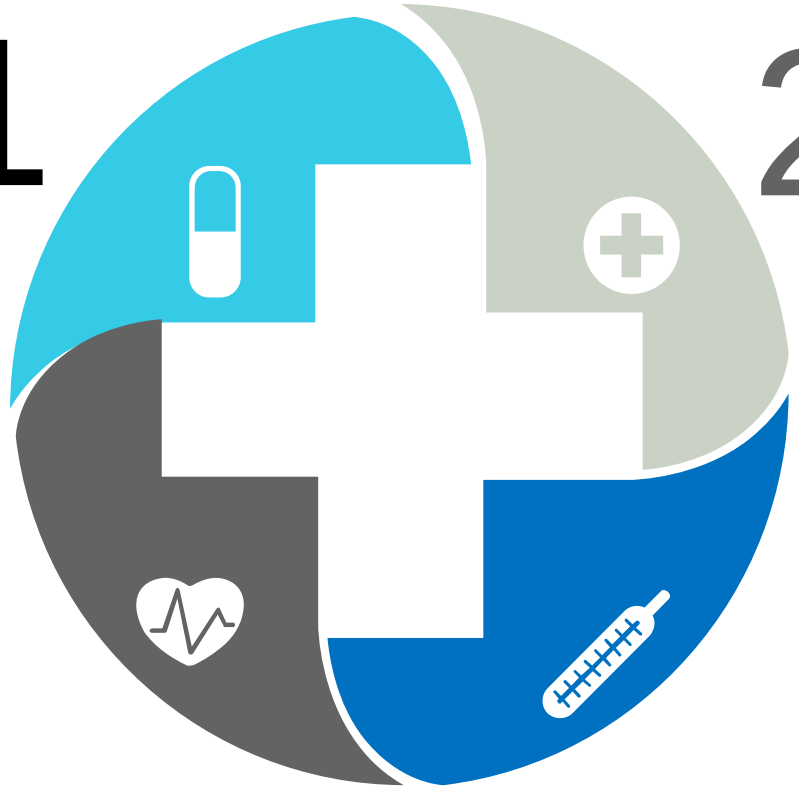
Sharing content

- Introduction
- Pharmacopoeia Compliance
- Pharmacopoeia: Use and benefits

NPRA promotes access to medicines while protecting public health

1 PROMOTING ACCESS

Facilitates approval of essential and innovative medicines



2 PROTECTING PUBLIC HEALTH

Ensures approval of medicines of acceptable quality, efficacy and safety

NPRA registers products that fulfill registration criteria

New Chemical Entities

Biologics

Generics

Veterinary

Natural/herbal

Health Supplements

Regulatory Functions

Product Life cycle

Pre marketing → Post marketing

National Regulatory System
Regulatory Inspection
Licensing premises
Laboratory access and Testing
Clinical Trial's Oversight
Marketing authorization
Vigilance
Market surveillance and Control
Lot Release

Standards for pharmaceutical products

International

WHO
ICH
EMA
US FDA

Regional

ASEAN Guidelines for:
Stability
Process validation
Variation

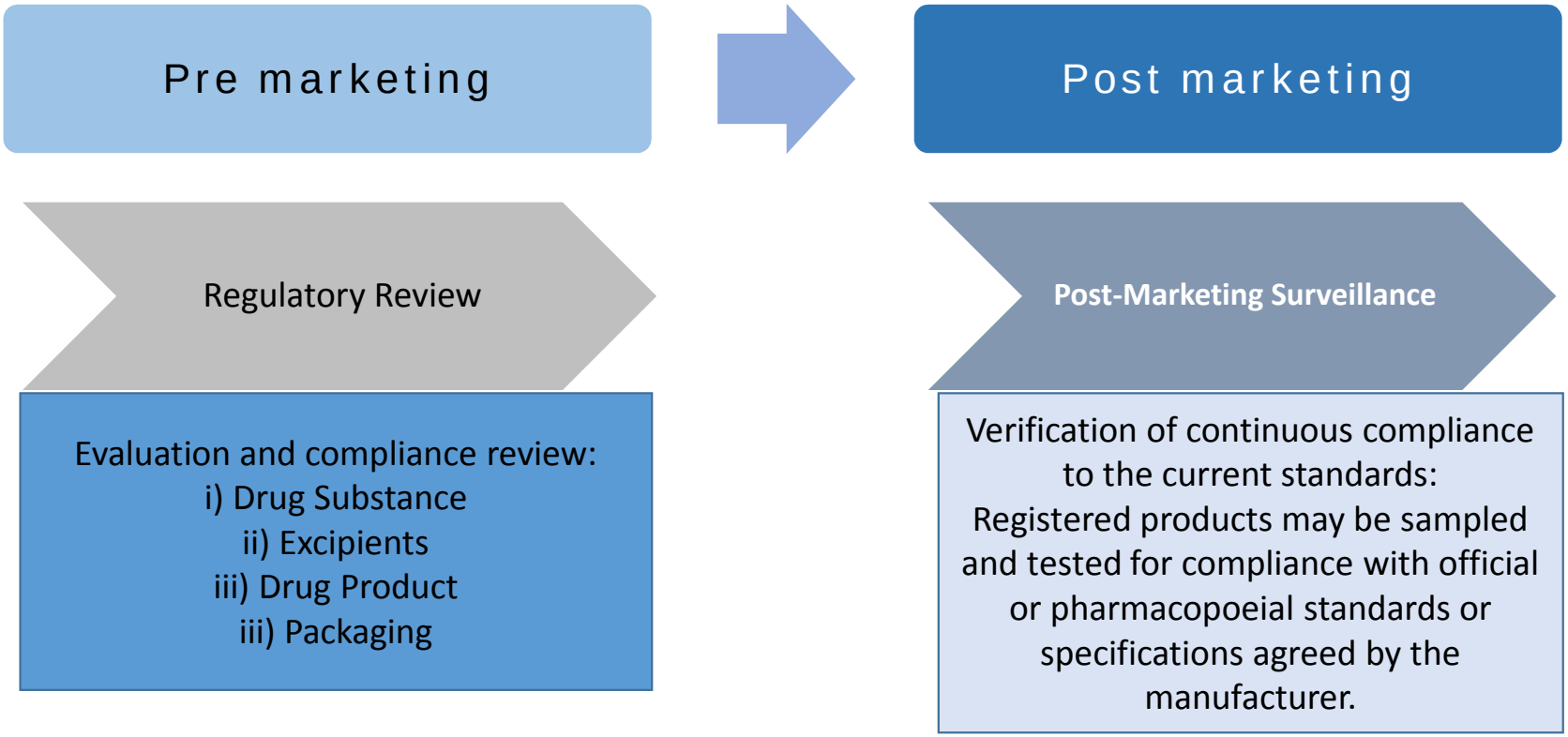
Local

Drug Registration Guidance Document
NPRA Guidelines
DCA Directives
Circulars

Pharmacopoeia Compliance

- Pharmacopoeia references such as USP, BP, etc. are stated in the Drug Registration Guidance Document (DRGD) as recognized standards for product registration in Malaysia.
- Compliance with requirements published by the referenced pharmacopoeia is mandatory if the drug substance/product claimed as such (e.g. Drug Product compliant with the BP).
- Compliance applies to the relevant and current compendial requirements.

Activities Involving Use of Pharmacopoiea



Utilisation of Pharmacopoiea

- As main references for regulators for both pre and post market activities (throughout drug product lifecycle). The activities include Post-approval changes.
- Currently, NPRA subscribe to USP and BP : Important to understand the whole structure of the content, information provided and the relationship between one section to the other relevant section.
- The electronic version facilitate the effective use by the evaluators particularly in the data retrieving process : ease of reference, timely, comprehensive and up to date information.
- Useful tool for technical and capacity building.
- Further clarification and scientific rationale can be obtained from the USP/BP scientific support team.

Challenges

- For country that heavily utilise the leading pharmacopoeias, inconsistent standards leads to the more stringent reference being used. However, limited scientific rationale is available to justify the differences.
- There is a need for harmonization of pharmacopoeias for consistent product quality across the world, which comply with the common compendial and other regulatory expectations.

THANK YOU

TERIMA KASIH