GMP COMPLIANCE ASSESSMENT IN INDONESIA

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Republic of Indonesia
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OUTLINE

- Brief Profile of Badan POM
- Legal Basis of Drug Registration and GMP Compliance
- Regulatory Framework on Ensuring S, Q, E of Medicine
- Registration Process for Imported Medicine
- **Badan POM in improving efficiency of GMP compliance review**
- Summary

Brief Profile of Badan POM

Our Vision

•Safe Food and Medicine to Improve Public Health and National Competitiveness.

Our Mission

- Intensifying Risk-based Drug and Food Control System to protect public health
- Encouraging Self Reliance of Bussiness Actors in ensuring Drug and Food Safety and strengthening partnership with stakeholders
- Enhancing NADFC institutional capacity.

ORGANIZATION STRUCTURE OF BADAN POM

MINISTRY OF HEALTH

Coordination

NATIONAL AGENCY OF DRUG AND FOOD CONTROL

INSPECTORATE

PERMANENT SECRETARY

1. Bureau of Planning and Financing
2. Bureau of International Cooperation
3. Bureau of Legal and Public Relation
4. Bureau of General Affairs

National Laboratory of Drug and Food Control

Centre of Drug And Food Investigation

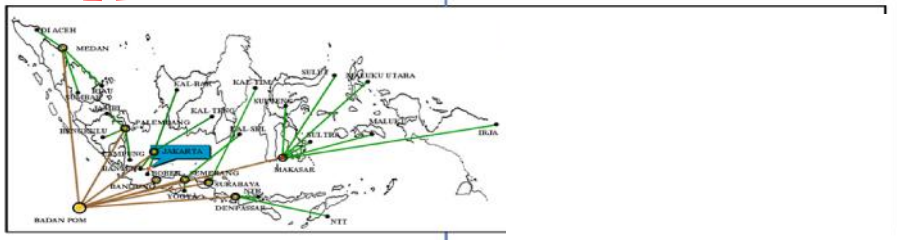
Centre of Drug And Food Research

Centre of Drug And Food Information

Deputy I
Therapeutic Products, Narcotics, Psychotropic and Addictive Control

Deputy II
Traditional Medicines, Cosmetics and Complementary Products Control

Deputy III
Food Safety and Hazardous Substance Control



SECRETARIAT

FUNCTIONAL GROUP

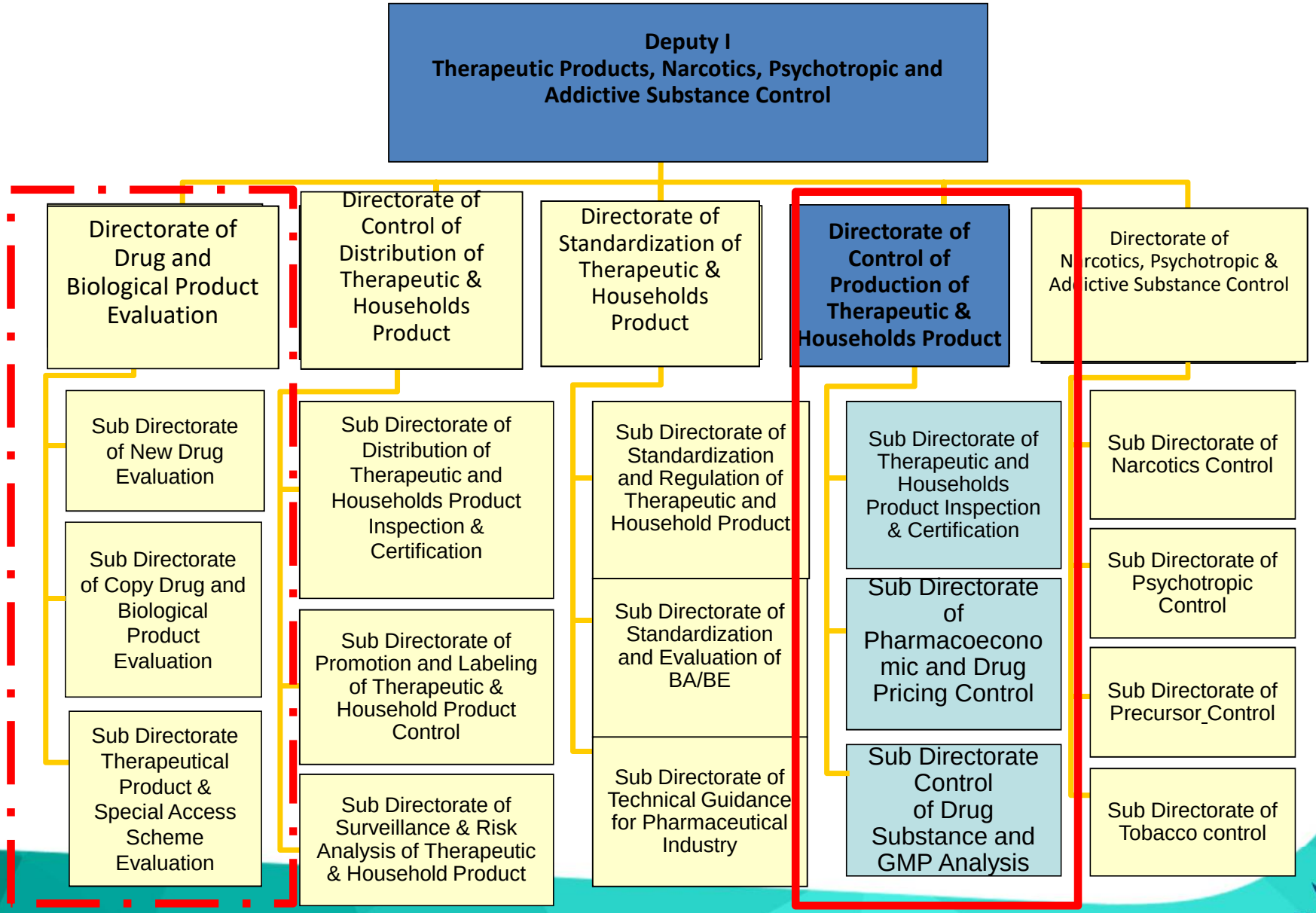
Laboratory Division For Therapeutic Product, Narcotic, Traditional Medicines and Cosmetic

Laboratory Division For Food and Hazardous Substances

Laboratory Division for Microbiology

Inspection and investigation Division

Certification and Information Division


Deputy I
Therapeutic Products, Narcotics, Psychotropic and Addictive Substance Control
Directorate of Drug and Biological Product Evaluation
Directorate of Control of Distribution of Therapeutic & Households Product
Directorate of Standardization of Therapeutic & Households Product
Directorate of Control of Production of Therapeutic & Households Product
Directorate of Narcotics, Psychotropic & Addictive Substance Control
Sub Directorate of New Drug Evaluation
Sub Directorate of Copy Drug and Biological Product Evaluation
Sub Directorate Therapeutical Product & Special Access Scheme Evaluation
Sub Directorate of Distribution of Therapeutic and Households Product Inspection & Certification
Sub Directorate of Promotion and Labeling of Therapeutic & Household Product Control
Sub Directorate of Surveillance & Risk Analysis of Therapeutic & Household Product
Sub Directorate of Standardization and Regulation of Therapeutic and Household Product
Sub Directorate of Standardization and Evaluation of BA/BE
Sub Directorate of Technical Guidance for Pharmaceutical Industry
Sub Directorate of Therapeutic and Households Product Inspection & Certification
Sub Directorate of Pharmacoeconomic and Drug Pricing Control
Sub Directorate Control of Drug Substance and GMP Analysis
Sub Directorate of Narcotics Control
Sub Directorate of Psychotropic Control
Sub Directorate of Precursor_Control
Sub Directorate of Tobacco control

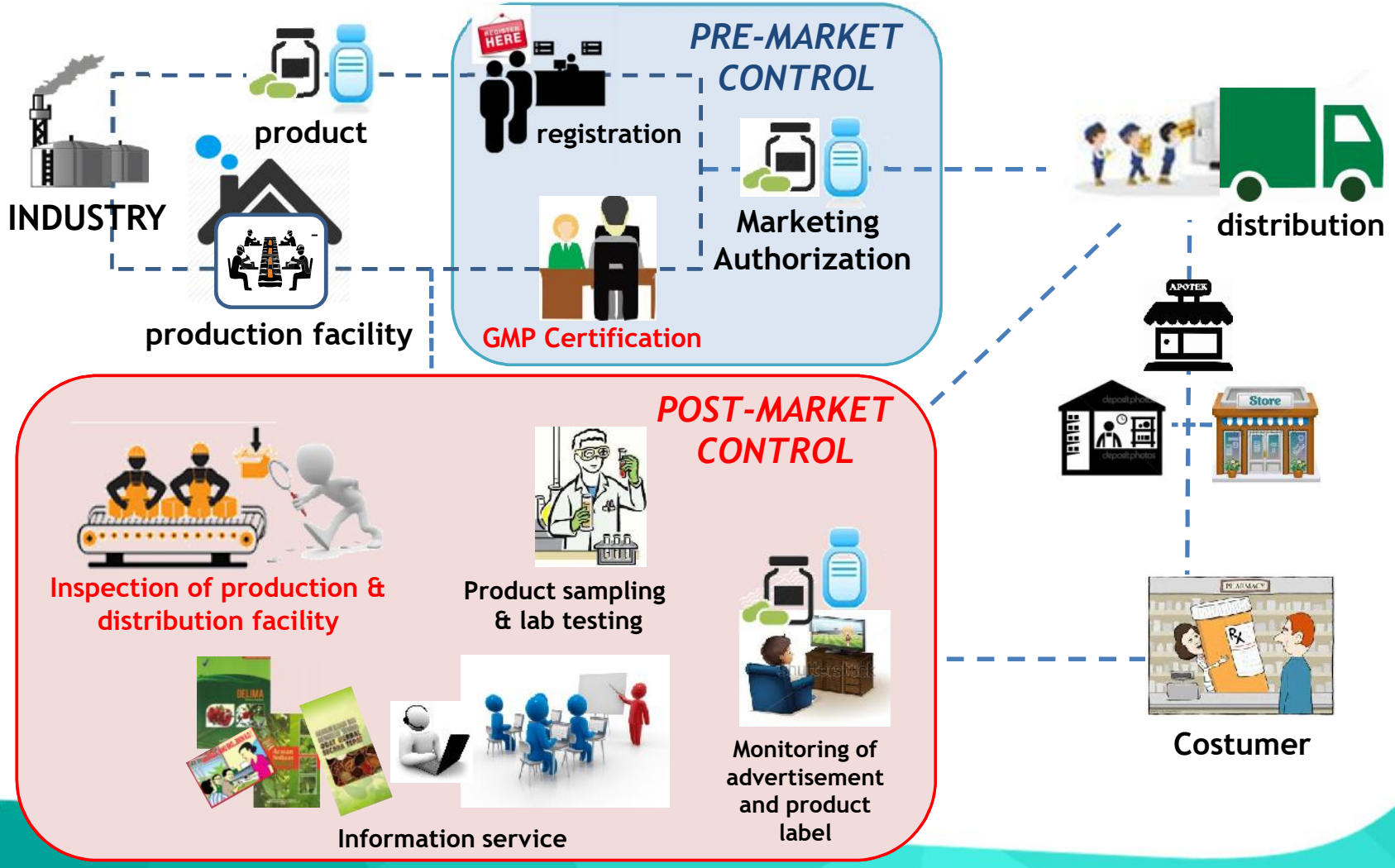
Legal Basis of Drug Registration and GMP Compliance

- Law No.36 of 2009 on Health
- Government Regulation No. 72 of 1998 on Safety of Pharmaceutical and Medical Devices
- MoH Decree No.1010/MenKes/Per/XI/2008 on Drug Registration
- MoH Decree No.1799 of 2010 on Pharmaceutical Industry
- Head of Badan POM Decree No. HK.04.1.33.12.11.09937 of 2011 on GMP Certification
- Head of Badan POM Decree No. HK 03.1.33.12.12.8195 of 2012 on Implementation of GMP Guideline
- Head of Badan POM Decree No. HK.03.1.23.10.11.08481 of 2011 on Criteria and Procedure for Drug Registration

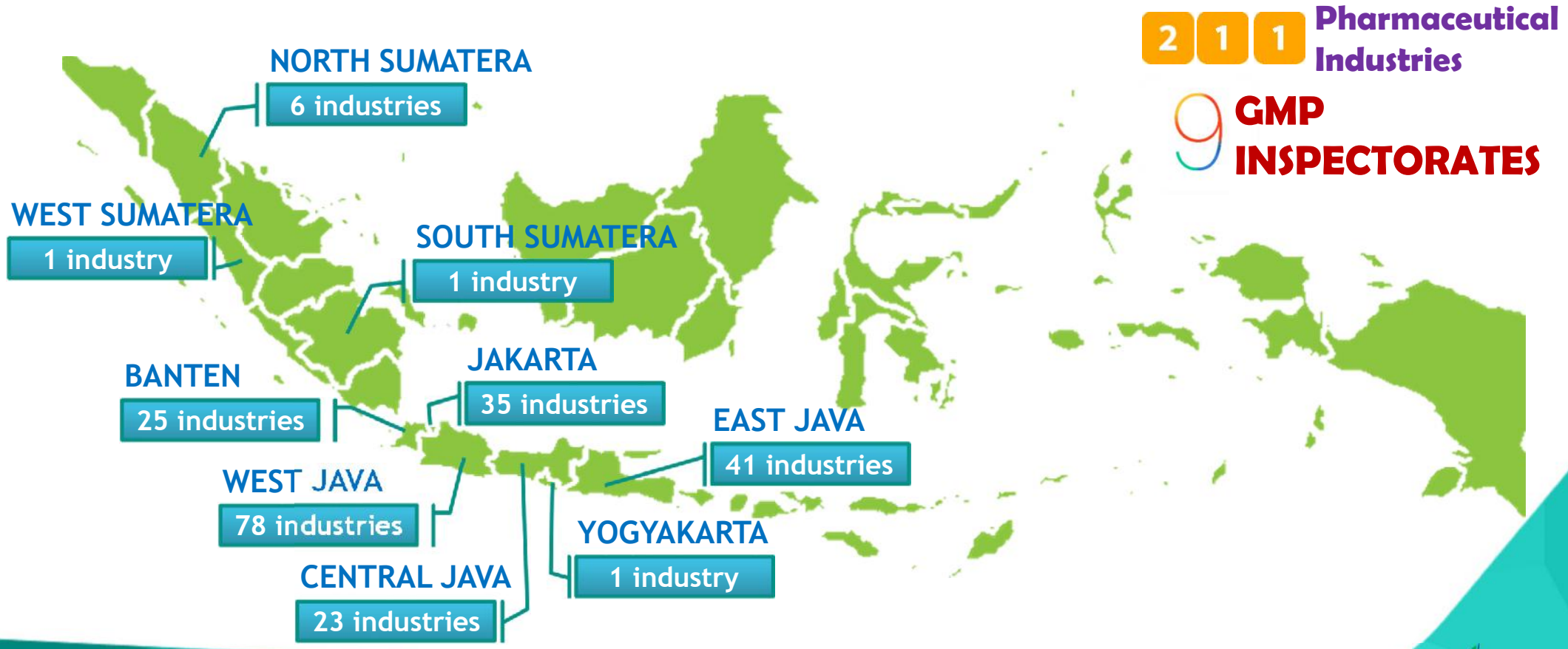
BADAN POM

PIC/S

Regulatory Framework on Ensuring S, Q, E of Medicine



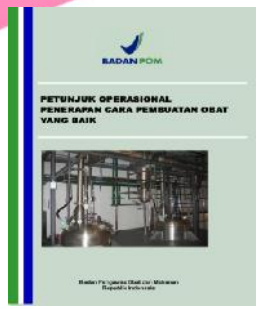
National Networking of GMP Inspection System



History of GMP Code and Technical Guideline 2006-now

Good Manufacturing Practice Ed 2006

2006



Operational Manual 2006

GMP for Active Pharmaceutical Ingredient 2009

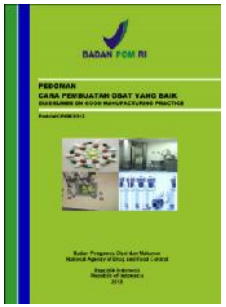
2009

2010

1st Supplement to National GMP Code 2010

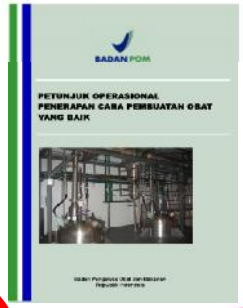
NADFC became PIC/S' 41st participating authority

2012



Good Manufacturing Practice Ed 2012*

2013



Operational Manual GMP 2013

2017

- Drafting the GMP Guideline for Blood Establishment
- Revising GMP Annexes for Biological Medicinal Substances & Products

Registration Process for Imported Medicine (1)

Consideration for foreign inspection

Risk Based Assessment:

- Manufacturer never been inspected by Badan POM
- Last inspection done > 2 years
- Production facility of product(s) applied are different facilities where ever been inspected
- Manufacturer does not hold any MA of the same product type and dosage form as applied
- There is a history of the recall / rapid alerts due to non compliance to GMP
- The results of previous inspections by Badan POM / other NRA

- alleged cases of S, Q, E
- Renewal of MA; and/or
- surveillance based on risk assessment

FOLLOW UP ON CRITICAL FINDINGS OF POST-MARKET INSPECTION

- ✓ **Prohibition of supply**
- ✓ **Tight monitoring of distribution**
- ✓ Unfinished CAPA within a month → **Recall of all batches & suspension of MA** → unfinished CAPA for the next following month → **withdrawal of MA**

Registration Process for Imported Medicine (2)

GMP Inspectorate Unit

Registration Unit

Imported Medicinal Product

Registration process (dossier application)

Evaluation of GMP Documents

Does inspection needed?

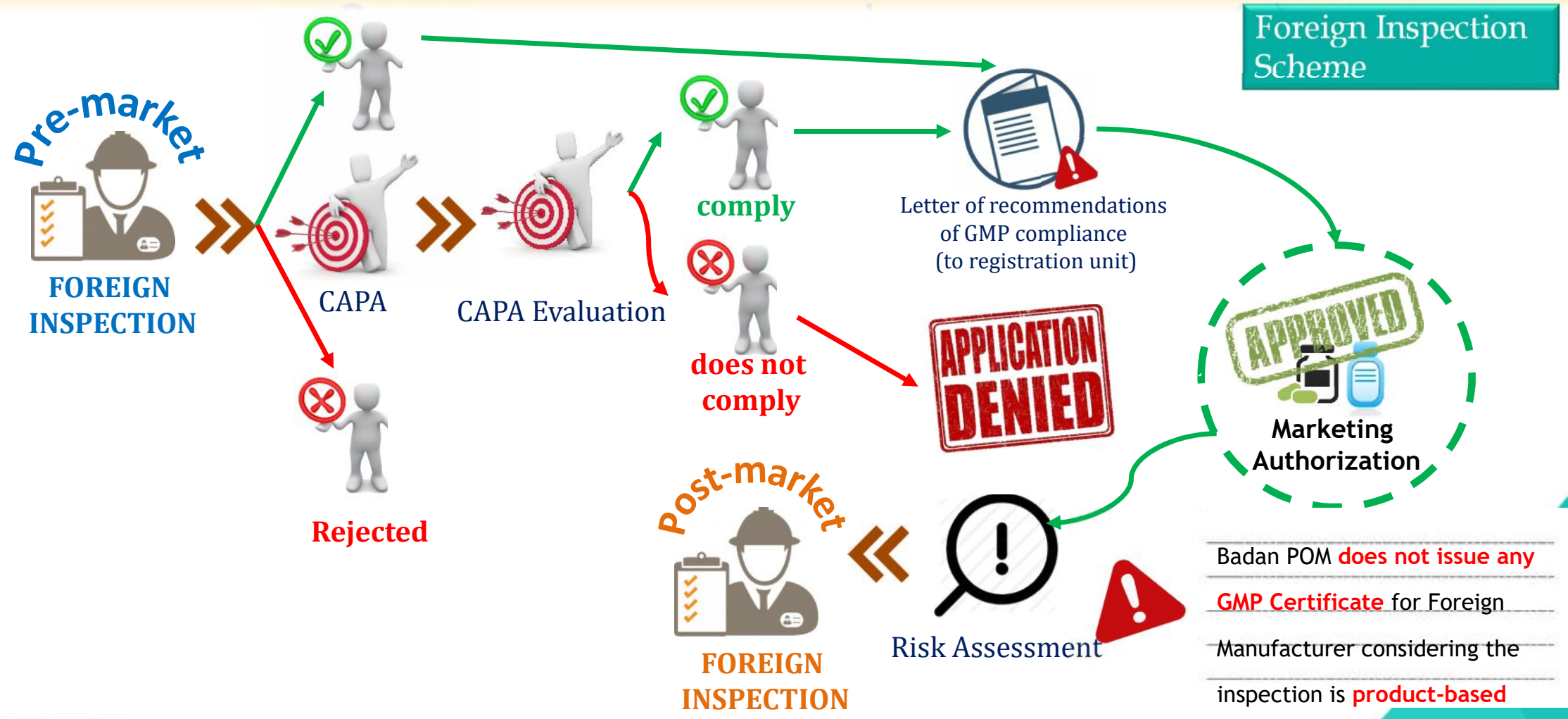
Issuance of letter of recommendations of GMP compliance

FOREIGN INSPECTION

satisfied

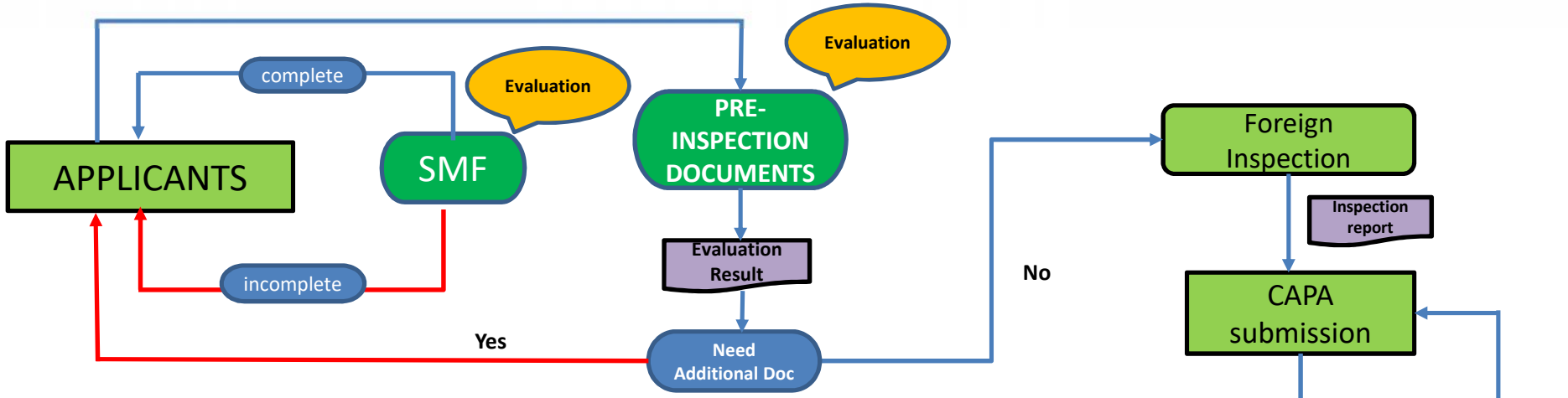
Marketing Authorization

Registration Process for Imported Medicine (3)



Badan POM **does not issue any GMP Certificate** for Foreign Manufacturer considering the inspection is **product-based inspection**

Previous NADFC Foreign GMP Inspection Scheme



Pre Inspection Docs:

1. VMP
2. Qualification of Critical Equipments
3. Qualification of HVAC System
4. Qualification of Water System
5. Process Validation
6. Cleaning Validation
7. Media Fill Validation (where applicable)
5. Analitycal Method Validation
6. Release procedure of finished product
7. SOP for Recall
8. SOP for Change Control
9. SOP for Deviation handling
10. SOP for Complaint Handling

Badan POM in improving efficiency of GMP compliance review

ASEAN SECTORAL MUTUAL RECOGNITION ARRANGEMENT FOR GOOD MANUFACTURING PRACTICE (GMP) INSPECTION OF MANUFACTURERS OF MEDICINAL PRODUCTS

The Governments of Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand and the Socialist Republic of Viet Nam, Member States of the Association of Southeast Asian Nations (hereinafter collectively referred to as "Member States" or singularly as "Member State"),

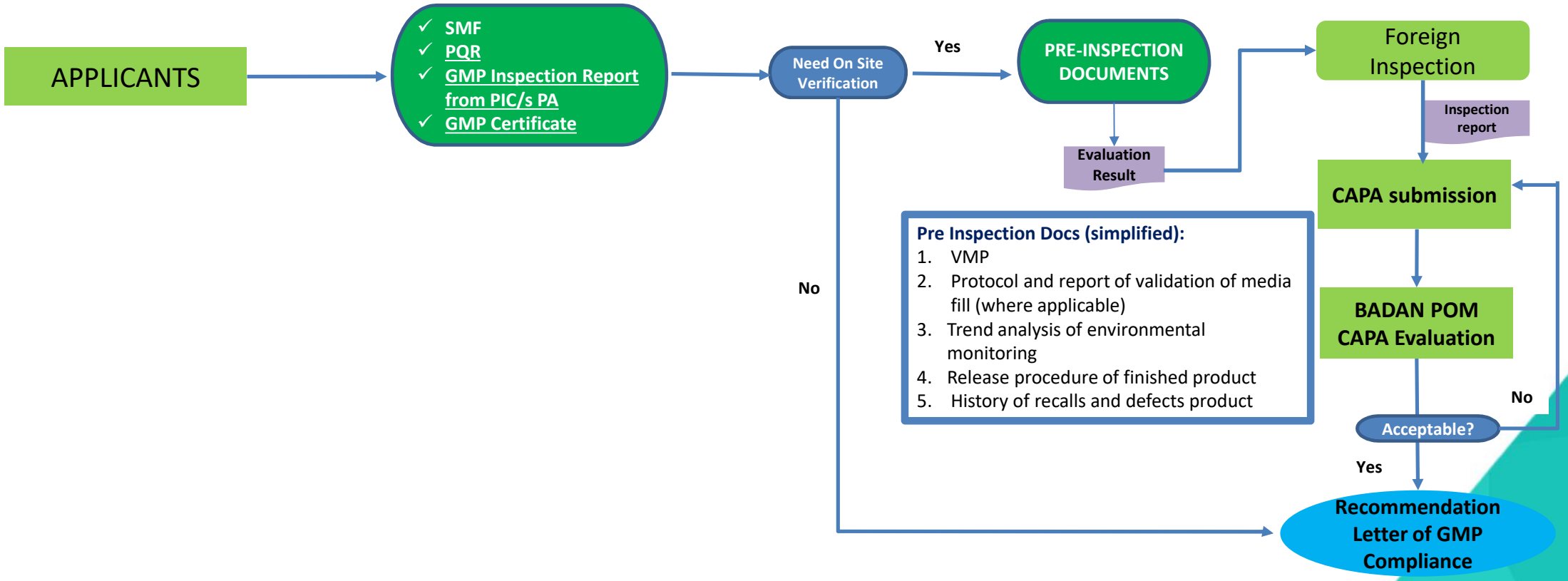
Simplification of the documents
to be evaluated

- Site Master File → will be used for planning & conducting GMP Inspection
- Pre-inspection documents (simplified)
- Shortened timeline for evaluation

Simplification of review process

- Performing initial screening on the doc(s) completeness
- Consultation & discussion on the result of review/ additional data required

Current NADFC Foreign GMP Inspection Scheme



Summary

- Badan POM commits to **support harmonisation and simplification** of drug evaluation including GMP review in order to **accelerate the launch of new drugs** without compromising the S, Q, E of the product
- Both of domestic and foreign manufacturer **must comply with the regulation** on drug registration and GMP compliance
- **On-site inspection** to foreign manufacturer regarding the MA apllication **will be based on risk assessment**
- Domestic and foreign manufacturer are **subjected to Post Market Control**, including the routine GMP inspection

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Thank You