NATIONAL AGENCY FOR DRUG AND FOOD CONTROL (NADFC)
REPUBLIC OF INDONESIA

BADAN PENGAWAS OBAT DAN MAKANAN (BPOM)
REPUBLIK INDONESIA

"AN OVERVIEW OF THE DRUG REGULATORY SYSTEM IN INDONESIA"

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Outline

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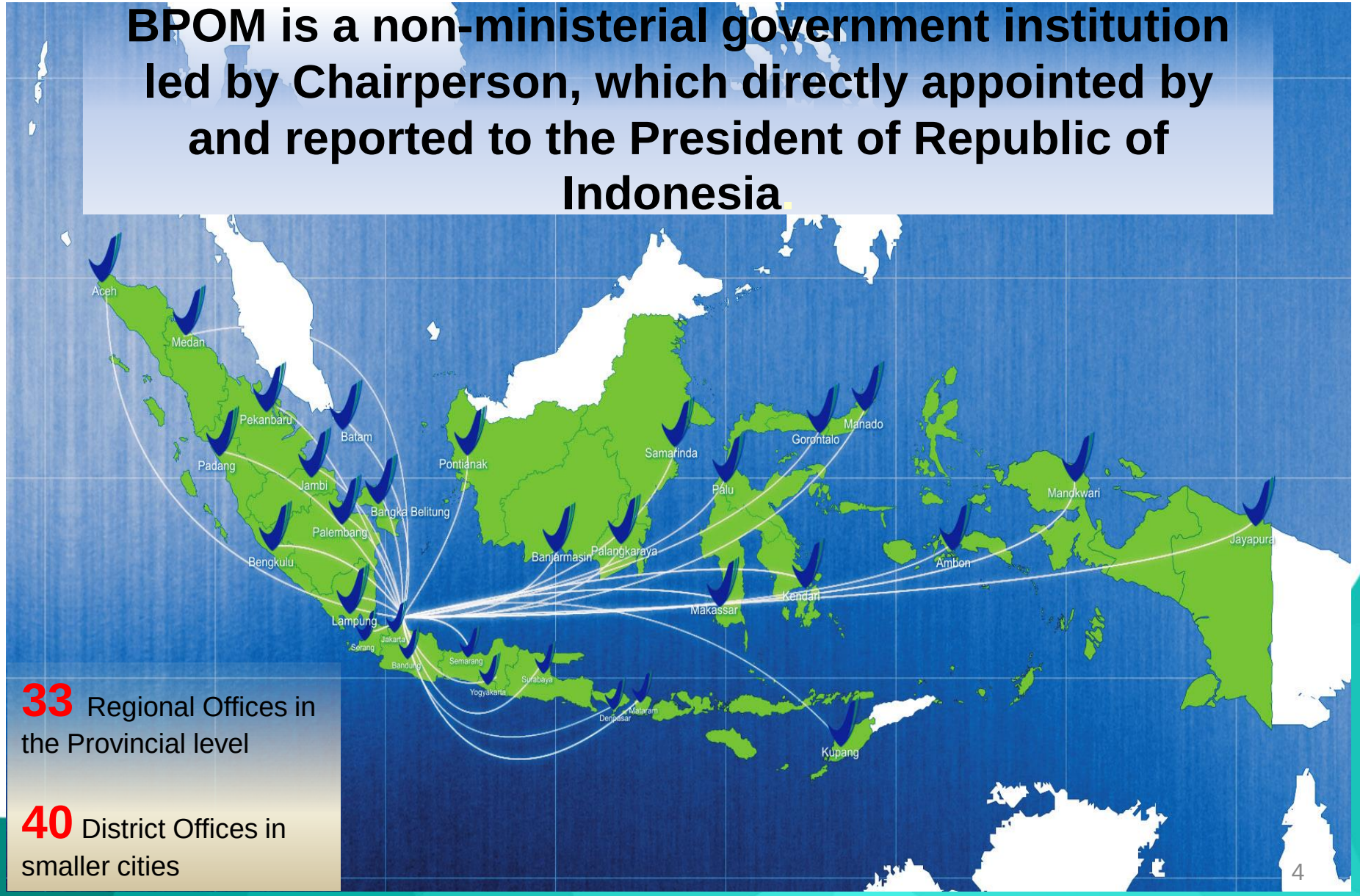
2. PRE MARKET CONTROL
3. POST MARKET CONTROL
4. FACILITATION FOR PHARMA INVESTMENT
5. CONCLUSION

INTRODUCTION

BPOM is a non-ministerial government institution led by Chairperson, which directly appointed by and reported to the President of Republic of Indonesia



33 Regional Offices in the Provincial level

40 District Offices in smaller cities

Legal Framework

- **Presidential Decree no 80/2017 regarding BPOM to strengthen BPOM's regulatory function in law enforcement.**
- **Presidential Instruction no 3/2017 regarding the Drug and Food Control Effectiveness Improvement.**

- **Regulation of the Head of the NADFC no. 26/2017 on the organization and business process of NADFC**
- **Regulation of the Head of the NADFC no. 11/2018 on Classification Criteria of Technical Implementation Unit in NADFC**
- **Regulation of the Head of the NADFC no. 12/2018 on Organization and Technical Implementation Unit in NADFC**

Vision and Mission

Our Vision

To provide safe food and medicine to improve public health and national competitiveness

Our Mission

- **Strengthening Risk-based Drug and Food Control System to Protect Public Health.**
- **Encouraging Self Reliance of Business Actors in Ensuring Drug and Food Safety and Strengthening Partnership with Stakeholders.**
- **Enhancing NADFC Institutional Capacity.**

ORGANIZATIONAL STRUCTURE
(as Chairperson of BPOM Regulation No 26/2017)

BPOM Chairperson

Permanent Inspector (RS)

- Inspector I
- Inspector II

Permanent Secretary (RS)

- Bureau of Planning and Finance
- Bureau of Legal and Organization
- Bureau of Cooperation
- Bureau of General Affairs and Human Resources
- Bureau of Public Relation and Strategic Support

Deputy for Drug, Narcotic, Psychotropic, Precursor, Addictive Substance Control

- (RS) Directorate of Drug, Narcotic, Psychotropic, Precursor, Addictive Substance Standardization
- (MA, CT) Directorate of Drug Registration
- (LI, RI) Directorat of Drug, Narcotic, Psychotropic, Precursor Production Control
- Directorat of Drug, Narcotic, Psychotropic, Precursor Distribution and Service Control
- (MC, VL) Directorat of Safety, Quality, and Export-Import of Drug, Narcotic, Psychotropic, Precursor, Addictive Substance Control

Deputy for Traditional Medicine, Health Supplement and Cosmetic Control

- Directorate of Traditional Medicine, Health Supplement and Cosmetic Standardization
- Directorate of Traditional Medicine, Health Supplement and Cosmetic Registration
- Directorate of Traditional Medicine, and Health Supplement Control
- Directorate of Cosmetic Control

Deputy for Processed Food Product Control

- Directorate of Processed Food Standardization
- Directorate of Processed Food Registration
- Directorate of Low Risk Processed Food Control
- Directorate of High Risk and New Technology of Processed Food Control
- Directorate of Community and Industries Empowerment

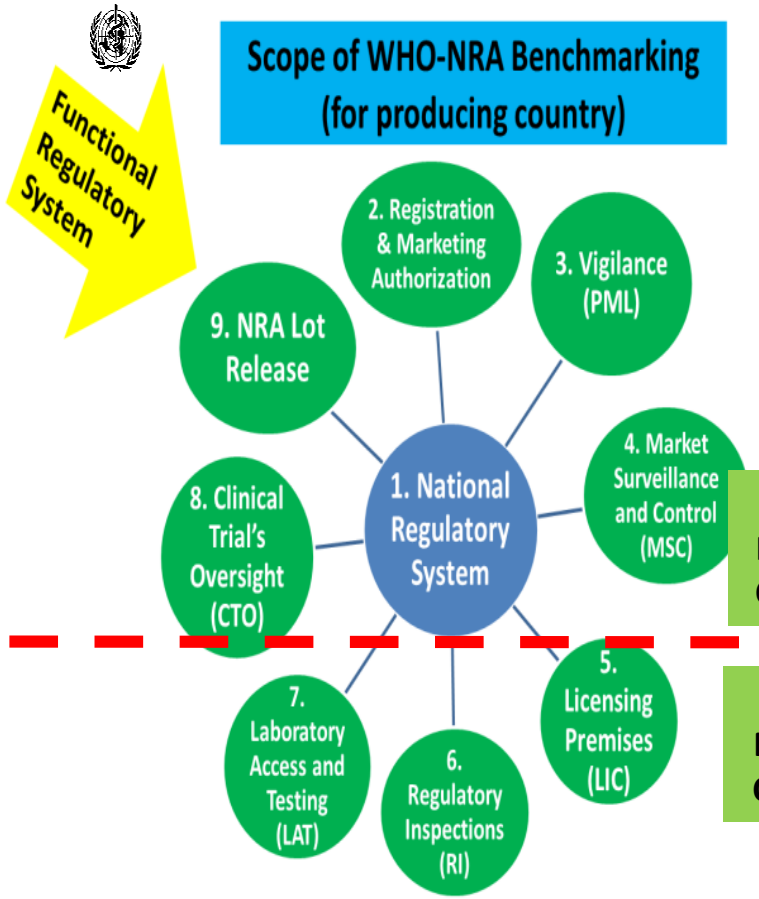
Deputy for Law Enforcement

- Directorate of Pacification
- Directorate of Drug and Food Intelligence
- Directorate of Drug and Food Investigation

Provincial Offices

- Center of Drug and Food Information
- Center of Human Resources Development
- (LA, LR) Center of National Quality Control Development of Drug and Food
- Center of Drug and Food Research and Studies

Drug Regulatory Framework in Indonesia



Pre Market Control

Drug Development & Establishment of Manufacturing Facility

- IND regulatory system
- Clinical Trial Authorization
- GCP Inspection

- Manufacturing facility's certification
- GMP certification & inspection

Marketing Authorization

Drug evaluation system for MA

Post Market Control

Post Marketing Surveillance & Control

Regulatory inspections (GMP & GDP)

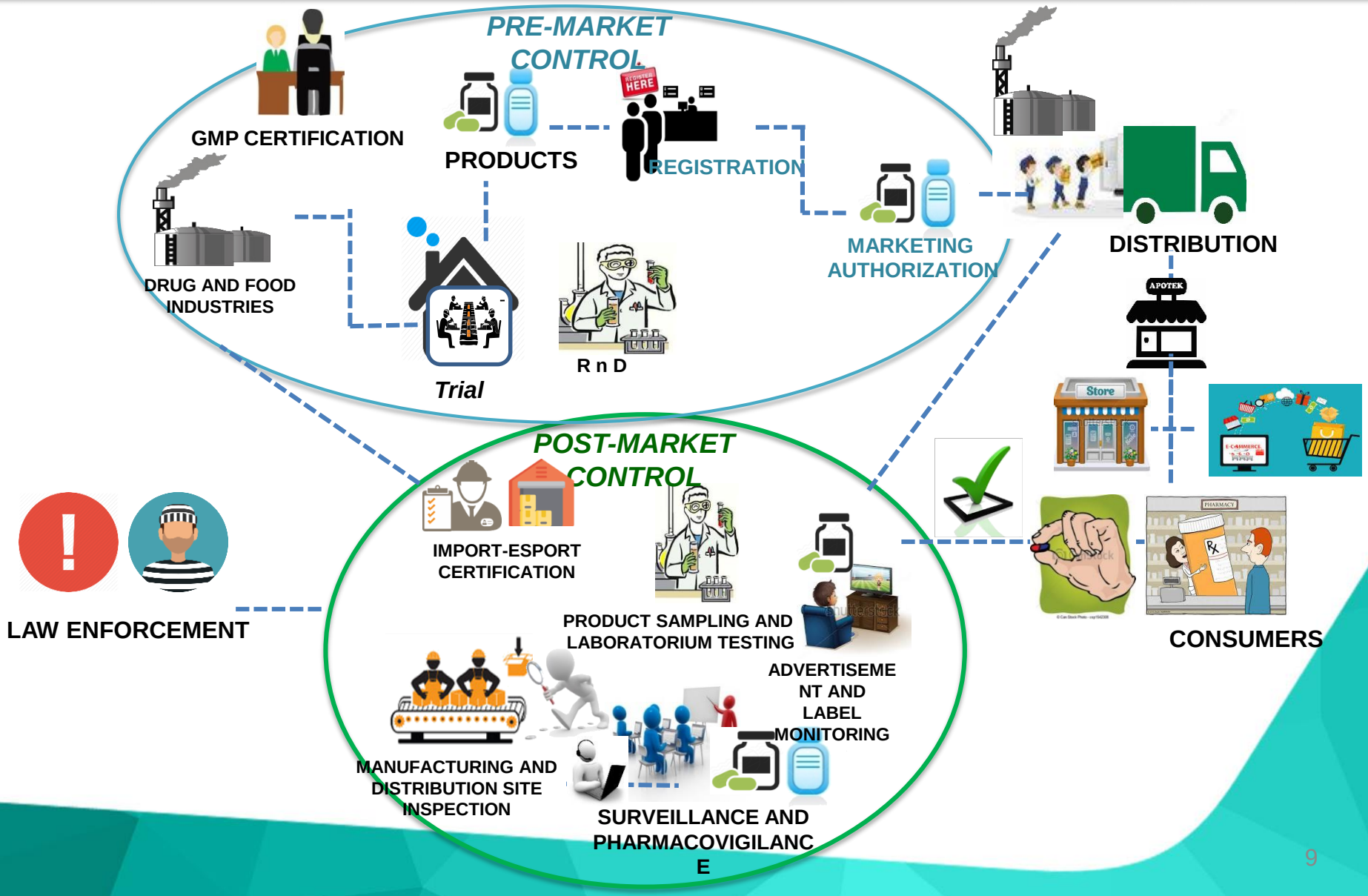
Post Market Sampling & Laboratory Access

Pharmacovigilance

Lot release (Vaccine & biologics)

Drug labelling & advertisement control

FULL SPECTRUM OF DRUG AND FOOD CONTROL



Pre Market Control

Legal Basis

1. Health Law No 36/2009,
2. MoH Decree No. 1010/2008 on Drug Registration
3. Regulation of the Head of NADFC No. 24/2017 on Criteria and Drug Registration Procedure

All medicines marketed in Indonesia should be applied for registration to obtain Marketing Authorization.

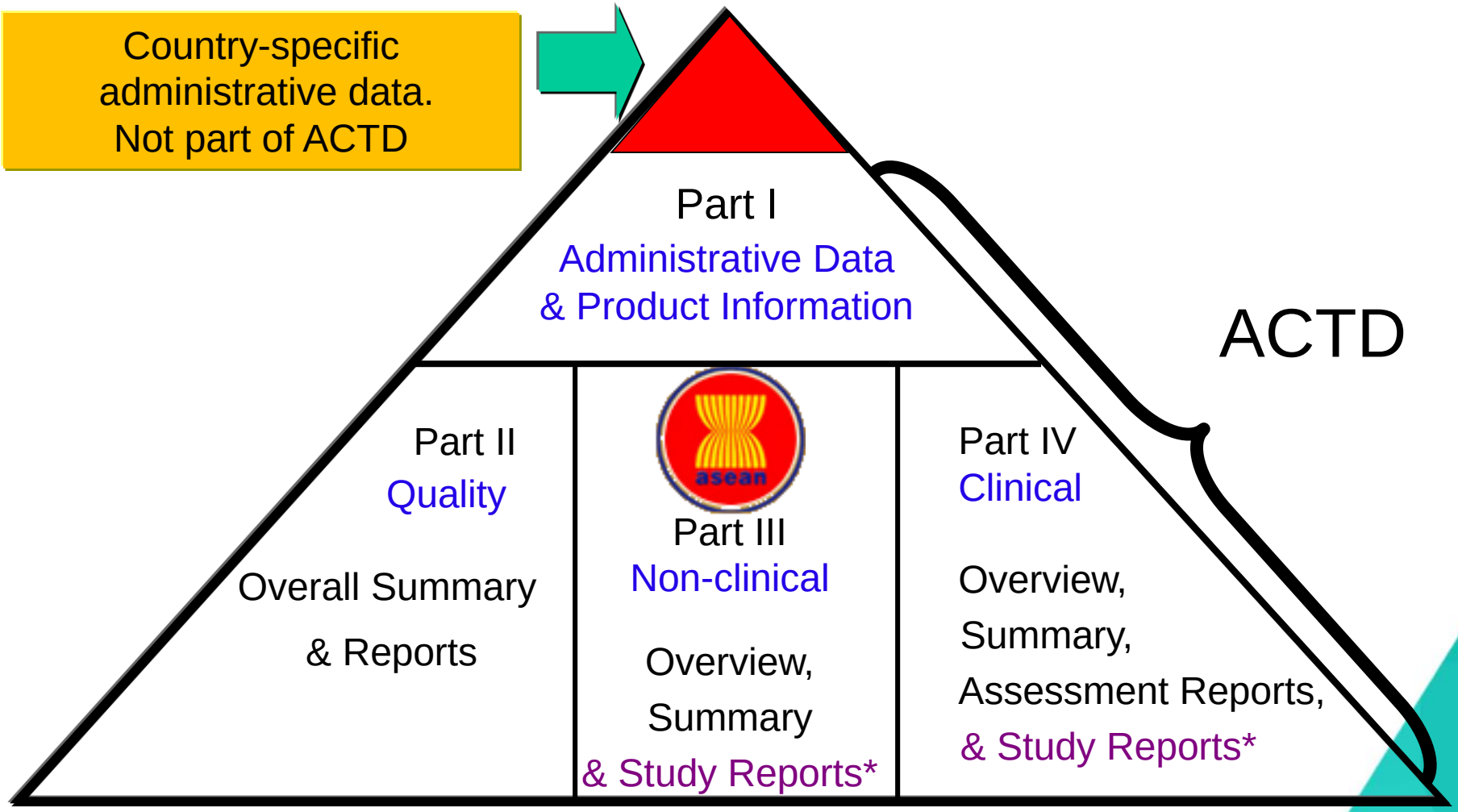
BADAN POM (NADFC)

- **Registration of Medicines**

Objective:
Public protection towards un-expected risk medicines by providing assurance on the quality, safety and efficacy of medicinal product marketed in Indonesia.

DOSSIER Format-in line with ACTD

Country-specific administrative data. Not part of ACTD



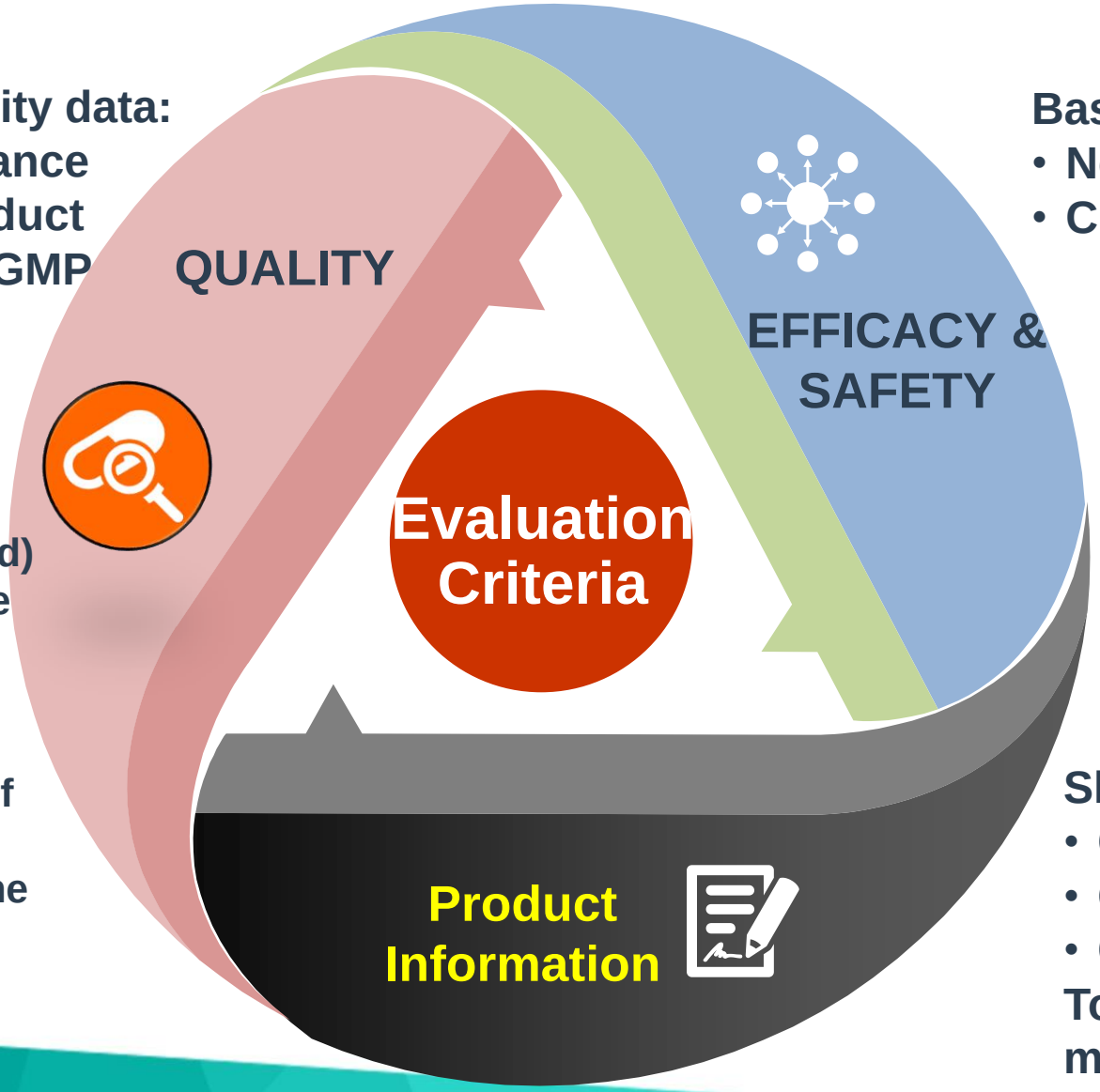
* Upon Request

Criteria On Drug Evaluation (Risk Based Assessment)

Based on Quality data:
- **Active substance**
- **Finished product**

Comply with cGMP

Based on:
- **Nonclinical studies**
- **Clinical studies**



Onsite (if needed)
- **To ensure the validity of information written in documents of Quality**
- **To support the quality of products**

Should be:
- **Complete**
- **Objective**
- **Clear**

To ensure rational medicine use

Flowchart of Drug Registration

DRUG REGISTRATION PROCEDURE

Decree of the Head of the National Agency of Drug and Food Control No.24 of 2017 on Criteria and Procedure for Drug Registration

TIMELINESS

Additional data required

Applicant

Registration Dossier Screening

Review Process: Efficacy, Safety, And Quality

Decision Making

Finalization: Labelling and Licensing

APPROVAL

Post-Approval Changes

- Scientific and Evidence Based
- Identify , measure and evaluate safety & efficacy
- Quality control of product and production process
- Inspection of Manufacturing Facility
- Risk vs benefit assessment

evaluation approach

Registration Category

- New Drugs or Biological Products (including Biosimilars)
- Generic Drugs
- Other Dosage Form with New Technology

→ New Registrations

- Major Variation
- Minor Variation
- Notification

→ Variation Registrations

- Renewal

Registration Pathway (1)

7 WD

- Registration of Drug for export only

10 WD

- Renewal Registration (without any variations)

40 WD

- Registration for Minor variation

100 WD

- Drug and biological products used for life threatening diseases which the medication is unavailable
- Orphan drug or biological products
- Drug or biological product for national program;
- drug or biological product which the development and clinical trials in Indonesia
- Generic drugs with the same quality as branded generic drugs that have been marketed
- Major variation of new indication/posology for the drugs category of 100 WD mentioned above (bullets 1-4)
- Major variation (except indication/posology)

PROCEDURE TO REGISTER DRUG IN INDONESIA

Decree of the Head of the National Agency of Drug and Food Control No. 24 of 2017

Registration Pathway (2)

120 WD

- Drug or Major variation, i.e. new indication/posology, which has been approved in 3 countries which have well established evaluation system

150 WD

- Generic and branded generic drugs which are not included in 100 WD

300 WD

- New drugs or biological products or major variation which are not included in path 100WD and 120WD category

PROCEDURE TO REGISTER DRUG IN INDONESIA

Decree of the Head of the National Agency of Drug and Food Control No. 24 of 2017

Validity of Marketing Authorization

5 Years

Exception for License & Contract Manufacturing product

Can be extended through Renewal registration mechanism

CRITERIA FOR IMPORTED DRUG

Drugs for public health program

✓**Based on decision by Health program.**

✓**New innovated drugs**

✓**Under patent protection**

✓**Originator drugs**

Drugs which are needed but not feasible to be produced locally

- ✓Manufacturing technology & facility not available in Indonesia
- ✓Manufacturing capacities insufficient to fulfill national need
- ✓Economically not feasible to be produced in Indonesia due to low need (i.e Orphan drugs)
- ✓Produced through centralized system by foreign pharmaceutical industry which has invesment in Indonesia, supported by balance of import and export activity-

REQUIREMENT FOR IMPORTED DRUG

Applicant

✓Pharmaceutical Industries in Indonesia having written authorization from the manufacturer abroad.

•**Manufacturer**

✓**Have manufacturing Licence and meet GMP requirement as proven by :**

- Valid GMP Certificate
- Data of last inspection within the last 2 years

✓**Submit latest Site Master File (SMF) document, if :**

- The manufacturer has not had any product with the same dosage form authorized to be marketed in Indonesia
- The manufacturer has product with the same dosage form authorized to be marketed in Indonesia, but there is a change of production facilities.

Site Inspection

✓If SMF evaluation results requires evidence of compliance to GMP, site inspection will be conducted**.**

Indonesian Facilitation for Pharmaceuticals Investment

BADAN POM

PRESIDENTIAL REGULATION NO. 44 OF 2016 ABOUT THE LIST OF CLOSED BUSINESS FIELD AND OPENED BUSINESS FIELD BY REQUIREMENT IN THE INVESTMENT SECTOR

NEGATIVE INVESTMENT LIST

OPEN FOR DIRECT FOREIGN INVESTMENT (FDI)

Business Field	Condition	Incentives	
		Import Duty	Tax Allowance
Pharmaceutical industry	A maximum of 85% foreign ownership	☆	
Pharmaceutical Raw Material Industry	100% FDI	☆	☆
Distributors are affiliated with the production	100% FDI	☆	
Distributors are not affiliated with the production	67% FDI	☆	

Pharmaceutical Raw Material Industry Can Be Obtained Tax Allowance (Product Coverage: The Compound Derivatives Of Statins, The Amino Phenol, Cephalosporin, Rifampicin, Chloramphenicol and Derivates, Amoxicillin, Ampicillin, Vitamin A, Vitamin B, Vitamin C, Pharmaceutical Raw Materials Obtained By Biotechnological Processes, Paracetamol, Pseudoephedrine, Lactose, Folic Acid, Acetosal, Anaesthesin).

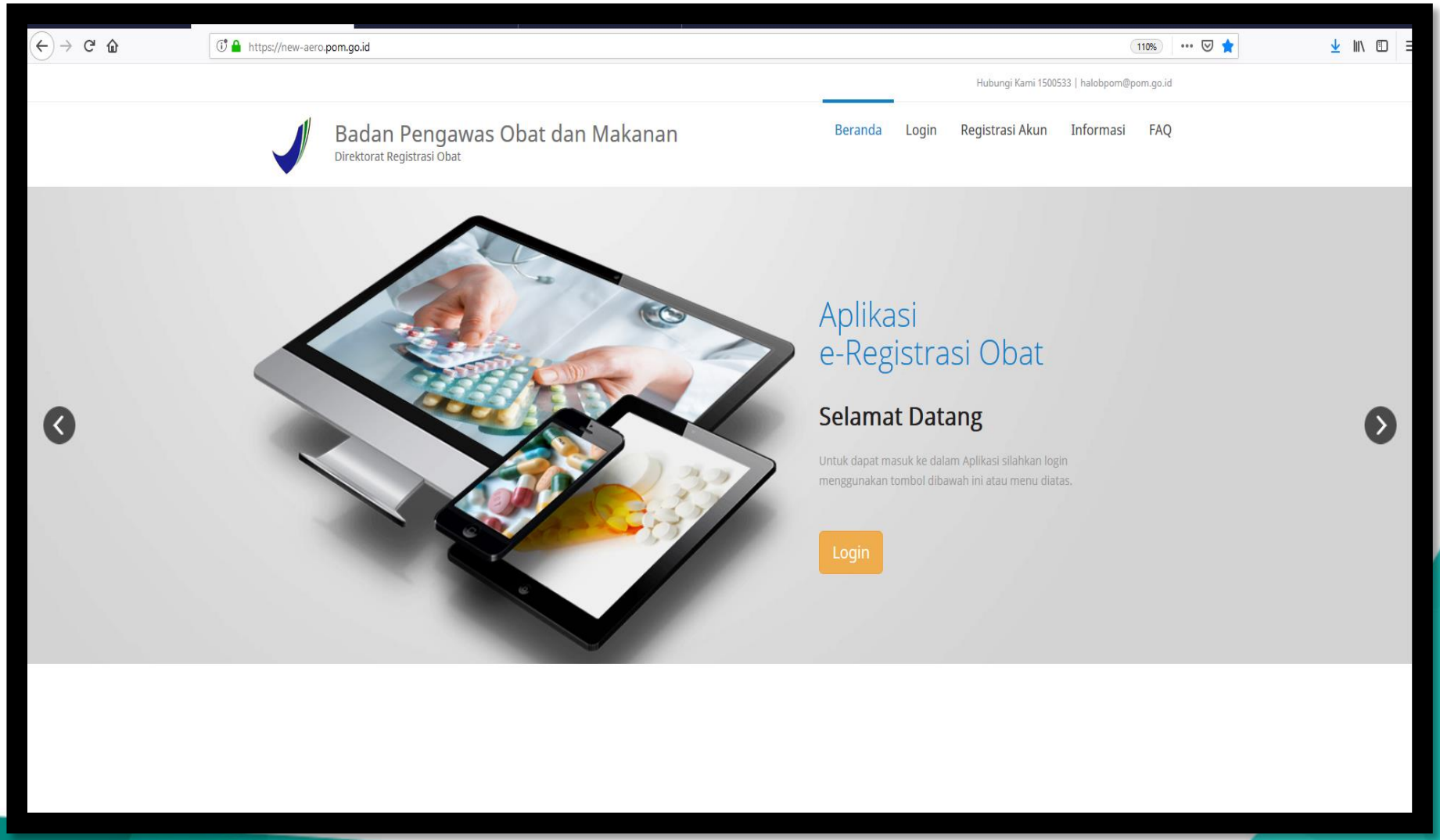
Source : *himawan, indonesia investment coordinating board, 2017

Indonesian Facilitation for Pharmaceuticals Investment : **Online Single Submission Service (OSS)**

Government Regulations Decree No 24 in 2018 concerning Online Single Submission Service (OSS), a new licensing system to accelerate the licensing procedure so that the ease of doing business in Indonesia will improve through an integrated online system

To supports the regulation, The head of NADFC issued Regulation Head of NADFC Decree No 26 in 2018 of Online Single Submission Service in Pharmaceutical and Food Sector, which provide **fast tract** and is allowing **parallel process** for GMP submission for first drug registration for new pharmaceutical company which makes investation in Indonesia

Online Registration



POST MARKET CONTROL

POSTMARKET CONTROL (1)

Safety aspects :

Monitoring of Adverse Drug Reactions /Pharmacovigilance

- **Quality aspect:**
- **Inspection on GMP:**
- to ensure that the drug products are consistently manufactured according to standard of Q requirement.
- **Inspection on GDP :**
- to ensure that the drug products are distributed in expedited manner to provide its accessibility for the patients.
- **Sampling, Laboratory testing**

Monitoring of labelling, adverstising and other promotional activities

FACILITATION FOR PHARMA INVESTMENT

FACILITATION FOR PHARMA INVESTMENT

- Indonesia's President has issued an Instruction Number 6 of 2015 on the Acceration of Pharmaceutical and Medical Device Industries's Development, reflecting Indonesia's Goverment seriousness in supporting ease of doing bussiness in Indonesia to attract foreign investment.
- Indonesia supports and welcomes any foreign investment opportunities, including from India in the field of Pharmaceutical Active Ingridients and Pharmaceutical Products in Indonesia.
- This commitment was also conveyed by our President at the meeting with India's Prime Minister on January, 2018 and followed up by the Head of NADFC visiting India on March 2018 and made MoU with Central Drugs Standard Control Organization (CDSCO) at May 28th, 2018.
- Indonesian government issued Government Regulations No 24 in 2018 concerning Online Single Submission Service (OSS), a new licensing system to accelerate the licensing procedure so that the ease of doing business in Indonesia will improve through an integrated online system.
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CONCLUSION

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- Drug registration is one form of pre-market evaluation to ensure safety, efficacy and quality of marketed drugs.
- The Goverment of Indonesia has a strong commitment to continuously improving investment's climate for a sustained pharmaceutical industries development in Indonesia.

Terima Kasih

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