“AN OVERVIEW OF THE DRUG REGULATORY SYSTEM IN INDONESIA”

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Outline

1. INTRODUCTION
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
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
- Inspector I
- Inspector II

Deputy for Drug, Narcotic, Psychotropic, Precursor, Addictive Substance Control
- Directorate of Drug, Narcotic, Psychotropic, Precursor, Addictive Substance Standardization
- Directorate of Drug Registration
- Directorate of Drug, Narcotic, Psychotropic, Precursor Production Control
- Directorate 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

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

Provincial Offices

Center of Drug and Food Information
Center of Human Resources Development
Center of National Quality Control Development of Drug and Food
Center of Drug and Food Research and Studies
FULL SPECTRUM OF DRUG AND FOOD CONTROL

PRE-MARKET CONTROL
- GMP CERTIFICATION
- PRODUCTS
- REGISTRATION
- MARKETING AUTHORIZATION
- DISTRIBUTION
- DRUG AND FOOD INDUSTRIES
- R & D
- TRIAL

POST-MARKET CONTROL
- IMPORT-ESPORT CERTIFICATION
- PRODUCT SAMPLING AND LABORATORIUM TESTING
- MANUFACTURING AND DISTRIBUTION SITE INSPECTION
- SURVEILLANCE AND PHARMACOVIGILANCE
- LAW ENFORCEMENT
- ADVERTISEMENT AND LABEL MONITORING
- CONSUMERS
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

Part I
Administrative Data & Product Information

Part II
Quality
Overall Summary & Reports

Part III
Non-clinical
Overview, Summary & Study Reports*

Part IV
Clinical
Overview, Summary, Assessment Reports, & Study Reports*

* Upon Request
Based on Quality data:
- Active substance
- Finished product
Comply with cGMP

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

Based on:
- Nonclinical studies
- Clinical studies

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

1. Applicant
   - Registration Dossier Screening
2. Review Process: Efficacy, Safety, and Quality
   - Scientific and Evidence Based
   - Identify, measure and evaluate safety & efficacy
   - Quality control of product and production process
3. Decision Making
   - Inspection of Manufacturing Facility
   - Risk vs benefit assessment
4. Finalization: Labelling and Licensing
   - Additional data required
5. Post-Approval Changes
   - Evaluation approach

Approval
Registration Category

New Drugs or Biological Products (including Biosimilars)

Generic Drugs

Other Dosage Form with New Technology

Major Variation

Minor Variation

Notification

Renewal

New Registrations

Variation Registrations
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
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 investment 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

**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)

<table>
<thead>
<tr>
<th>Business Field</th>
<th>Condition</th>
<th>Import Duty</th>
<th>Tax Allowance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical industry</td>
<td>A maximum of 85% foreign ownership</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical Raw Material Industry</td>
<td>100% FDI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distributors are affiliated with the production</td>
<td>100% FDI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distributors are not affiliated with the production</td>
<td>67% FDI</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Source: *himawan, indonesia investment coordinating board, 2017*
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 track and is allowing parallel process for GMP submission for first drug registration for new pharmaceutical company which makes investment in Indonesia.
Online Registration
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, advertising and other promotional activities
FACILITATION FOR PHARMA INVESTMENT
Indonesia’s President has issued an Instruction Number 6 of 2015 on the Acceleration of Pharmaceutical and Medical Device Industries’s Development, reflecting Indonesia’s Government seriousness in supporting ease of doing business in Indonesia to attract foreign investment.

Indonesia supports and welcomes any foreign investment opportunities, including from India in the field of Pharmaceutical Active Ingredients 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.

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CONCLUSION
• Drug registration is one form of pre-market evaluation to ensure safety, efficacy and quality of marketed drugs.

• The Government of Indonesia has a strong commitment to continuously improving investment's climate for a sustained pharmaceutical industries development in Indonesia.
Terima Kasih
धन्यवाद

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