Presented by
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MINISTRY OF HEALTH REPUBLIC OF INDONESIA

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UPDATES OUTLINE

Background

Medical Device Regulation in Indonesia

National Medical Devices Policy

Indonesia Regulation System for Medical Devices
INDONESIA: Gateway to ASEAN
UNIVERSAL COVERAGE

- Medicines
- Medical Devices

- Important component in the healthcare system
- Tightly related with technology and economy
- One of trade commodity and social need

UNIVERSAL COVERAGE
1 Jan 2014

- Quality
- Cost
INDONESIA MEDICAL DEVICE OVERVIEW

- Population > 240.000.000
- Human Dev. Index = 0.6 (medium)
- GDP per capita = $ 3.015
- Medical Devices Manufactures = 234
- Medical Devices Suppliers > 800
- Registered Medical Devices (2011)
  - Import = 37.851 items
  - Local = 3.872 items
- Market values for medical device (2011) : USD 780 m

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Ministry of Health of Republic Indonesia
LEGAL BASIS REGULATION

1. Act on health
2. Gov. Regulation: Law enforcement
3. MoH: Production
4. MoH: Distribution
5. MoH: Registration of Medical Devices and Household Production
Ensure the safety, quality and effectiveness of medical devices

Ensure the availability of medical device technology and the use of appropriate and affordable

Protect the public against the risk of misuse and abuse of medical devices

**PRODUCT**

**REGULATION**

**USE**

**HEALTH TECHNOLOGY MANAGEMENT**

**PREMARKET CONTROL**

**POSTMARKET CONTROL**

**NEED ASSESSMENT**

**PROCUREMENT**

**USER**

**MAINTENANCE**

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## GOALS OF THE REGULATORY SYSTEM IN INDONESIA

<table>
<thead>
<tr>
<th>Goal</th>
<th>Description</th>
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<tr>
<td>Risk Based Approach</td>
<td>Both product risk and compliance risk can be managed by premarket activities and post market activities</td>
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<tr>
<td>ASEAN HARMONIZATION</td>
<td>Indonesia which one of ASEAN members economies will have the same vision to achieve the ASEAN Economy Society</td>
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<td>International Standard</td>
<td>Indonesia as one of world Nation, has the same standard of quality that use in global harmonization regulation</td>
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<td>Transparency and excellent service</td>
<td>One of the priority of Indonesian Health reformation is strengthen the public service</td>
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PREMARKET CONTROL

- For registration requirement, Indonesia has adopted:
  1. Common Submission Dossier Template CSDT
  2. ISO 13485 for Quality Management System
  3. National and International Standard for ensuring the safety, quality and effectiveness of medical device

- Validity of registration number: 5 years

- All classification of medical device must get registration number before entering the Indonesia territory.

- Spare part and accessories, is not required to be registered

- All accessories of the product will attached in registration number in order to simplify the custom release
Example for Registration License

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Directorate General of Pharmaceutical and Medical Device Service

Example for Registration License

Name of Product: ROHTO Eye Fields Lotion
SS Code: 902 14 03 09
Category: Eye Drops
Sub Category: Medical Eyewax
Dosage Form: Solusli Eyewax
Packaging: Box containing 12 bottles of 10 ml
Place of Manufacture: PT. ROHTO LABORATORIES INDONESIA, PADJADJARAN
Name of Distributor: PT. ROHTO LABORATORIES INDONESIA, PADJADJARAN
Order-Limit from Distributor:

Rules and Regulations:
1. If the applicant fails to comply with the provisions of the regulations, the license will be revoked.
2. If the applicant fails to comply with the provisions of the regulations, the license will be revoked.

Drs. Haryanto, M.M., M.M.
M.F.: 10910011 10901 2001

Obviously described
Example for Attachment Accessories or Type Registration License

MINISTRY OF HEALTH OF THE REPUBLIC OF INDONESIA
DEPARTMENT OF HEALTH CARE AND MEDICAL DEVICES

Example for Attachment Accessories
or Type Registration License

Example for Attachment Accessories
or Type Registration License

Obviously described
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<table>
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<tbody>
<tr>
<td>1.</td>
<td>Registration number</td>
</tr>
<tr>
<td>2.</td>
<td>Name of Product</td>
</tr>
<tr>
<td>3.</td>
<td>Generic Name of Product</td>
</tr>
<tr>
<td>4.</td>
<td>Type/ size</td>
</tr>
<tr>
<td>5.</td>
<td>Name &amp; Address Manufacturer</td>
</tr>
<tr>
<td>6.</td>
<td>Name &amp; Address Distributor</td>
</tr>
<tr>
<td>7.</td>
<td>Tax Number</td>
</tr>
<tr>
<td>8.</td>
<td>HS Code Number</td>
</tr>
<tr>
<td>9.</td>
<td>Release date</td>
</tr>
<tr>
<td>10.</td>
<td>Expired date</td>
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<tr>
<td>11.</td>
<td>Country of origin</td>
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Obviously described
Indonesia national single window

- National Single Window (NSW) is a national system that will integrate all entities which related to customs release and clearance of cargoes with the aim of accelerating the settlement process of import-export services and increased effectiveness and performance of traffic handling import-export goods.

Indonesia Trade Repository

- repository contains trade rules and regulations through the existing Indonesian National Single Window (INSW) portal. The information in INTR are about HS code, regulation issued by Government Authority's related to import or export permit license, exchange rates, rules of origin and also trade simulation.

Single Sign On

- Is a facility to provide users with single and simultaneous access to INSW and licensing systems.
- Once logged in to the system, users do not have to log in to other INSW-affiliated systems (once signed-in, multiple access)

www.eservice.insw.go.id
E-REGISTRATION FOR MEDICAL DEVICE

BACKGROUND

- Wide area of Indonesia territory
- Optimize public service
- Quick registration system and can be accessed anywhere

http://regalkes.depkes.go.id

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FEATURES In E-REGISTRATION

- Registration Number
- Production License
- Distributors License

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Who can distribute Medical Device in Indonesia?

Company which have Distribution license issued by MOH

DISTRIBUTOR

- Good Distribution Practice

A routine assessment for all Distributors by MOH
POST MARKET CONTROL

SAMPLING
- A routine activity to taking sample from market and then testing it to laboratory for compliance check

MONITORING
- A routine activity to audit the production and distribution facilities compliance with Quality System standard

VIGILANCE
- A program activity for Adverse event report

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Post Market Surveillance

PMS should be supported by strict law enforcement.

To control the PMS, MOH have government Civil police Investigator for medical devices who works together with Hospital/Healthcare facilities, police, custom and Health province officer.
THANK YOU / 谢谢