ASIAN HARMONIZATION WORKING PARTY

INDONESIA

UPDATED MEDICAL DEVICE REGULATION

Presented by

ARIANTI ANAYA

Director of Medical Device Production and Distribution Service

MINISTRY OF HEALTH REPUBLIC OF INDONESIA

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TICC – Taipei,
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UPDATES OUTLINE

- Background
- Medical Device Regulation in Indonesia
- National Medical Devices Policy
- Indonesia Regulation System for Medical Devices

Directorate General of Pharmaceutical and Medical Device Service
Ministry of Health of Republic Indonesia

INDONESIA:
Gateway to ASEAN

UNIVERSAL COVERAGE

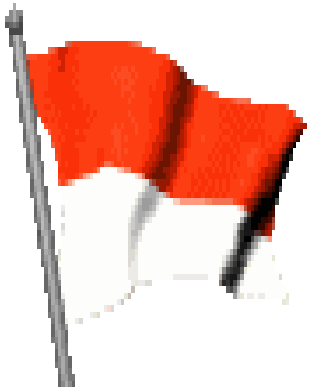
- Medicines
- Medical Devices

UNIVERSAL COVERAGE 1 Jan 2014

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

✓Quality
✓Cost

ASIAN HARMONIZATION WORKING PARTY



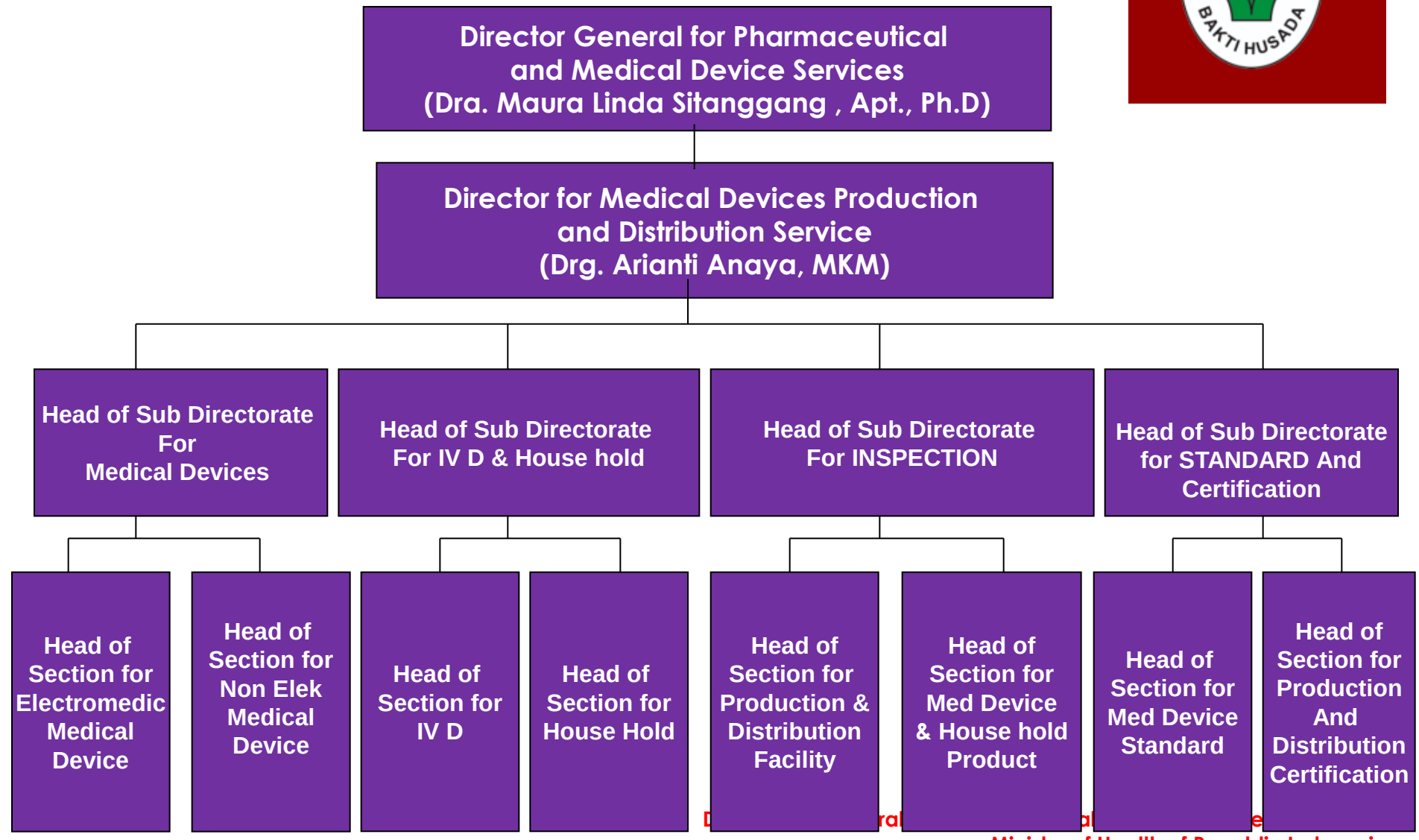
INDONESIA MEDICAL DEVICE OVERVIEW

- 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

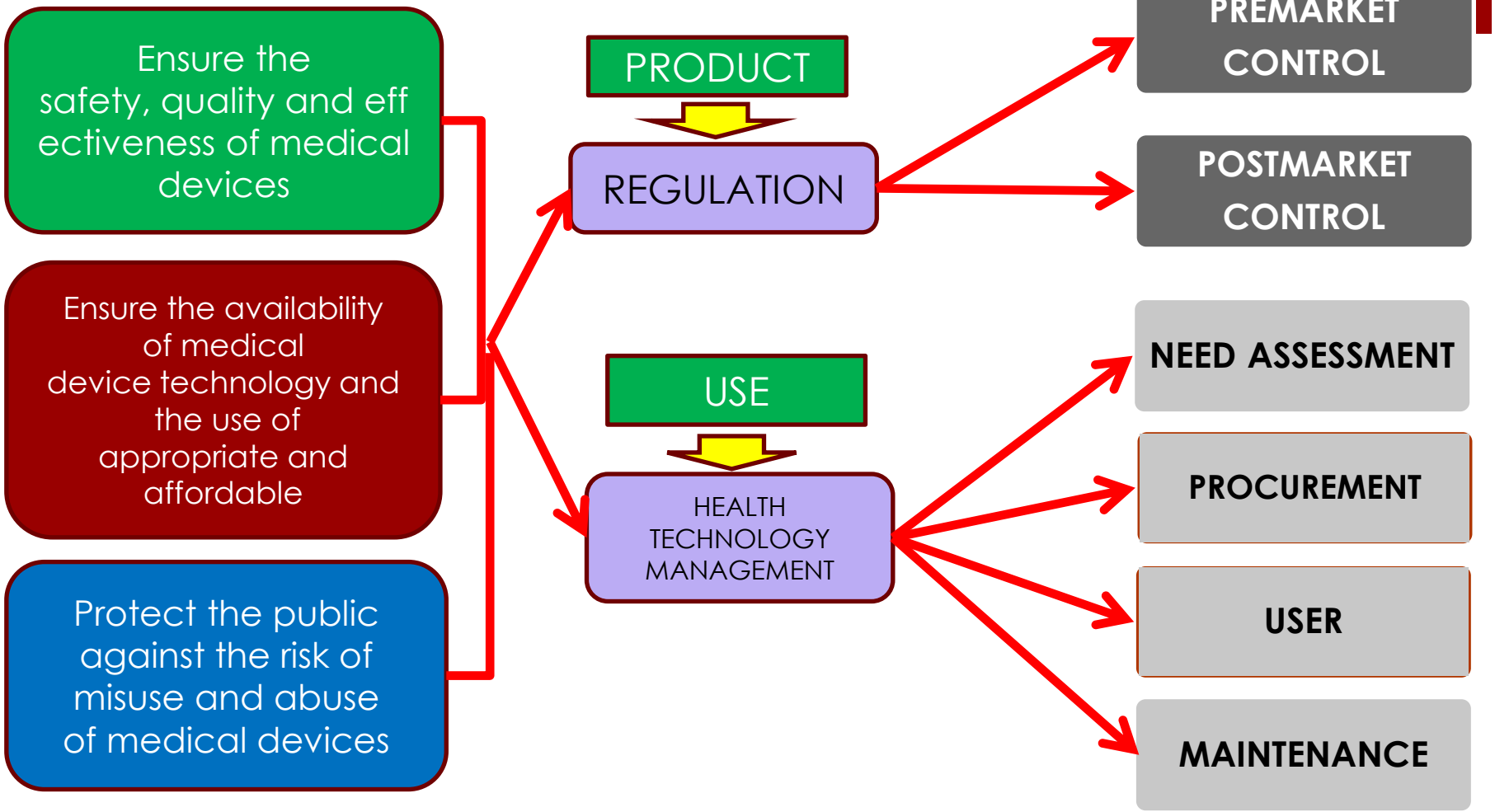
LEGAL BASIS REGULATION

1. Act on health
2. Gov. Regulation: Law enforcement
3. MoH: Production
4. MoH: Distribution
5. MoH: Registration of Medical Devices and House Hold Production

ORGANIZATIONAL STRUCTURE



NATIONAL MEDICAL DEVICE POLICY



Directorate General of Pharmaceutical and Medical Device Service
Ministry of Health of Republic Indonesia

GOALS OF THE REGULATORY SYSTEM IN INDONESIA

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

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

MINISTRY OF HEALTH OF THE REPUBLIC OF INDONESIA
DIRECTORATE GENERAL OF PHARMACEUTICAL AND MEDICAL DEVICES DEVELOPMENT
Jl. H. R. Rasuna Said Blok X5 Kavling No. 4-9 Jakarta 12950
Phone: +6221-5201590 (Hunting) Facsimile: +6221-52964838 Po BOX 203

In accordance with:

The Regulation of The Minister Health Of The Republic Of Indonesia No. 1190/Menkes/Per/VIII/2010 dated August 23, 2010 regarding Medical Devices and Household Products Registration License

Hereby given the marketing licence under:

NUMBER OF REGISTRATION LICENSE
MEDICAL DEVICE

KEMENKES RI AKL 20502214455

Name of Product	:	**ROHTO Neo Eye Foldable Lens**
Generic Name	:	Intraocular Lens
HS Code	:	9022.14.00.00
Category	:	Eye Device
Sub Category	:	Prosthetic Eye Device
Type/Size	:	RF-22L/ Dioptre +4 s/d +40
Packaging	:	Box Containing Lens Holder @ 1 Lens
Name of Manufacturer	:	PT. ROHTO LABORATORIES INDONESIA, PADALARANG
Name of Distributor	:	PT. ROHTO LABORATORIES INDONESIA, PADALARANG
Under License from	:	-
Stipulation	:	1. This registration license is valid within ..... 2. Submit the periodical report every 1 (one) year concerning type and side effect of the marketing products is an obligation
Rules and Regulations	:	1. if on the other day there is another party who has a right upon the above agency appropriate with the valid regulation, the agency should be willing to release of the distributor authorization for the product. 2. if on the other day there is any fault, this license will be reviewed.

Jakarta, ..., 20....

On behalf of Director General,
Director for
Medical Device Production and Distribution Development,

Dra. Nasirah Bahaudin, Apt., MM
NIP. 19531031 198501 2 001

Example for Attachment Accessories or Type Registration License

MINISTRY OF HEALTH OF THE REPUBLIC OF INDONESIA
DIRECTORATE GENERAL OF PHARMACEUTICAL AND MEDICAL DEVICES DEVELOPMENT
Jl. H. R. Rasuna Said Blok X5 Kavling No. 4-9 Jakarta 12950
Phone: +6221-5201590 (Hunting) Facsimile: +6221-52964838 PO BOX 203

Attachment

NUMBER OF REGISTRATION LICENSE
MEDICAL DEVICE
KEMENKES RI AKL 20502214455
Dated February 21, 2012

NO	TYPE	SIZE	PACKAGING BOX
1	RE-01	Diopter + 4 s/d + 40	1 piece
2	RE-02	Diopter + 4 s/d + 40	1 piece
3	RE-03PH	Diopter + 4 s/d + 40	1 piece
4	RE-04PH	Diopter + 4 s/d + 40	1 piece
5	RE-05	Diopter + 4 s/d + 40	1 piece
6	RE-06	Diopter + 4 s/d + 40	1 piece
7	RE-06F	Diopter + 4 s/d + 40	1 piece
8	RP-11	Diopter + 4 s/d + 40	1 piece
9	RP-12	Diopter + 4 s/d + 40	1 piece
10	RP-13	Diopter + 4 s/d + 40	1 piece
11	RJ-51	Diopter + 4 s/d + 40	1 piece
12	RJ-51PH	Diopter + 4 s/d + 40	1 piece
13	RA-15	Diopter + 4 s/d + 40	1 piece
14	RA-25	Diopter + 4 s/d + 40	1 piece
15	RA-25	Diopter + 4 s/d + 40	1 piece

Number of Registration License of Medical Device only valid for Type, Size, and Packaging are listed in this attachment.

Jakarta, ……., 20….

On behalf of Director General,
Director for
Medical Device Production and Distribution Development,

Dra. Nasirah Bahaudin, Apt., MM
NIP. 19531031 198501 2 001

INDONESIA NASIONAL SINGLE WINDOW

MINISTRY OF HEALTH

1. Registration number
2. Name of Product
3. Generic Name of Product
4. Type/ size
5. Name & Address Manufacture
6. Name & Address Distributor
7. Tax Number
8. HS Code Number
9. Release date
10. Expired date
11. Country of origin

INSW
CONSISTENCY | TRANSPARENCY | SIMPLICITY | EFFICIENCY
Portal Indonesia NSW

Bea Cukai
Customs

Release

Directorate General of Pharmaceutical and Medical Device Service
Ministry of Health of Republic Indonesia

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.

www.eservice.insw.go.id

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)

e-REGISTRATION FOR MEDICAL DEVICE

http://regalkes.depkes.go.id

BACKGROUND

- **Wide area of Indonesia teritory**
- **Optimize public service**
- **Quick registration system and can be acess anywhere**

e-Registration Online

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FEATURES In e-REGISTRATION

Registration Number

Distributors License

Production License

DISTRIBUTION

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
VIGILLANCE	• A program activity for Adverse event report

Post Market Surveillance

PMS should supported by strict law enforcement

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

THANK YOU / 谢谢