MEDICAL DEVICES CONTROL SYSTEM IN INDONESIA

AHWP

Chengdu, China

October 2007

INDONESIA

- Population = more than 214.000.000
- GNP = $1,110 (1999)
- Health Expenditure 1.7 % of GNP
- Life expectancy = 69,0 (2000)
- Hospital = 1,145 (2000)
- Medical Devices Manufactures = 375 (70 % Home Industry)
- Registered Medical Devices year to date :

  - Import = 22654 items
  - Local = 6274 items

Basic Regulation

1. Law of the Republik Indonesia in 1992 regarding health
2. Government regulation no. 72 in 1998, regarding the safety of pharmaceutical preparation and medical devices
3. Ministerial regulation of Health of RI no 1184/Menkes/Per/X/2004, regarding medical devices and household safety.

Medical Devices

Any instrument, apparatus, appliance, material on other article, whether used alone or in combination, including the necessary software. This proper application intended by the manufacturer for human for the purpose of.

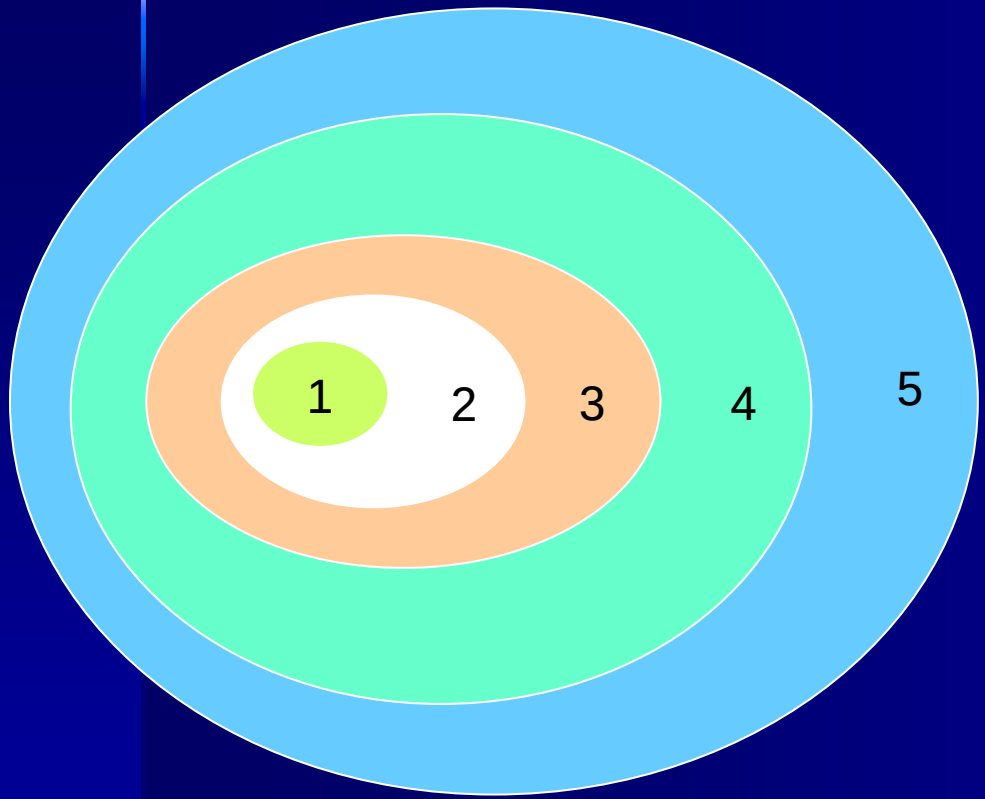
- Diagnosis, prevention, monitoring, treatment on alleviation of disease
- Diagnosis, monitoring, treatment, alleviation or compensation for injury or handicap

Medical devices.... continue

- Investigation, replacement or modification of the anatomy on of a physiological process
- Control of conception

  And which does not achieve its principal intended action in or on the human body. By pharmacological, imonological or metabolic means, but which may be assisted in its function by such means.

Scope of Medical Devices Control System



1. Production
2. Conformity assesment (registration)
3. Distribution
4. Market
5. User

Production

- Before ministerial regulation 1184
  Production Licences : - Who produce
  - Infra Structure
- After :
  Production Certificate
  - Who produce
  - How is implemented ISO 13485

Assessor

- Regulator : center and province Health officer
  We recognize what CAB done for production certificate

Distribution

Distribution licence issued by MOH.

Point to access :

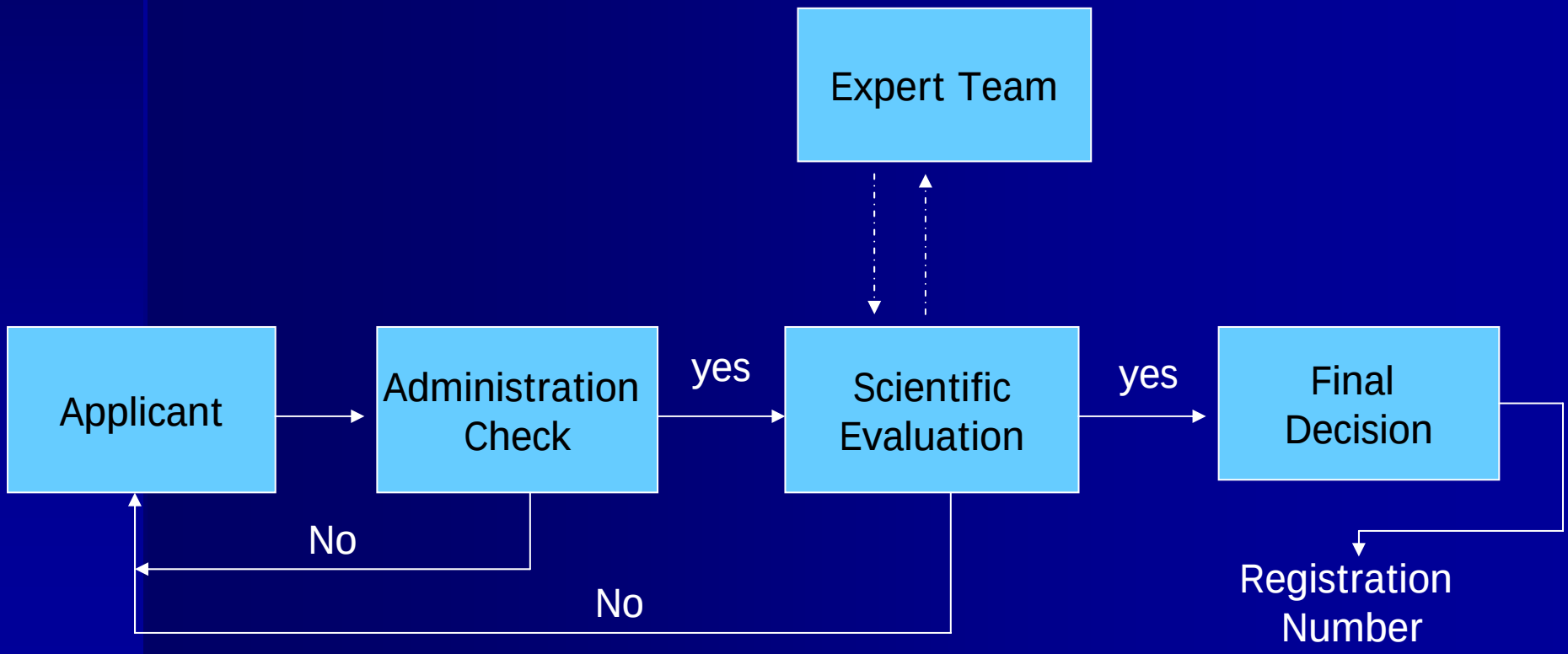
Who distribute (letter of appoitment)

- Infra structure
- Documention

Conformity Assesment (Registration)

- Applicant should have :
  - Import : Distribution licence
  - Local : Production licence
- Submit registration form

REGISTRATION PROCEDURE



Matriks of registration requirement for medical devices
base on medical devices clasification

Form	Class I	Class II (A&B)	Class III
Form A : Administration data	• Letter of authorization as a sole agent by principal • Certificate of production • Distribution licence • any administration doc. Such as : - Tax no - Location	• Letter of authorization as a sole agent by principall • Certificate of production • Distribution licence • any administration doc. Such as : - Tax no - location	• Letter of authorization as a sole agent by principal • Certificate of production • Distribution licence • any administration doc. Such as : - Tax no - location

Registration Requirment (continue)

Form	Class I	Class II (A&B)	Class III
Form B : Post Market requirement	Procedure, record sys, complaint handling	Procedure, record sys, complaint handling, adverse affect report and recall system	Procedure, record sys, complaint handling, adverse affect report and recall system

Form	Class I	Class II (A&B)	Class III
Form C : Product Information	- Objective and instruction for use - Product information. Brochure/ leaflet - component /formula qualitative - labeling	- Objective and instruction for use - Product information. Brochure/ leaflet - component /formula qualitative - labeling - Indication - contra indication - warning - attention - product description	- Product information. Brochure/ leaflet - component /formula qualitative/ quantitative - labeling - Objective and instruction for use - Indication - contra indication - warning - attention - product description - Potential adverse effect - Raw material and packaging

Form	Class I	Class II (A&B)	Class III
Form D : Conformity Statement	- Statement about conformity to standard safety – requirement and quality system	Certificate or document about : - Quality and Safety requirement (COA finish product, etc.) - Quality system - Product standard	Certificate or document about : - Quality and Safety requirement (COA finish product, etc.) - Quality system - Product standard - Quality plan - production process
From E : Distribution status	C F S	C F S Summary of the problem has been recorded	C F S Summary of the problem has been recorded

Form	Class I	Class II (A&B)	Class III
Form F : Product Safety data	none	- Summary of safety and efficacy study (II B) - Sterilization method References	Risk assessment - Risk analysis - evaluation - measurement Summary of safety and efficacy study - Pre clinic test - clinical test - validation - summary of study References
From G : Clinical Data	none	none	- Scientific references - result of clinical study

Post Market Surveillance

1. Monitoring
2. Sampling

PMS is carried out by

- MOH and Province Health Officer
- Manufacturer in order to warranty of their product

Thank you ...