Indonesian Medical Device Regulation

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MEDICAL DEVICES LIFE CYCLE & REGULATION

1. MANUFACTURE
   - CONCEPTION & DEVELOPMENT
   - MANUFACTURER
     - Clinical study
     - Medical Devices Distributor Licence (for facilities)
     - Marketing Licence (for product)
     - Control of advertisement
     - GMP (CPAKB)

2. PACKAGING & LABELLING
   - PRE-MARKET

3. ADVERTISING
   - PLACING/ON MARKET
   - VENDOR
     - GDP (CDAKB)

4. SALE

5. USE
   - POST-MARKET
   - USER
     - Post-Market Surveillance
Referring to Government Regulation Number 5 of 2021, implementation of Risk-Based Licensing through Online Single Submission (OSS RBA) by Ministry of Investment has been applied since August 2021,

In OSS RBA, the businesses need to apply for licensing according to the level of their business risk.

Producers and distributor of medical devices required to have business licenses from OSS prior to registering marketing licence.

Licencing for all businesses in Indonesia are done through OSS (Http://oss.go.id)
Medical device is classified based on the risk associated with the device.

Risk-base classification:
- Class A (low)
- Class B (low moderate)
- Class C (high moderate)
- Class D (high)

Refers to national standards (SNI) or International standards (ISO, IEC, US FDA Guidelines, WHO Guidelines, IMDRF Guidelines, AMDD, etc) in evaluating safety, quality, and performance of Medical Devices.
Medical Devices Supervision

Routine dan Incidental Activities

- **AUDIT**: Evaluation on QMS implementation in production and distribution means
- **INSPECTION**: Inspection on regulatory compliance of production and distribution means
- **SAMPLING DAN TESTING**: Testing of MD & household products in accordance to national & international standard
- **CONTROL ON ADVERTISEMENT**: Control on advertisement of products after being widespread
- **CONTROL ON LABEL**: Control on label according to distribution permit
- **POST-BORDER SURVEILLANCE**: Supervision of MD importation through on-site inspection
POST MARKET SURVEILLANCE

New Guideline
Adopt the Minister of Health Regulation No. 20 – 2017, Regarding Good Manufacturing Practices of MD (CPAKB)

Post Market Online System

- e-Watch National Reporting System of MD Adverse Reactions – synchronized with hospital information system, currently integrate with patient safety reporting
- e-Report National Reporting System of MD Distribution

Mandatory
All Medical Device Industries must implement GMPMD (CPAKB)

Current Guidelines
1. Guidelines for Auditing the Production Facility
2. Guidelines for Inspection of Production and Distribution Facility
3. Guidelines for Surveillance Sampling
4. Guidelines for MD Advertisement Control
5. Upcoming guideline for disposal MD and IVD
POST MARKET SUPERVISION

- List of Product Marketing Licence
- Complaint Report from user, Adverse Event
- Supervision of Medical Device and Household Product

Alkes Mobile

E-postborder
E-watch
E-infoalkes

ALKES MOBILE

Alkes Mobile
Seralkes
Regalkes
Thank You

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