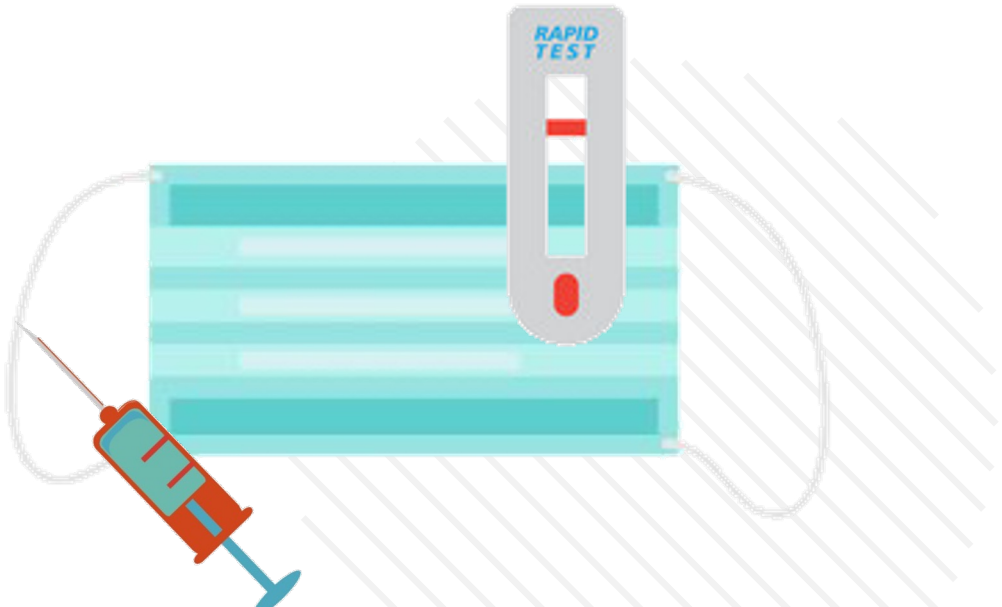
KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

GERMAS
Gerakan Masyarakat Hidup Sehat

Indonesian Medical Device Regulation



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Ministry of Health of Republic of Indonesia

Presented at U.S.- Indonesia Healthcare Standards and Innovation Workshop
27 Juli 2022

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

MEDICAL DEVICES LIFE CYCLE & REGULATION

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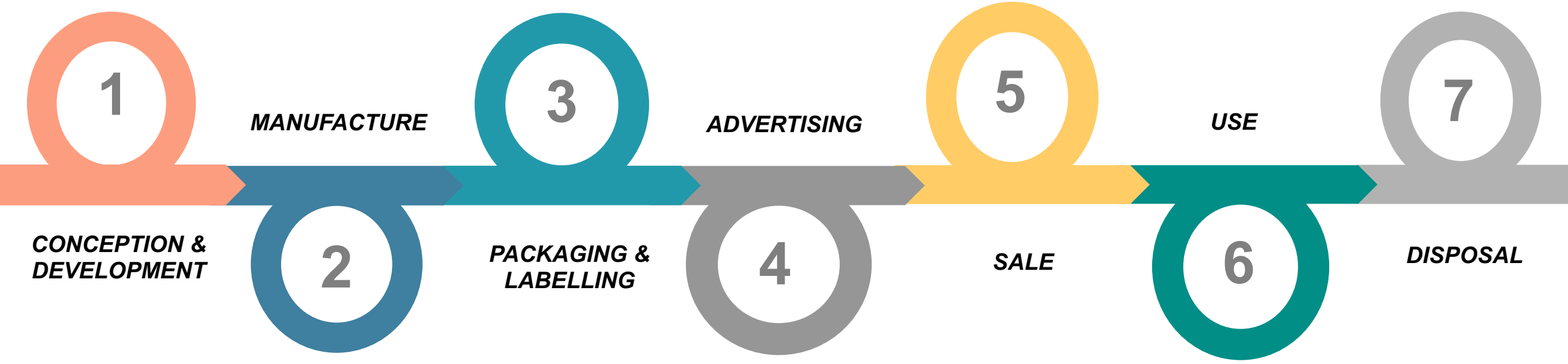
Gerakan Masyarakat Hidup Sehat



PRE-MARKET

MANUFACTURER

Clinical study

- Medical Devices Distributor Licence (for facilities)
- Marketing Licence (for product)
- Control of advertisement
- GMP (CPAKB)

PLACING/ ON MARKET

VENDOR

GDP (CDAKB)

POST-MARKET

USER

Post-Market Surveillance

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RISK-BASED LICENSING APPROACH

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- ✓ 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)

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REGULATION FOR MEDICAL DEVICES

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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

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Medical Devices Supervision

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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

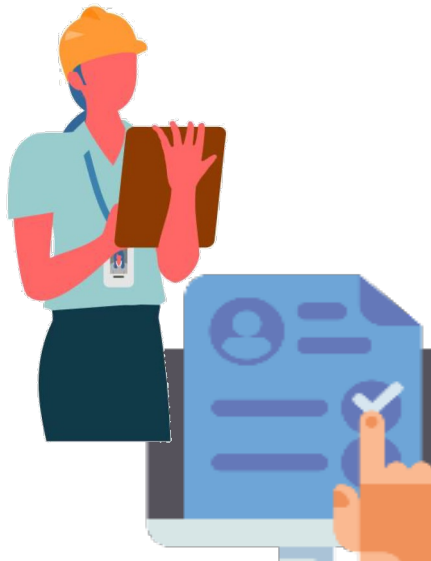
- Control on advertisement of products after being widespread

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)

Mandatory

All Medical Device Industries must implement GMPMD (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

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

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POST MARKET SUPERVISION

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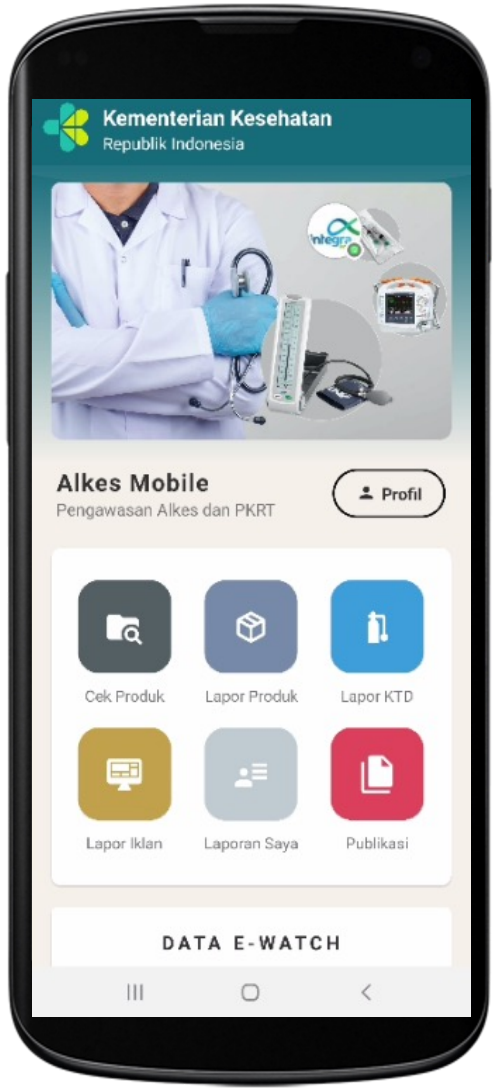

Alkes Mobile

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

GET IT ON Google Play

Thank You

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