KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

GERMAS
Gerakan Masyarakat Hidup Sehat

Post-Market Surveillance of Medical Devices in Indonesia

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KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

REGULATORY / CYCLE OF MEDICAL DEVICES

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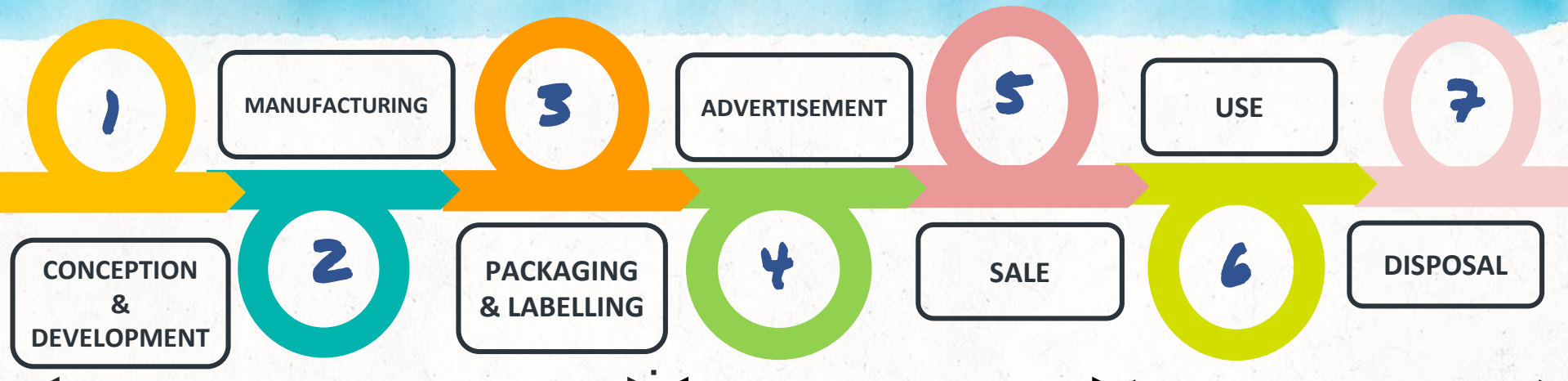

PRE-MARKET

MANUFACTURER

Clinical Test

Marketing License, Production Permit, Advertising approval, **Distribution Permit, GMPMd (CPAKB)**

PLACING/ ON MARKET

VENDOR

GDPMd (CDAKB)

Post-Market Surveillance

POST-MARKET

USER

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

Post-Market Surveillance of Medical Device

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To ensure the safety, quality, and efficacy of Medical Device which are distributed in Indonesia

Assestment for GMPMd (CPAKB), GDPMd (CDAKB) implementetion

- Assessment of the implemententation of GMPMd and GDPMd in medical devices production and distribution facilities through audit process

FACILITIES INSPECTION

- Verification of medical device production and distribution facilities to ensure that they still impelement the aspects of GMPMd (CPAKB) and GDPMd (CDAKB)

SAMPLING DAN TESTING

- Quality Conformity and safety testing of medical devices according to standards/provisions.

ADS SURVEILLANCE

- Monitoring the advertisement of medical device to ensure that the advertisement meet the ads provision, that is objective and not misleading.

LABELING SURVEILLANCE

- Surveillance of medical device labeling to ensure comply with the provision

POST-BORDER SURVEILLANCE

- Surveillance of importation trading outside the customs area for 81 HS Code through on-site inspection.

Medical Device COMPLAINTS & ADVERSE EVENTS

- The handling of complaint reports from the public and companies related to medical device
- The handling of adverse events related to medical devices and prevent the occurrence of the same event.

Government, Local Government, Academia, Professional Organizations, Social Media, Industries, and Society

GUIDANCE AND APPLICATION FOR SURVEILLANCE

Guidance for Supervision of Production Facilities of Medical Devices

Guidance for Sampling & Testing of Medical Devices

In line with global regulation

WHO; AMDD; APEC

Guidance for Recalls and Disposal of Medical Devices

Guidance for Adverse Events Investigation of Medical Devices

E-inspeksi

E-postborder

E-watch

Alkes Mobile

MOBILE ALKES

E-infoalkes

Seralkes

Regalkes

“To facilitate and optimize the post market surveillance of medical device in Indonesia”

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

Challenges on Post-Market Surveillance

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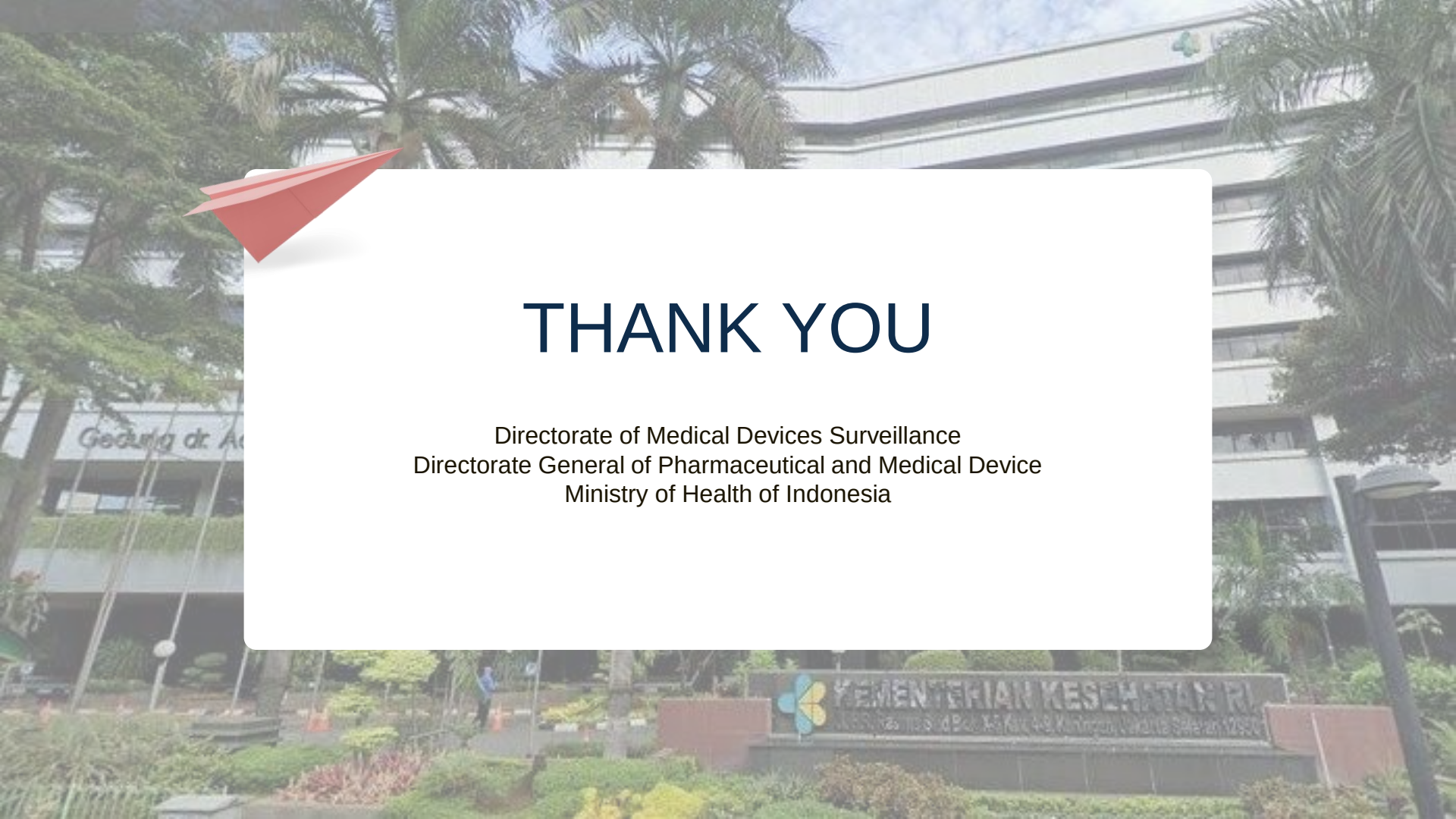
Limited Testing Laboratories in Indonesia

Limited human resources to supervise the medical devices production and distribution facilities

Some medical device manufacturers and distributors do not comply with the regulations

The large cost of expenses for sampling and testing medical devices

The ease of business for Medical Device Manufacturers and Distributors which leads to greater challenges for post market surveillance



THANK YOU

Directorate of Medical Devices Surveillance
Directorate General of Pharmaceutical and Medical Device
Ministry of Health of Indonesia