



▶ INDONESIA MEDICAL DEVICES REGULATORY UPDATE 2018

Ministry of Health
Directorate General of Pharmaceutical and Medical Device
Directorate of Medical Device and Household Health Product Evaluation

Presented on 23rd AHWP, KL Malaysia

GOALS OF MD REGULATORY SYSTEM IN INDONESIA

Ensure the safety, quality, performance / efficacy,
affordable and appropriate Medical Devices

Facilitating medical device technology innovation
into Indonesia

CURRENT PHASE OF MEDICAL DEVICE REGULATORY

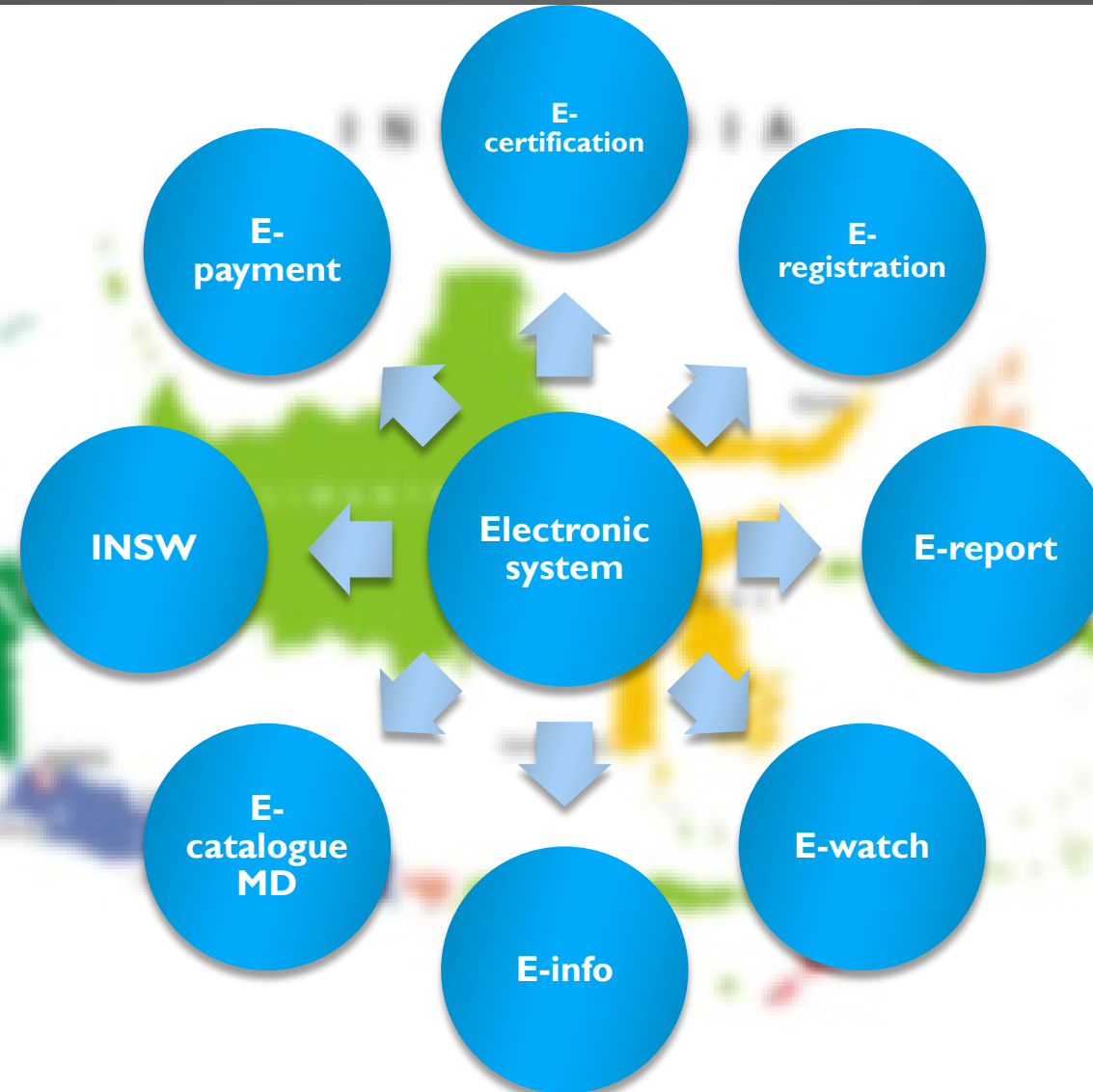


Deregulation and Debureaucracy Regulation including Medical Device Sector:

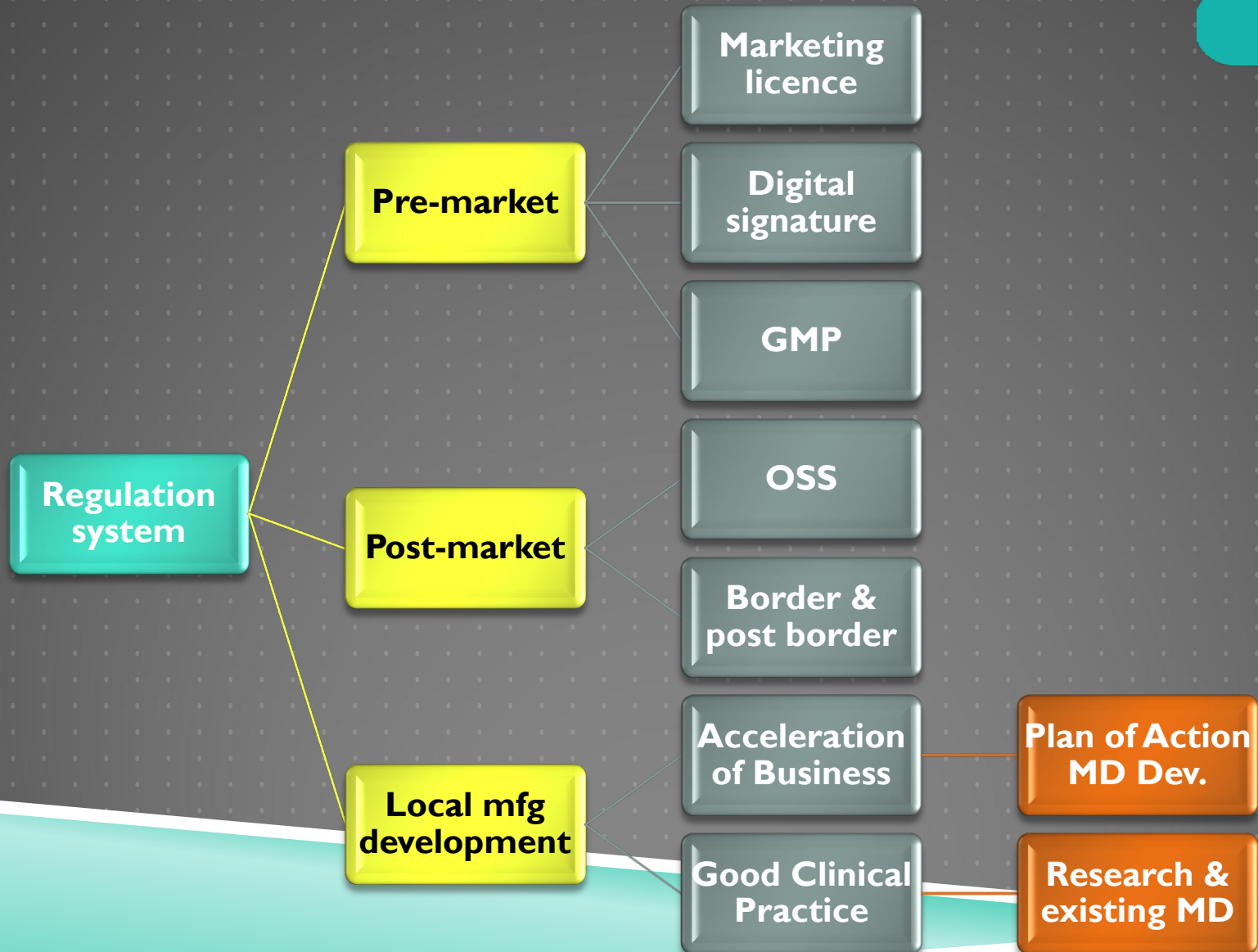
1. Strengthening industrial competitiveness, law enforcement, easiness to invest
2. Accelerate strategic national project
3. Increasing the investment

E-SYSTEM FOR MEDICAL DEVICE

Optimize public service, faster and accessible



REGULATORY UPDATE



REVIEW TIMELINE (DAYS)*



PROCESS	CLASS A	CLASS B	CLASS C	CLASS D
NEW LICENSE	15	30	30	45
RENEWAL	7	7	7	7
VARIATION	10	10	10	10

CLASS	PREVIOUS REGULATION 2010
A	45
B	90
C	90
D	120
Renewal	45
Variation	45

*for completed document at the first submission
 Applicant : 10 days for fulfilling lack of document(s), one chance

DIGITAL SIGNATURE

- ▶ Indonesia is about to launch Digital signature system on November 2018
- ▶ Marketing license approval is signed in the form of electronic formate
- ▶ Doesn't need stamp and direct signature
- ▶ Marketing license may be printed by Applicant and other designated bodies through official website
- ▶ Collaborate with State Cyber and Cryptography Agency
- ▶ QR Code used for safety and verify-able by Android and IOS application

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN
Jalan R.A. Kartini Satek Blok K-2 Kawang 4-9 Jakarta 12950
Telepon : (021) 5201590 Ponsel 2020, 8011
Faksimile : (021) 52904838 Kode Pos : 203

GERMAS

Berdasarkan Peraturan Menteri Kesehatan RI Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN EDAR
ALAT KESEHATAN
KEMENKES RI AKD 20501810570

Nama Dagang / Merek : Test Pending
Kelompok / Kelas Resiko : Diagnostik In Vitro / B
Kategori Produk : Peralatan Kardologi
Sub Kategori : Peralatan Kardologi
Jenis Produk : Blood pressure
Tipe / Ukuran :
Kemasan :
Nama Produsen / Pabrik :
Nama Pendaftar :
Atas dasar Izemi dari :
Keterangan :
1. Persetujuan ini berlaku sejak tanggal 09 Januari 2021.
2. Wajib melaporkan jika ada kejadian yang tidak diinginkan akibat penggunaan alat di atas sesuai ketentuan berlaku.
3. Produsen harus menyerahkan produknya melalui Penyakar Alat Kesehatan (PAK).
4. Apabila ditemukan alat di pihak lain yang bertukar atas merek dan/atau keagenan produk, maka produsen wajib mengembalikan izin edar.
5. Apabila ditemukan alat di pihak lain yang bertukar atas merek dan/atau keagenan produk yang bertamper merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
6. Apabila terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

Jakarta, 13-08-2018
Direktur Jendral Kesehatan Dan Alat Kesehatan
Dokter Endang Sutopo Nugroho, Sp. WJ, WJ
NIP. 19631119 198202 001

QR Code

Undang-Undang No. 27 Tahun 2007 Pasal 5 ayat 1
Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.
Pencarian dan/atau pengunduhan secara elektronik menggunakan perangkat elektronik yang terhubung dengan Sistem Elektronik.



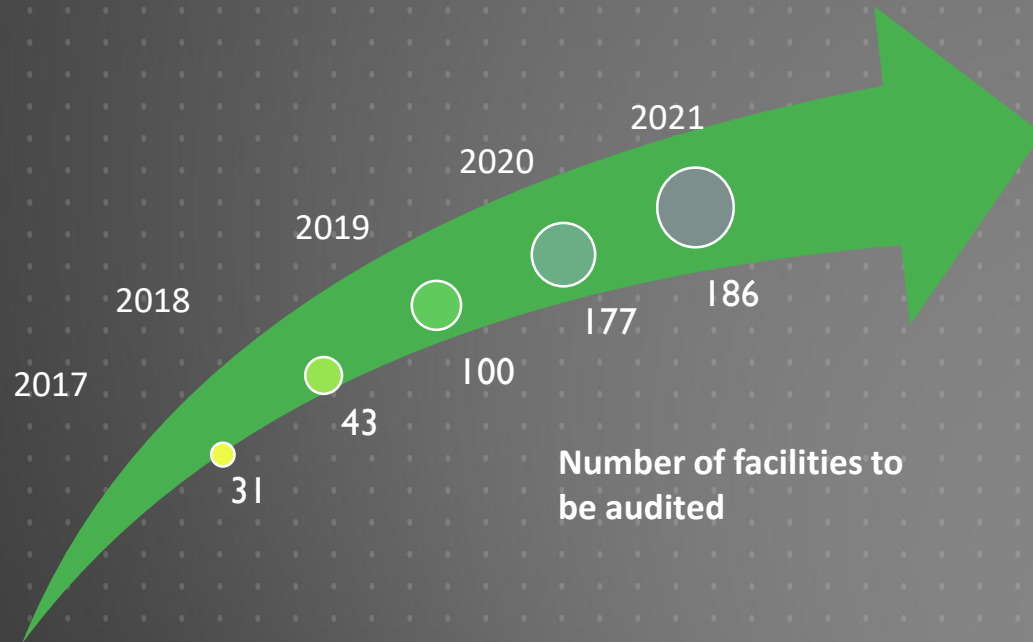
G M P

Mandatory
Good Manufacturing Practice
Medical Device



All Medical device industry must
implement Good Manufacturing practice
on MD within 4 years at the latest

Roadmap Audit GMP certification 2017 - 2021



10 Potential Industries

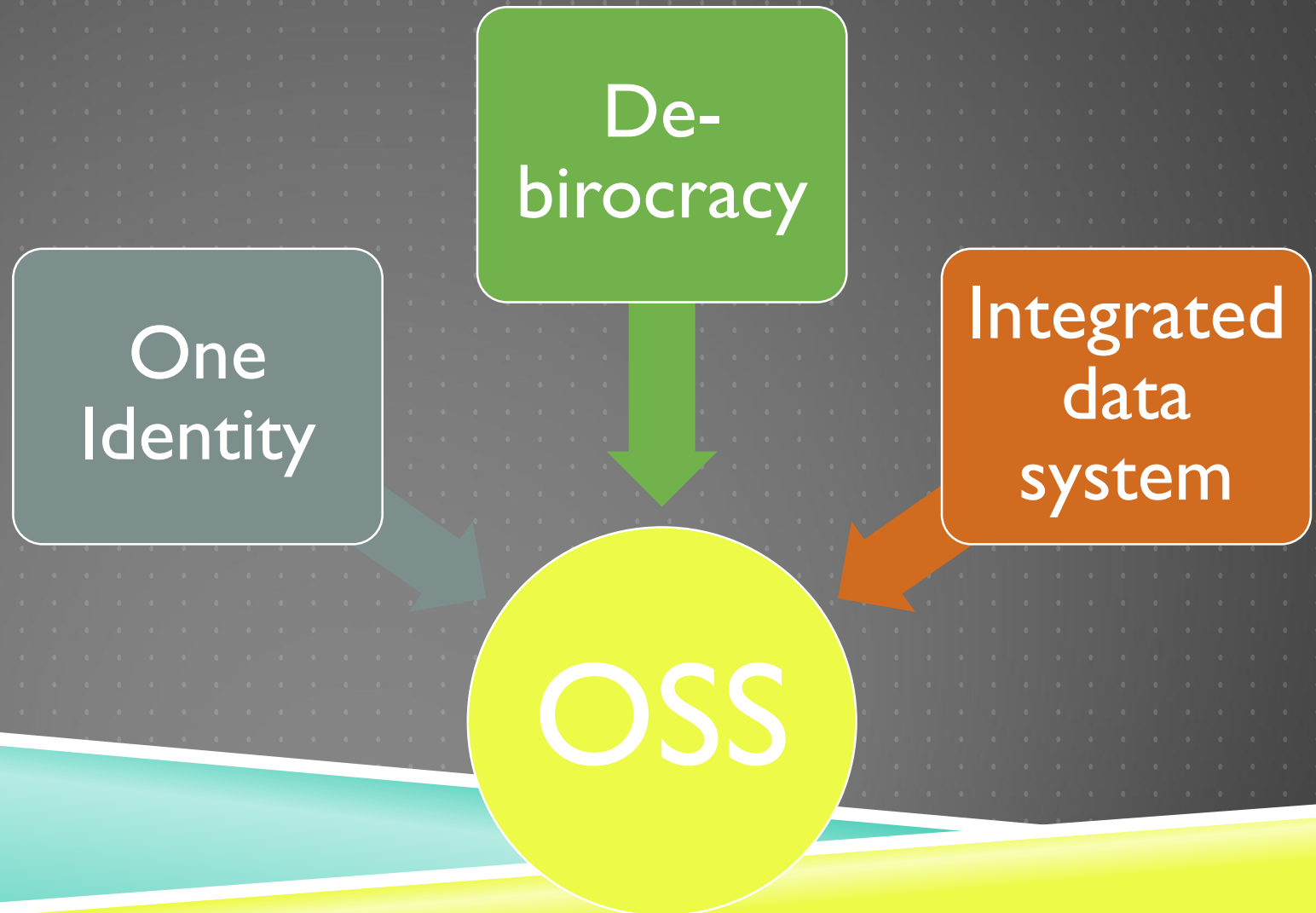
- | | |
|--------------------|-----------------------|
| Contact Lens | Surgical instrument |
| Blood monitor | Hemodialysis Solution |
| Condom | Rapid test |
| Surgical Suture | Sterilisator |
| Orthopedic Implant | Bandage |

OSS *ONLINE SINGLE SUBMISSION*

DEVELOPED BY COORDINATING MINISTRY FOR ECONOMIC AFFAIRS

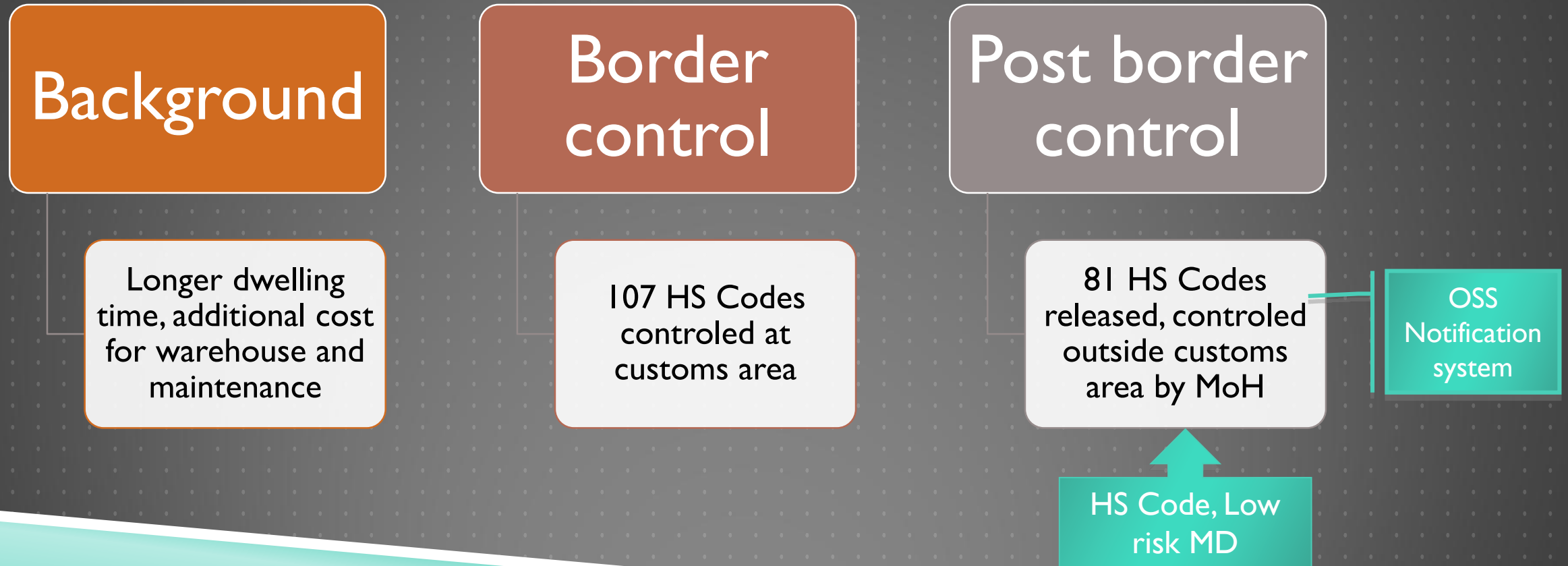
Government efforts to simplify business licensing and create integrated and fast licensing service models and provide certainty

<https://www.oss.go.id/>



BORDER DAN POST BORDER

IMPLEMENTATION ON MEDICAL DEVICE IMPORT TRADE CONTROL



PROGRESS OF ACCELERATION TO DEVELOP PHARMACEUTICAL AND MEDICAL DEVICE INDUSTRY



○ Economic Policy Package XI

○ President Instruction No. 6 year 2016

○ Minister of Health Regulation No 17 year 2017



Presidential Regulation No. 44 Year 2016 regarding list of open and closed business fields (Sector: Medical devices, distribution and production)



No	Business Field in Indonesia territory	Capital ownership
1.	Medical Device Distributor	Foreign capital ownership maks. 49% Special permittance from MOH
2.	Class A MD Manufacturer	Foreign capital ownership maks. 33% Special permittance from MOH
3.	Class B MD Manufacturer	Foreign capital ownership open 100% or may join ventures to local owner Special permittance from MOH
4.	Class C MD Manufacturer	Foreign capital ownership open 100% or may join ventures to local owner Special permittance from MOH
5.	Class D MD Manufacturer	Foreign capital ownership open 100% or may join ventures to local owner Special permittance from MOH

GOOD CLINICAL PRACTICE OF MD

Applied for Risk Class

- C and D medical device

Pre market Clinical Research

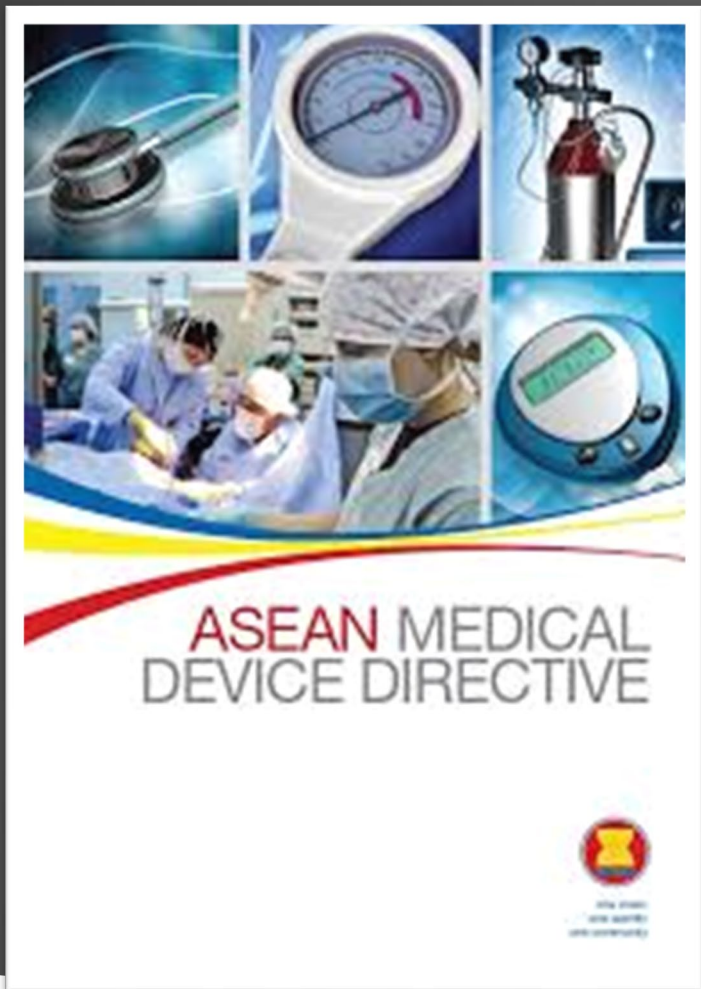
- Sample test does not yet have approval
- Endorsement from Health Minister

New product, New indication or intended use

Post market Clinical Research

- Sample test has marketing license
- Endorsement from Director General

Obtain safety data, performance evidence



ASEAN Medical Device Directives (AMDD) Ratification Progress

AMDD signed on Nov 2014

Minister of Health propose the permission initiative to ratify AMDD (Dec 30th 2015)

- Law or President Regulation Preparation is still in domestic Process
- Legislative Approval is needed.

Ratification and the deposit of the instrument of ratification to ASEAN Sec

Fully adoption to National Regulation



T H A N K Y O U

TERIMA KASIH