ASEAN MRA for GMP Inspection: Malaysia's Perspective on GMP Inspection Reliance

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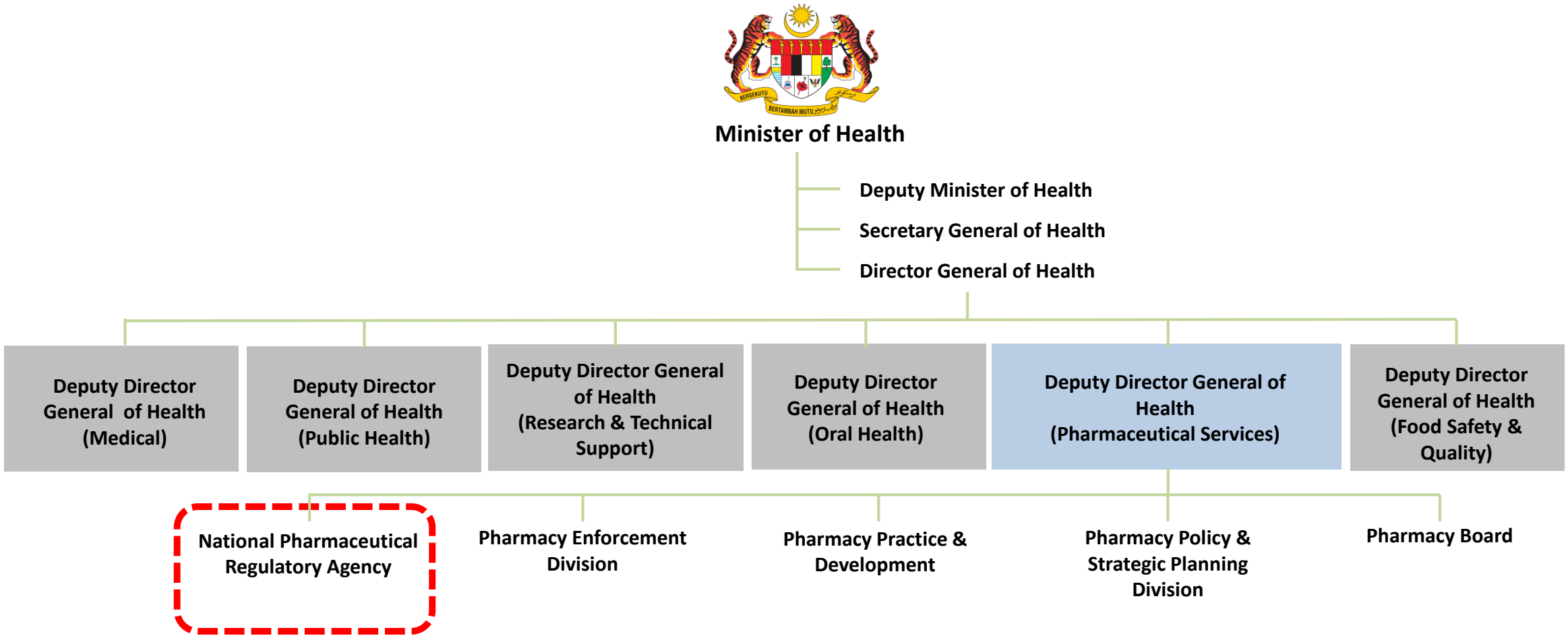
Presentation Outline

- Brief Introduction of NPRA
- Overview of ASEAN MRA for GMP Inspection
- Benefits of ASEAN MRA for GMP Inspection
- ASEAN Listed Inspection Service (LIS)
- Inspection Reliance in Malaysia
- Challenges in Promoting Inspection Reliance
- Mechanisms to Promote Inspection Reliance

Brief Introduction of NPRA



Overview of ASEAN MRA for GMP Inspection

- ASEAN Sectoral Mutual Recognition Arrangement (MRA) for Good Manufacturing Practice (GMP) Inspection of Manufacturers of Medicinal Products was signed on 10th April 2009 in Pattaya, Thailand.

- The Agreement includes:
  - Scope and coverage of the Sectoral MRA
  - Criteria for listing (and delisting) the Inspection Service
  - Mutual recognition obligations
  - Implementation
  - Dispute settlement

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Overview of ASEAN MRA for GMP Inspection

- Scope and coverage:
  - GMP inspection and certification of manufacturers of medicinal products in finished dosage forms
  - Includes prescription and non-prescription medicinal products for human use
  - Excludes biopharmaceuticals, radiopharmaceuticals, traditional medicines and investigational medicinal products intended for clinical trials

- Expansion of scope to include biologics / biopharmaceuticals and Active Pharmaceutical Ingredients (API) is currently being discussed.

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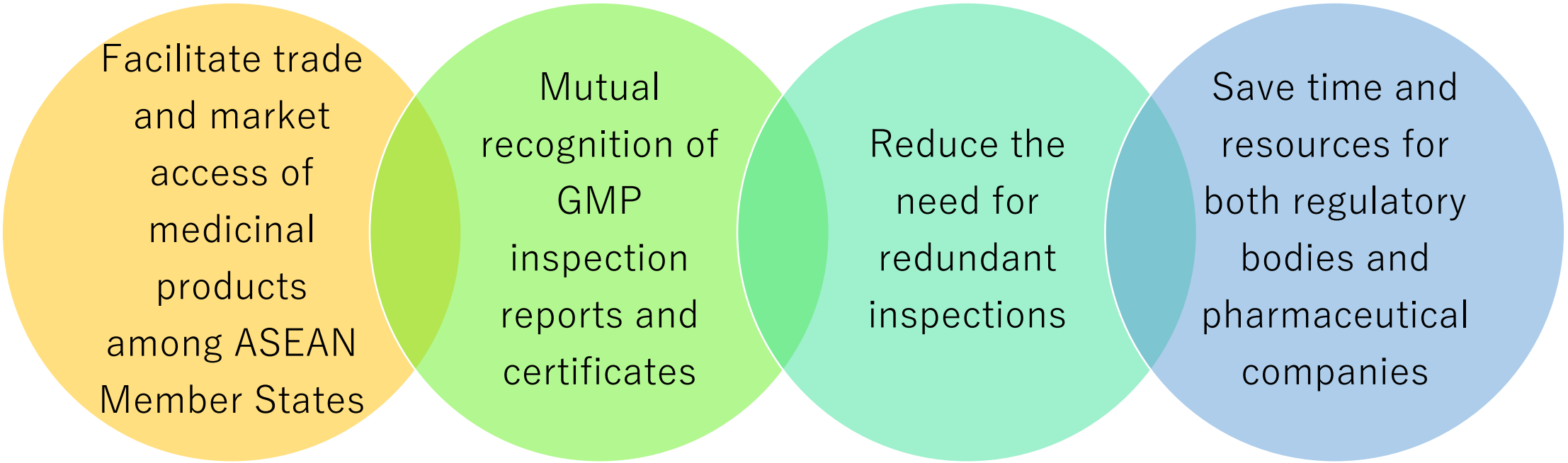
Benefits of ASEAN MRA for GMP Inspection



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ASEAN Listed Inspection Service (LIS)

- An ASEAN Listed Inspection Service (LIS) is the inspection service of a National Drug Regulatory Authority (NDRA) within an ASEAN member state that has been formally accepted by the Joint Sectoral Committee (JSC) under the ASEAN Mutual Recognition Arrangement (MRA) on GMP Inspections.

- For an inspection service to become listed, it needs to demonstrate that its GMP inspection and manufacturer's licensing system is equivalent to that of the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

ASEAN Listed Inspection Service (LIS)

- Key requirements for becoming an LIS include:
  - Operating a GMP inspection and manufacturer's licensing system equivalent to PIC/S.
  - Adopting the PIC/S Guide to GMP for Medicinal Products (or an equivalent GMP code).
  - Adhering to the PIC/S Quality System Requirements for Pharmaceutical Inspectorates.
  - Having an adequate legal framework for GMP inspection and licensing.

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ASEAN Listed Inspection Service (LIS)

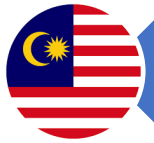
- Once an inspection service meets these criteria and is accepted by the JSC, it is included in the list of recognized inspection services.

- GMP certificates and inspection reports issued by an LIS are then recognized and accepted by the regulatory authorities of other ASEAN member states that are part of the MRA, without the need for further GMP inspections.

ASEAN Listed Inspection Service (LIS)

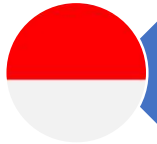
Health Sciences Authority (HSA), Singapore

(since 1st January 2000)



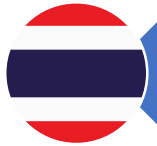
National Pharmaceutical Regulatory Agency (NPRA), Malaysia

(since 1st January 2000)



National Agency of Drug and Food Control (NADFC), BPOM, Indonesia

(since 1st July 2002)



Food and Drug Administration (FDA), Thailand

(since 13th March 2015)

Food and Drug Administration (FDA), Philippines

(since 7th January 2020)

5 out of 10 ASEAN Member States

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Inspection Reliance in Malaysia

- Pharmaceutical Inspection Co-operation Scheme (PIC/S)
  - GMP certificate
  - GMP inspection report

- ASEAN Listed Inspection Service
  - GMP certificate
  - GMP inspection report

Challenges in Promoting Inspection Reliance

- Variable regulatory development and resources → benchmarking against PIC/S GMP framework.

- Limited scope → ASEAN MRA on GMP inspections currently does not include biopharmaceuticals, radiopharmaceuticals, traditional medicines and investigational medicinal products.

Mechanisms to Promote Inspection Reliance

- Benchmarking against internationally recognized standards, such as PIC/S.
- Harmonized GMP standards and guidelines.
- Robust assessment and monitoring of the competence and reliability of GMP inspection services via the Joint Sectoral Committee (JSC).

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Mechanisms to Promote Inspection Reliance

- Strengthening regulatory capacity via training programs and initiatives, such as:
  - Korea-ASEAN Pharmaceutical GMP Inspector Training (Korea MFDS, ASEAN)
  - ASEAN Educational Workshop on GMP for Biologicals / Biosimilars (Generics and Biosimilars Initiative [GaBI], ASEAN ACCSQ-PPWG, WHO)

- Implementing systems for efficient exchange of GMP inspection information.

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