The 22nd DIA Japan Annual Meeting 2025

Strong Ties of Japan with Asia and the World for Delivering
‘Tomorrow's Normal’

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Session Title: DIAmond S01

Implementation of ASEAN Joint Assessment (AJA) and Abridged Regulatory Pathways Philippines

Center for Device Regulation, Radiation Health, and Research
FDA Philippines

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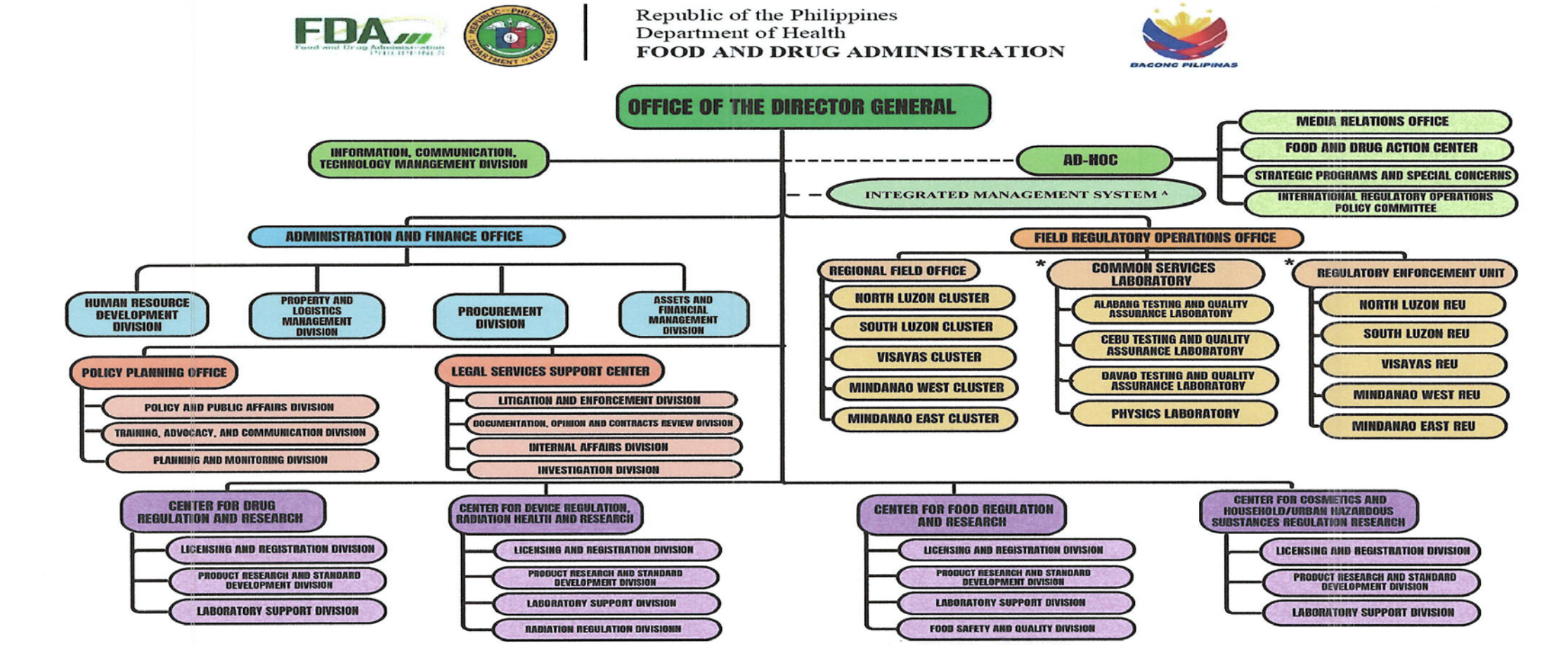
FDA Philippines Organogram



^ The integration of the FDA's management system into its operations is facilitated through the active involvement of Directors and Heads of each Center, Office, and Unit, with support from their designated Integrated Management Coordinators (IMCs). This structure ensures that quality, environmental, and safety management principles are embedded in day-to-day functions, promoting consistency, accountability, and continual improvement across all levels of the organization.

- Temporarily assigned under the direct control and supervision of the Director General pursuant to FDA Order 2025-0695

QM-FDA Annex 1 FDA Organizational Chart
DATE EFFECTIVITY: 23 June 2025
REVISION NO. 14
As per FDA Order 2025-0695

INTERNATIONAL COMMITMENTS AND COLLABORATIONS

ASEAN Joint Assessment (JA) Procedure

- Supported by the World Health Organization (WHO) including the establishment of the ASEAN Joint Assessment Information Management System or JAIMS (online platform for both applicants and assessors)
- Participated by national medicines regulatory authorities (NMRAs) of ASEAN Member States, wherein collective recommendations made at the ASEAN JA level are expectedly adopted and used as basis in the regulatory decision-making at the national level.
  - 1st JA Activity: Artesunate + Pyronaridine tetraphosphate granules for oral suspension and film-coated tablet [PYRAMAX], an antimalarial
    - NPRA Malaysia as the Lead NMRA
    - Participated by Brunei Darussalam, Cambodia, Lao People's Democratic Republic, Indonesia, Myanmar, Philippines, Singapore, Thailand and Vietnam NMRAs
  - 2nd JA Activity: Tafenoquine film-coated tablet [KOZENIS], an antimalarial
    - FDA Thailand as the Lead NMRA
    - Participated by Myanmar, Philippines and Vietnam NMRAs
  - 3rd JA Activity (On-going): Cabotegravir film-coated tablet and prolonged-release suspension for injection, for HIV Pre-Exposure Prophylaxis (PrEP)
    - FDA Philippines as the Lead NMRA
    - Other NMRAs from Malaysia, Myanmar and Vietnam are participating.

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INTERNATIONAL COMMITMENTS AND COLLABORATIONS

WHO Collaborative Registration Procedure (more formally known as the Collaborative Procedure for Accelerated National Registration)

- Facilitates the national registration of WHO Prequalified medicines and vaccines in participating NMRAs' jurisdictions via the granting of access to the WHO Prequalification Team's dossier assessment and facility inspection reports.
- FDA Philippines officially became a participating NMRA on 08 October 2015.

PMDA Japan-FDA Philippines Bilateral Meeting

- Partnership through exchange of information and cooperation in the areas of medical products and related administrative and regulatory matters.
  - To be formalized via a Memorandum of Cooperation (MOC) and the development of the Work Plan for Cooperation.
  - PMDA Japan to share its assessment reports to FDA Philippines for purposes of facilitating the marketing authorization of drug products in the Philippines.
- PMDA Japan committed to assist FDA Philippines in obtaining a member or observer status in distinguished circles of national medicines regulatory authorities at the global stage.
  - International Coalition of Medicines Regulatory Authorities (ICMRA)
  - International Council for Harmonization (ICH) of Technical Requirements for Pharmaceuticals for Human Use
- Inclusion of PMDA Japan in FDA Philippines' List of Reference Drug Regulatory Agencies (RDRAs) per FDA Circular No. 2022-004: Implementing Guidelines on the Abridged and Verification Review Pathways for New Drug Registration Applications

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Policies on Reliance

Administrative Orders:

AO No. 2020-0044

Adoption of the Collaborative Procedure for the Accelerated Registration of World of Health Organization (WHO) – Prequalified Pharmaceutical Products and Vaccines

AO No. 2020-0045

Establishing Facilitated Registration Pathways for Drug Products, including Vaccines and Biologicals

AO No. 2024-0013

General Rules and Regulations on the Registration of Pharmaceutical Products and Active Pharmaceutical Ingredients Intended for Human Use

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Policies on Reliance

FDA Circulars:

FC No. 2022-004

Implementing Guidelines on the Abridged and Verification Review Pathways for New Drug Registration Applications in accordance with Administrative Order No. 2020-0045 “Establishing Facilitated Registration Pathways for Drug Products including Vaccines and Biologicals”

FC No. 2022-004-A

Amendment to FDA Circular No. 2022-004 entitled, “Implementing Guidelines on the Abridged and Verification Review Pathways for New Drug Registration Applications in accordance with Administrative Order No. 2020-0045 Establishing Facilitated Registration Pathways for Drug Products including Vaccines and Biologicals” to include Generic Drug Registration Applications and update the list of Reference Drug Regulatory Agencies

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Policies on Reliance

FDA Circulars:

FC No. 2022-009

Implementing Guidelines of Administrative Order No. 2020-0044 “Adoption of the Collaborative Procedure for the Accelerated Registration of World Health Organization (WHO) – Prequalified Pharmaceutical Products and Vaccines”

FC No. 2023-004

Guidelines on Regulatory Reliance on the Conduct of Clinical Trials

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To further strengthen the reliance scheme…

- Currently, the FDA Philippines' list of reference regulatory agencies could be found under Annex A of FDA Circular No. 2022-004 Re: Implementing Guidelines on the Abridged and Verification Review Pathways for New Drug Registration Applications in accordance with Administrative Order No. 2020-0045 "Establishing Facilitated Registration Pathways for Drug Products including Vaccines and Biologicals".
- In order for FDA PH to undertake any formal inquiry or consultation with a reference regulatory agency, there should be a bilateral arrangement or agreement in the form of a Memorandum of Understanding/Cooperation between both parties.
- Currently underway are the MoUs/MoCs between FDA PH and PMDA Japan, TGA Australia and MFDS Korea in various stages of progress.

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To further strengthen the reliance scheme…

- Since no such MoU or MoC has been in place yet for implementation, queries and consultations through a **formal facility** could not be undertaken by FDA PH evaluators.
- For the time-being, the most that FDA PH evaluators can do is to seek clarifications or additional information from the applicant if discrepancies between their actual Q, S and/or E dossier submission and the full RDRA assessment report are found.
  - If the needed clarifications or additional details from the applicant were not provided, by all means, the FDA PH evaluator may discontinue the processing of the application following the Facilitated Registration Pathway and revert to the normal evaluation route which would entail greater scrutiny.

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To further strengthen the reliance scheme…

- Alternatively, FDA PH evaluators rely on their personal network of RDRA contacts and **informally** make their concerns known to their RDRA counterparts with the hope of being linked to the appropriate team within the RDRA for assistance.
  - Usually, the more seasoned the FDA PH evaluator is, the greater is his/her network of contacts from RDRAs and other competent NRAs.

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Questions?

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