Medical Device

The New Face of Philippine Medical Device Regulatory System

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- The Existing Regulatory System
- The Structure of the New Regulatory Authority
- Understanding the Implementation Process
- Comparison Between the Existing and the New Medical Device Regulatory System
- Timeline of Implementation
- Challenges

The Existing Regulatory Structure

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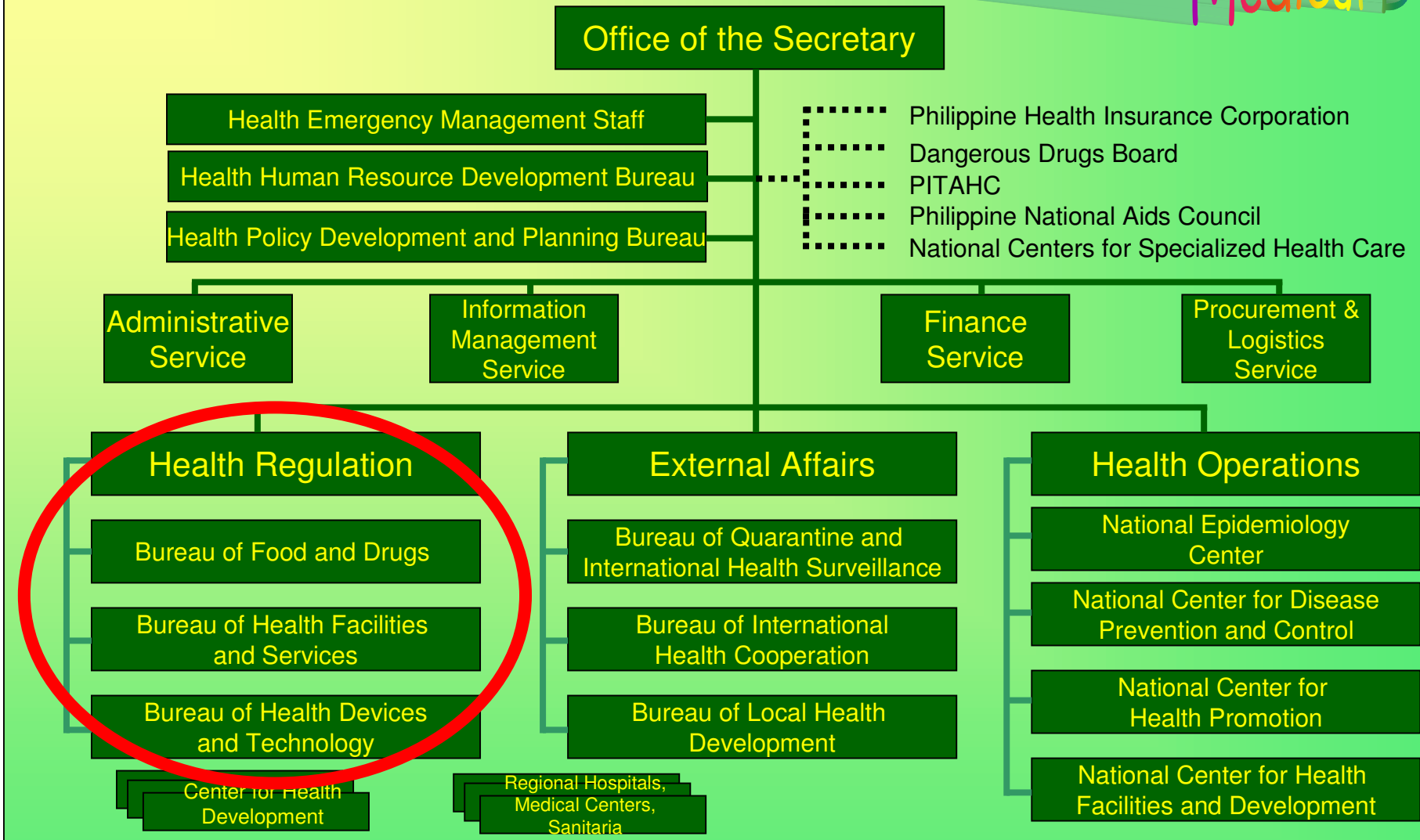

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Republic Act 3720 (1963): Food, Drug and Cosmetic Act as amended by Executive Order No. 175 (1987) → **BFAD: Drugs, Food, Medical Devices, Cosmetics, Hazardous Substances**

Administrative Order No.2007-003: → **Appointing the Bureau of Health Devices and Technology as technical arm of BFAD**

Joint Bureau Memorandum No. 2007-001 → **Registration of Medical Devices and License to Operate Medical Device Establishment filed, processed and released by BHDT**

Existing Regulatory Requirements

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The same requirements as set by BFAD

Retained the existing coverage of registration where only 74 medical devices are included in the list for mandatory registration including all invasive , implantable and sterile medical devices

The Structure of the New Regulatory Authority

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Bureau of Food and Drugs (BFAD)

Bureau of Healthe Devices and Technology (BHDT)

Republic Act. No. 9711
Food and Drug Administration Act of 2009

Created Four (4) Centers

1. Center for Drug Regulation and Research
2. Center for Food Regulation and Research
3. Center for Cosmetics Regulation and Research
4. Center for Device Regulation, Radiation Health, and Research

Center of Device Regulation, Radiation Health, and Research

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Three Main Divisions

Licensing and Regulation Division – Evaluation of health products and establishments

Product Research and Standards Development Division – Conduct research, develop standards and regulations, compliance monitoring and the oversight and audit of related researches that would ensure safety, quality, purity, and efficacy of health products

Laboratory Support Division – Conduct research and appropriate tests and calibration, analyses and trials of products

** requesting another division to focus on radiation health

Understanding the Implementation Process

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LAW: RA9711	Signed by the President of the Philippines (Legislation)	General provisions power and authority, violations, structure, appropriations, manpower
Implementing Rules and Regulation	Signed by the Department Secretary	Specific provisions and clarificatory provisions of the Law (real structure)
Administrative Issuances	Signed by the Department Secretary	Specific requirements, fees and charges, system of regulation, violations
Bureau Issuances	Signed by the Center Director	Clarifications of the requirements, more specific requirements

Comparison Between the Existing and the New Medical Device Regulatory System

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EXISTING	New System
• Two Regulatory Bureaus doing the regulation	• One Center
• Two signatories	• Single Signatory
• Classification: Registrable and non-registrable	• Four Classifications
• Documentary Requirements as per checklist	• CSDT format as per ASEAN agreement
	• Nomenclature System
	• Mandatory Reporting
	• Focus on surveillance through the enforcement units at the regional level

Timeline of Implementation

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August 2009 – passage of the LAW

Effectivity: 15 days upon publication (September 2009)

Development of IRR: within 120 days (December 2009)

Administrative Issuances (2010)

Creation of new plantilla position and hiring (target within 5 years full plantilla position)

Challenges

CREATION OF
PLANTILLA POSITIONS

BUILDING/RENOVATION
OF OFFICES

ESTABLISHMENT OF
DATA BASE SYSTEM

Thank you for listening