Updates in medical device regulation in Ethiopia

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Hilton Grand Nile Hotel, Cairo
November 2025

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The views and opinions expressed in this presentation are solely my own and do not represent or reflect the official position, policy, or opinion of the Ethiopian Food and Drug Authority (EFDA). The content is based on my personal professional experience and interpretation of relevant guidelines and practices. Any errors or omissions are my sole responsibility.

Outlines

- Introduction
- Main Functions of the regulatory Authority
- Market authorization process for Medical Devices
- Timelines and regulatory service charges

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Introduction

Regulatory framework: Hierarchy of law where mandate of EFDA emanated in Ethiopia

- Constitution
- Proclamations
- Regulations
- Directives

Guidelines (These are not legally binding)

Core regulatory Functions in medical device regulation Includes…

- Dossier Assessment
- GMP Inspection
- Quality Control Testing
- Clinical Trial Oversight
- Post marketing Surveillance

Market authorization process for Medical Devices

- Medical Devices and IVDs are subject to the registration process before marketing in Ethiopia
- Authorized local representative should be appointed by the manufacturer or license holder to process registration on behalf of the MAH
- Submission should be electronically via eRIS (electronic regulatory information system)

Market authorization process for Medical Devices

- The dossier submitted in need of registration passes the prescreening/validation, Assessment via two registration experts and finally review by medical device registration team leader.
- Final approval is given by the lead executive officer of medical device evaluation and marketing authorization lead executive office

Product registration shall pass through three basic regulatory activities

1. GMP audit/inspection (for medical devices above class III, condoms and gloves)
2. Dossier assessment

3. Laboratory quality test (for condoms, gloves and all sterile products)

Dossier requirements for medical device registration

A medical device registration application should at atleast (but not limited to) the following documents

1. Agency agreement/authorization to local agents
2. Free sale certificate from country of origin
3. GMP certificate (for two highest risk products)
4. Company profile

Dossier requirements for medical device registration…

5. Quality Management System
6. System for PMS
7. Technical Documentation
8. Declaration of Conformity
9. Registration status of the product worldwide
10. Essential safety and performance of the devices
11. Stability (If applicable)
12. Software validation (if applicable)

Average registration timeline for medical device registration

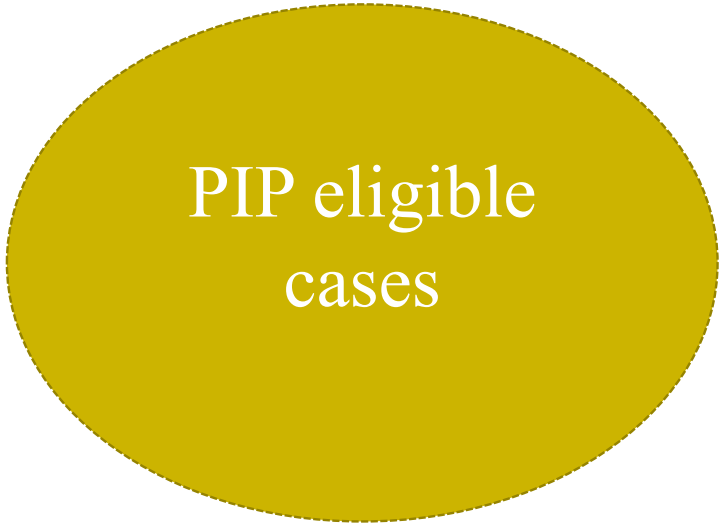
- The timelines depend on quality and completeness of the application dossier and backlogs submitted prior to the application (subjected to fluctuations)
- In general, it takes about 3 to 6 months to get approval for new registrations on average

- MA will remain valid for five years from date of approval

Exemption of Medical Devices from Registration

EFDA has flexibilities in the regulation of medical devices which are to be used in following circumstances:

- Custom made & personal use devices
- Devices for national health emergency
- Investigational devices
- Devices for research, education and other non-clinical uses



Registration service fees

Rate of service fee for inspection for Good manufacturing practice (GMP) of manufacturing sites

No.		Type of service	Fees in USD
1.	For one production company, one production site up to two production lines		
	A	East African countries	5400.00
	B	Other African countries other than east African countries	6930.00
	C	Middle East countries	7750.00
	D	Far East Countries	7400.00
	E	Latin American countries	8950.00
	F	Europe (not eligible for desk review)	7750.00
	G	North America (not eligible for desk review)	8950.00

Registration service fees

Rate of service fee of the registration processes

No.		Type of service	Fees in USD
	Medicine registration		
	A	Dossier prescreening and detailed review with BE/without BE	≈ 50
	B	Laboratory sample test fee per product	200
		Total	Less than 50 or 250 (for sterile products)

Thank you for your attention!

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Thanks