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ETHIOPIAN FOOD & DRUG AUTHORITY

Regulatory Pathways for Drug Registration in Ethiopia

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Presentation Outline

- Background
- EFDA Registration Pathways and Requirements
- Challenges and Opportunities

Background

- Ethiopia one of the fastest growing country with a total population of over 120 million, the second largest population in Africa.
- As a result, Ethiopia has made great progress to improve access to safe, quality and efficacious health products to the public.
- However, health product shortages are now becoming a major problem in Ethiopia.

Background

- EFDA as a public health agency is responsible to facilitate and increase access to essential medicines to Ethiopians.
- To this effect, EFDA is planning to register more product categories and alternative therapeutic agents in the coming Ten years (9,000 medicines and more than 10,000 medical devices).

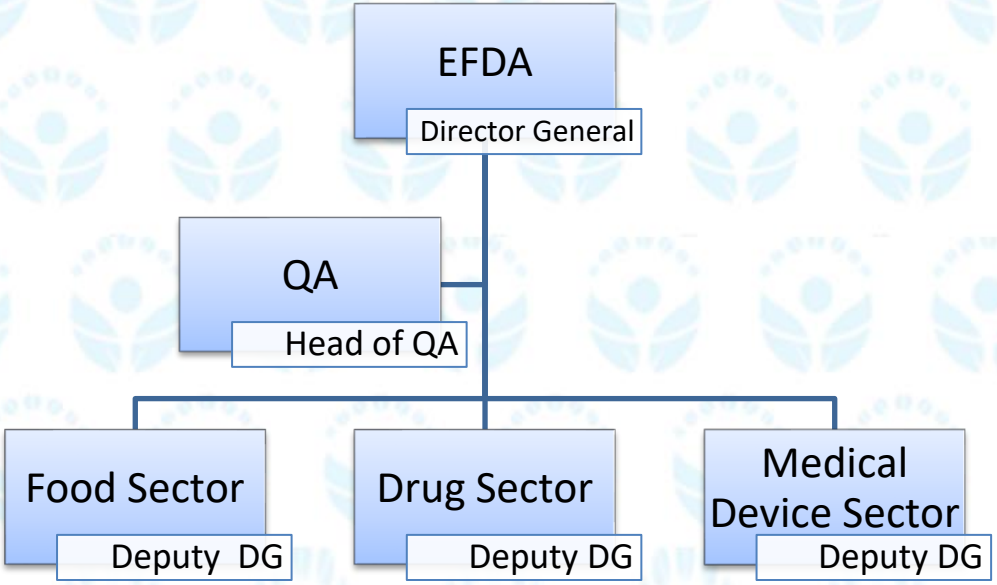
Background

- The Ethiopian Food and Drug Authority (EFDA) is the national regulatory body established by proclamation No. 1112/2019 and responsible for regulating Food, Medicines, Medical Devices, Cosmetics and Tobacco Products.

- History of Drug Regulation in Ethiopia

Background

- To accomplish this duty, it is organized in three major product oriented sectors:



Regulator Functions under DS

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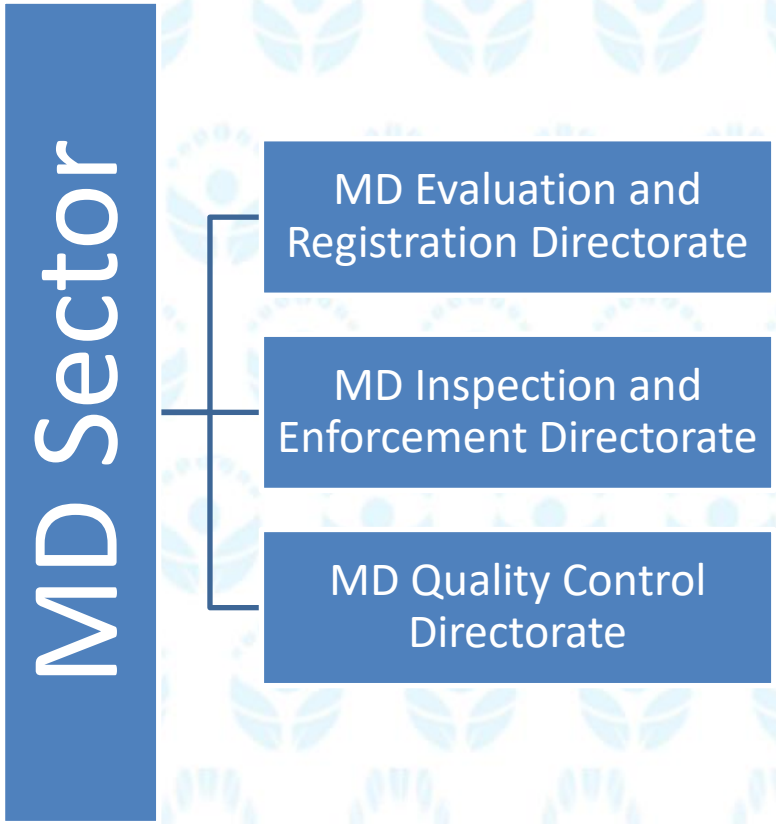
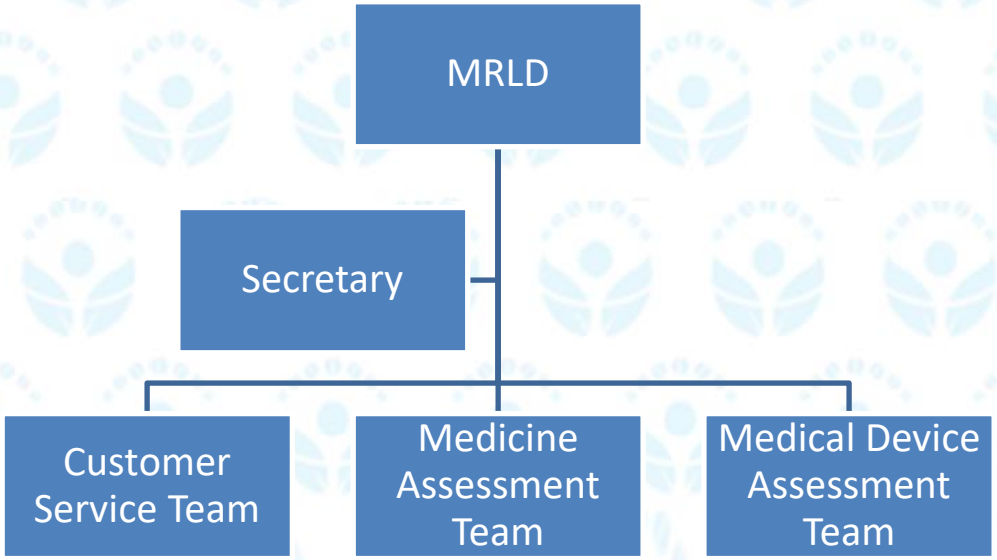

MD Sector
MD Evaluation and Registration Directorate
MD Inspection and Enforcement Directorate
MD Quality Control Directorate

Medicine Registration and Licensing Directorate (MRLD)

- The current MRLD is responsible for registration of:-
  - Medicines
  - Medical Devices
  - Cosmetics



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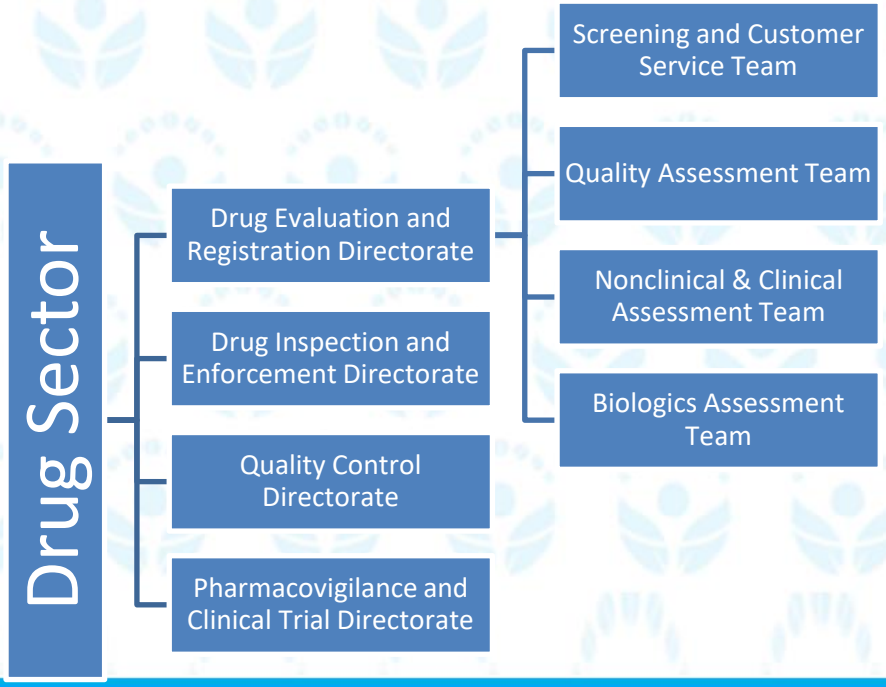
- The very near future organizational structure and the teams under the DERD are shown below:



EFDA's Registration Pathways

- There are different product registration pathways that the authority follows:-
- These are:-
  - **WHOPQ Pathway**
  - **SRA Pathway**
  - **Regular Pathway**
  - **Conditional Approval Pathway**
  - **Emergency Use Authorization Pathway (Covid19 products)**
  - **Low Risk Product Registration Pathway**

WHOPQ Pathway

- When an applicant wants to register its products on the basis of the WHO PQ (pre-qualification) pathway, the applicants should submit the following information:-

1. Administrative documents (Module I)
   - Application form and other documents should be submitted through eRIS.
   - Copy of signed consent form
   - Declaration letter of sameness of dossiers
   - Confirmation of prequalification (CPQ)
   - Good Manufacturing Practice certificate/waiver issued from EFDA
   - Product information
   - Agency Agreement
2. Dossier in CTD (Common Technical Document) format

SRA Pathway

- An applicant claiming to have a registration certificate issued by an SRA (stringent Regulatory Authority) should submit the following information:-

1. Administrative documents (Module I)
   - Application form and other documents should be submitted through eRIS.
   - Copy of signed consent form
   - Declaration letter of sameness
   - MA and CPP issued from an SRA
   - CEP or equivalent certificate for the drug substance
   - Good Manufacturing Practice certificate/waiver issued from EFDA
   - Product information
   - Agency Agreement
2. Dossier in CTD (Common Technical Document) format

SRA

- EFDA recognized stringent regulatory authorities are:-
  - Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Ireland, Italy, Japan, Netherlands, Norway, Switzerland, United Kingdom, United States of America, European Medicine Agency (EMA), and
  - WHO Prequalification Program

Applications through Regular Pathway

For Innovator Medicine

- Drug substance information
- Drug product
- Administrative part & Labeling
- Animal/In vitro studies
- Clinical Studies
- Bioavailability
- Inspection & Quality Testing

For Generic Medicine

- Drug substance information
- Drug product
- Administrative part & Labeling review
- Bioequivalence
- Inspection & Quality Testing

Low Risk Product Registration Pathway

- An applicant claiming its products to be low risk should provide the following documents:-

1. Administrative part & Labeling
2. Technical Document
   - Specifications of the API (s) and FPP
   - Methods of analysis of API(s) and FPP
   - Stability of FPP
   - certificate of analysis, and
   - compatibilities in relation to the following:
     a) Active pharmaceutical ingredient
     b) Excipients
     c) Container & closure.

Conti…

- List of products that are considered to be low risk are annexed in the Low Risk Product Registration Guideline.
- If an applicant claims its product to be low risk as per the guideline criteria for categorization, it is possible to consult the assessment team leaders for possible inclusion in the list.

Conditional Approval and EUA guidelines

- These guidelines are used for products that are considered to be medically in need and for unforeseen emergency situations.

Conditional Approval Guideline	• Unmet medical need • Agents for rare diseases
Emergency Use Authorization Guideline	• Covid19 products • Vaccines

Overall MA Requirements

MA Validity

- Every medicine or medical device registered in accordance with this proclamation shall have its registration renewed every five years.
  - Market authorization Validity- 5 years
  - GMP Compliance Validity- 5 years
  - Renewal period 180 days before expiry

Post-approval Variation

- There are procedures for postapproval variation applications.
- Variations has to be applied within the validity period of market authorization.
- There is facilitated procedure for renewal and variation assessment in order to avoid disruption of the product supply chain.

Registration Process involves the following steps:-

Application Reception

Check the formal validity of the application

Dossiers can be submitted prior to GMP inspection

Assessment

Quality (Chemistry, Manufacturing and control)

Interchangeability/Safety and efficacy

Product Information (Labeling, SmPC and PIL)

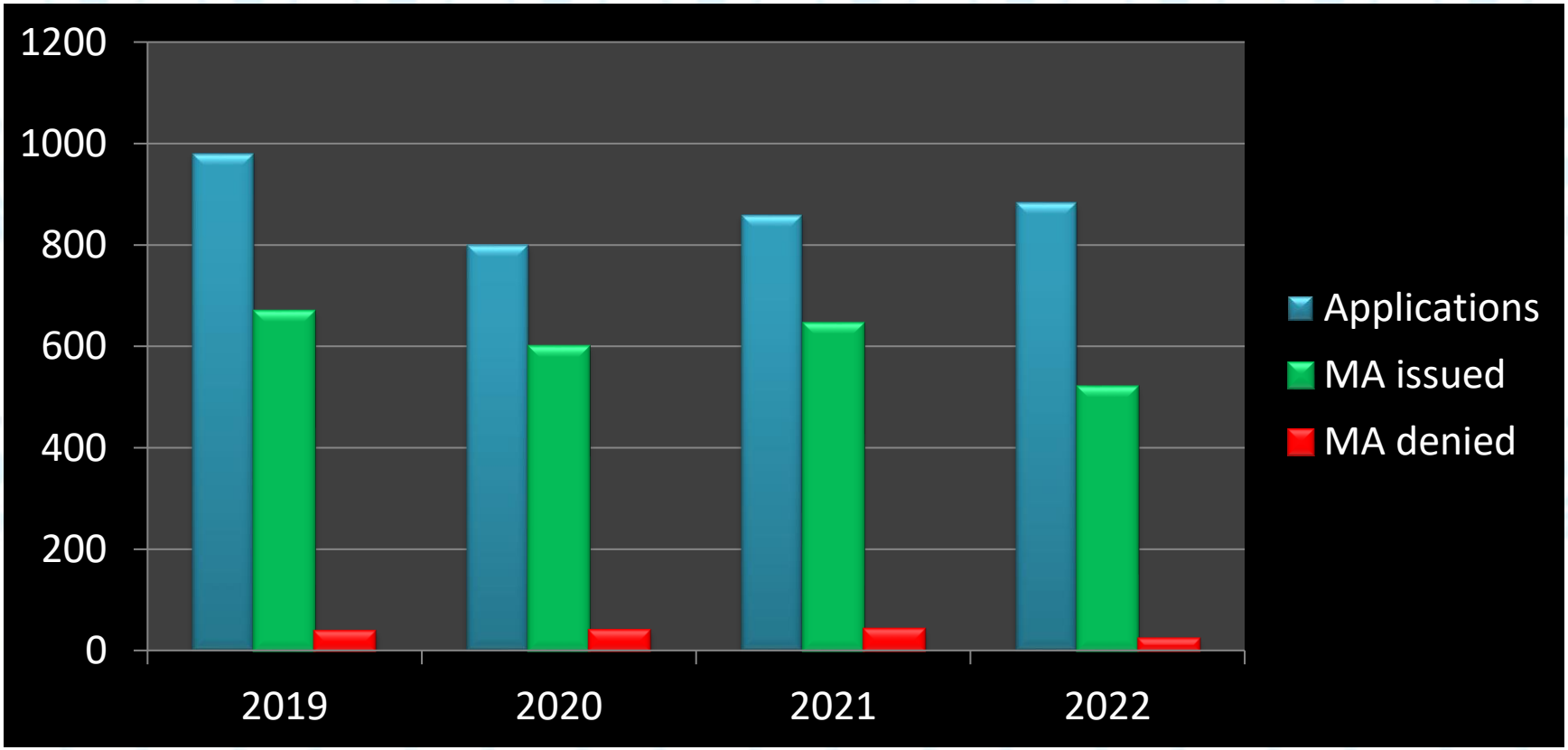
Outcome

The ultimate outcome of the registration process will be either denial or marketing authorization of the product .

Who Can Apply for Registration

- Market Authorization Holders or their representatives in Ethiopia such as:-
  - Local importers
  - Local pharmaceutical consulting firms

Trend of Application



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- There are mor than 500 further information requests that are waiting responses from applicants.
- Some of them are older than three years.
- The reasons for the delay not well documented. However, it is believed to be miscommunication between the Authority and MAH.

Fast Track Registration

- The authority has also a procedure for *Fast Track Registration* of medicines that are essential for public health programs such as:-
  - Antimalarial agents,
  - antiretrovirals,
  - Antituberculosis medicines,
  - Reproductive health care products,
  - anti-cancer drugs,
  - Vaccines and new medicines,
  - Medicines for neglected tropical diseases
  - Medicines required by EPSA (govn't procurement agency)

Registration Guidelines

- The authority has different technical guidelines that help to guide applicants for their specific product applications.
  - Guideline for the Registration of Medicines, 4th edition, 2020.
  - Guideline for the Registration of Vaccines, 1st edition
  - Guideline for the Registration of Biotherapeutics Products
  - Guidance on waiver of in vivo bioequivalence requirements
  - Guideline for Conditional Approval of Medicines

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- The Medicine Registration Guideline allows the authority to grant market authorization for FPPs with ongoing stability studies.
- However, we didn't apply the guideline so far because of absence of a system to trace them once approved.
- Now, we have developed the system and will start registering products as per the guideline.
  - For more information, please review the guideline

Registration Timeline

- According to our recent experience the registration timeline is shortened significantly as compared to many other countries.
- If complete information is submitted according to the requirements, MA can be granted:-
  - WHO-PQ……..30 days
  - SRA……..30 days
  - Own Assessment……120-180 days

Registration Timeline

- The application submitted for registration is screened and evaluated chronologically according to date of submission to the Authority.
  - Exception- fast track products
- *The eRIS helps applicants to follow their application virtually anywhere in the world.*

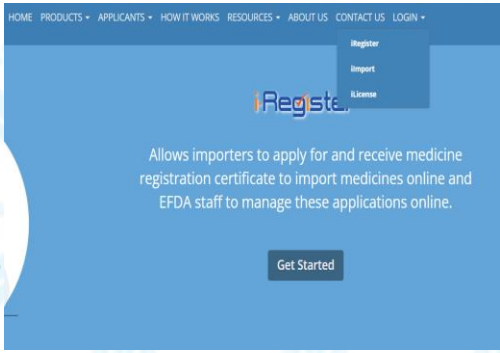
Registration Staff

Current Assessor 30

Near future 45 to 54

Information Management System

- The authority has implemented an electronic regulatory information system (eRIS) to make all of its regulatory activities transparent to users.
  - iRegister is used for Registration purpose.
  - All applications are applied through this system except cosmetics.
  - The system helps:
    - To facilitate registration
    - To improve communication
    - To follow the status of applications virtually elsewhere
    - To improve transparency and visibility



Challenges

- Current Challenges
  - Incomplete application submission
  - Late reply or do not reply at all to queries raised by assessors
  - Information gap between EFDA and actual applicants
  - Inability of suppliers to see their applications directly from the eRIS

Opportunities

- EFDA establishing systems that are more efficient, integrated and transparent to applicants and the general public.
  - Restructuring and reorganizing the office
  - Increased number of staff with proper expertise to accelerate regulatory functions.
  - Started construction of state of the art quality control lab to be center of excellence in Africa (costing more than ETB 2 billion).

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- For more information, please visit
  - ☞ http://www.efda.gov.et/

To be a center of excellence in food and health products regulation in Africa

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Thank You!

Questions?