

— We protect the safety of our people! —



EFDA

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ETHIOPIAN FOOD & DRUG AUTHORITY

Learning's from COVID-19 Pandemic

Heran Gerba, Director General, EFDA

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

Outline

- Introduction
- Regulatory Enablers for Fast track Registration
- Supply Chain Resiliency
- Regulatory preparedness for Healthcare Emergencies

Introduction

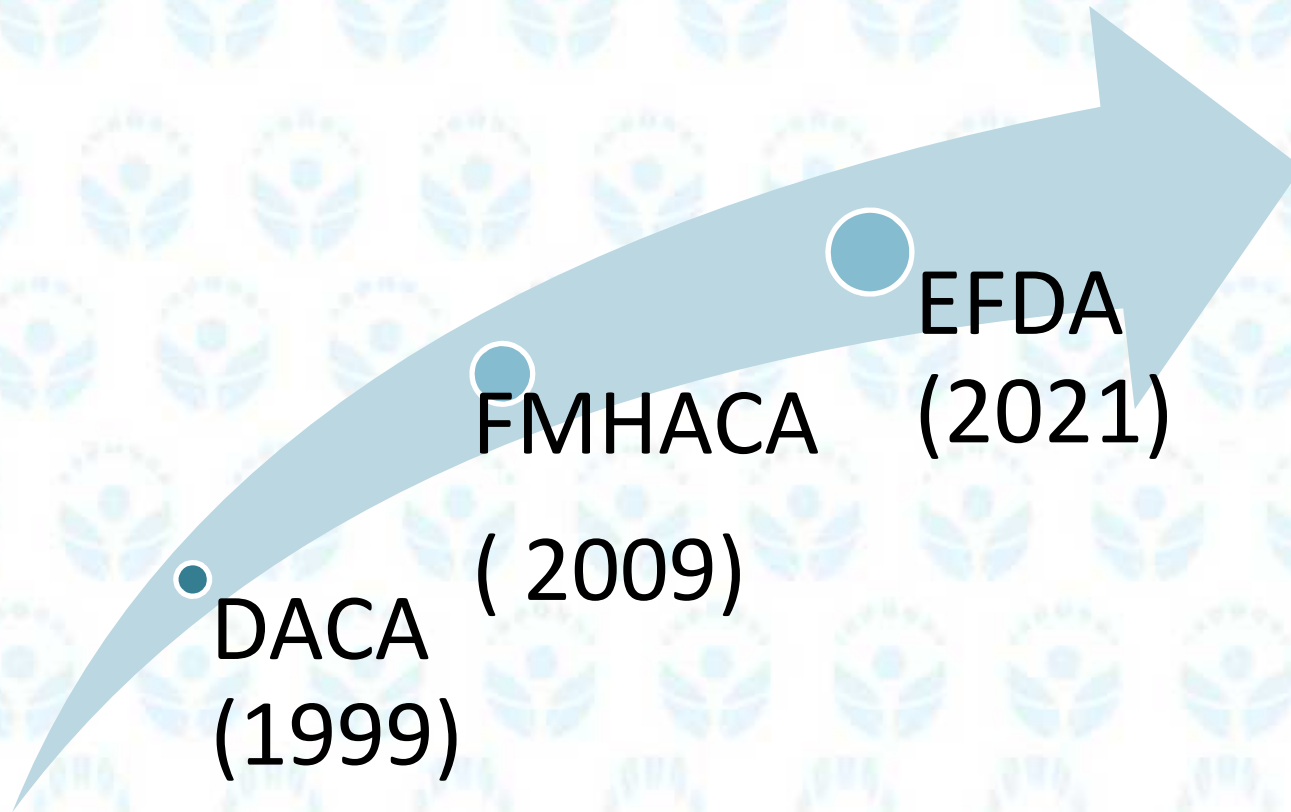
- Ethiopia is the second most populous country in Africa
 - An epidemiologic shift with high morbidity and mortality from the triple burden of diseases.
 - *Data from the GBD study shows that 52% of the total mortality is due to NCDs while it comprises of 15% share from the national health expenditure (NHA-7, 2016/17).*
 - Increasing demand from the community for high quality healthcare
 - High political commitment to improving health infrastructure.
 - Large population with high need for services and products
 - Increased number of health professionals' training institutions (public and private sectors) and programs
 - Introduction of insurance schemes (e.g., Community Based Health Insurance system (55%) , third-party road accident)
 - Efforts to introduce Social Based Health Insurance system

Introduction

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- The health sector has been primarily affected and tested like never before with the overwhelming number of to
 - Mass casualty victims,
 - Internal Displaced People (IDP),
 - Post traumatic Psychosocial Support,
 - Rehabilitation and
 - Basic health care service.
- Number of hospitals (Public) 411
- Number of health centers 4200
- Number of health posts 16600
- MMR (UN est.) 353 per 100000
- U5MR 59 per 1000
- Average Life Expectancy 66.6
- Health Professionals to Population Ratio 2.1/1000

Introduction



Regulatory Enablers for fast track approvals

- Proclamation 1112/2019 indicated that any medicine shall not be manufactured, imported, distributed,...used, or transfer to any other person without registration and marketing authorization.
- Thus, the authority is striving to increase access to quality assured essential drugs to the Ethiopian people.



Regulatory Enablers for fast track approvals

Different Guidelines in place:-

- Guideline for registration of Medicines
- Guideline for Registration of Vaccines
- Guidance for Emergency Use Authorization of COVID 19 Vaccine
- Guidance for Conditional approval of Medicines
- Guidance for registration of Low Risk Medicines

Regulatory Enablers for fast track approvals

- 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.
 - Locally Produced Medicines

Regulatory Enablers for fast track approvals

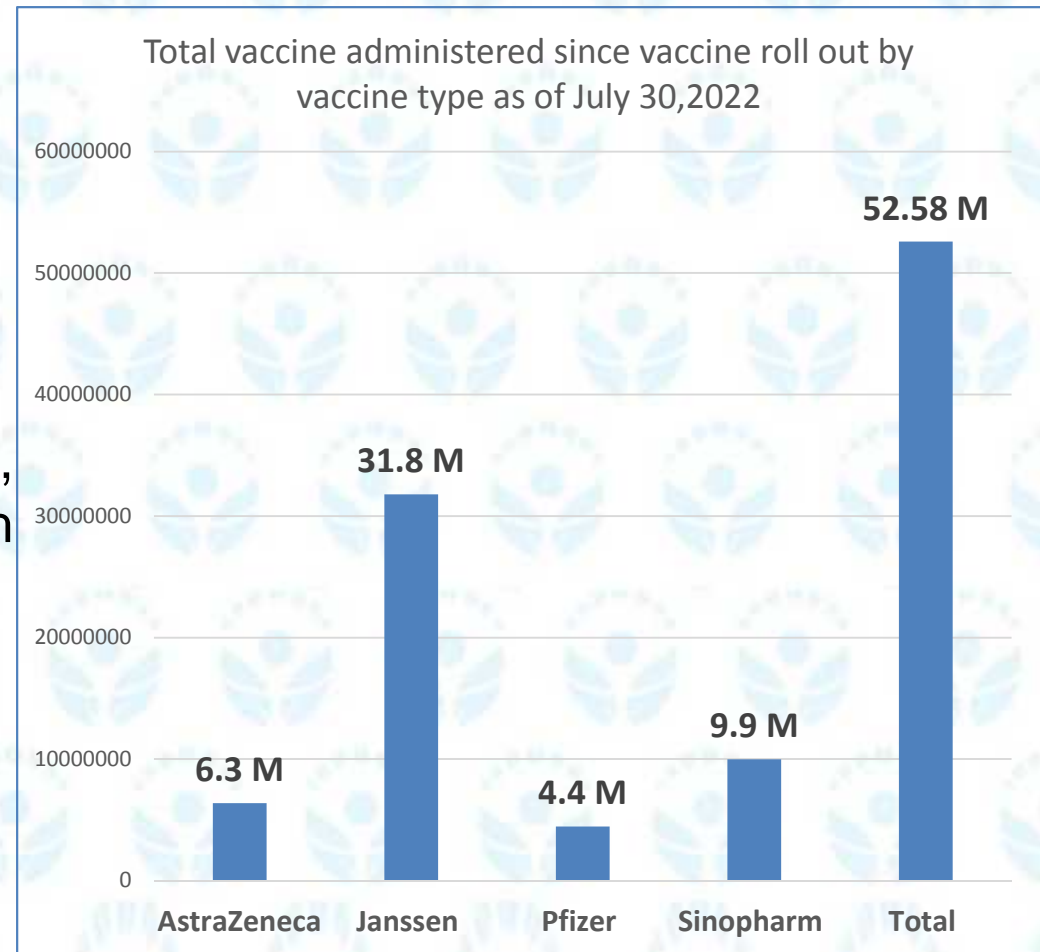
THE COVID EXPERIENCE:-

- Discussion with Manufacturers and Importers association
- Revision of directives/Development of Temporary Directives to cope up with the pandemic
- Stakeholders engagement
- Public Communication through different media outlets

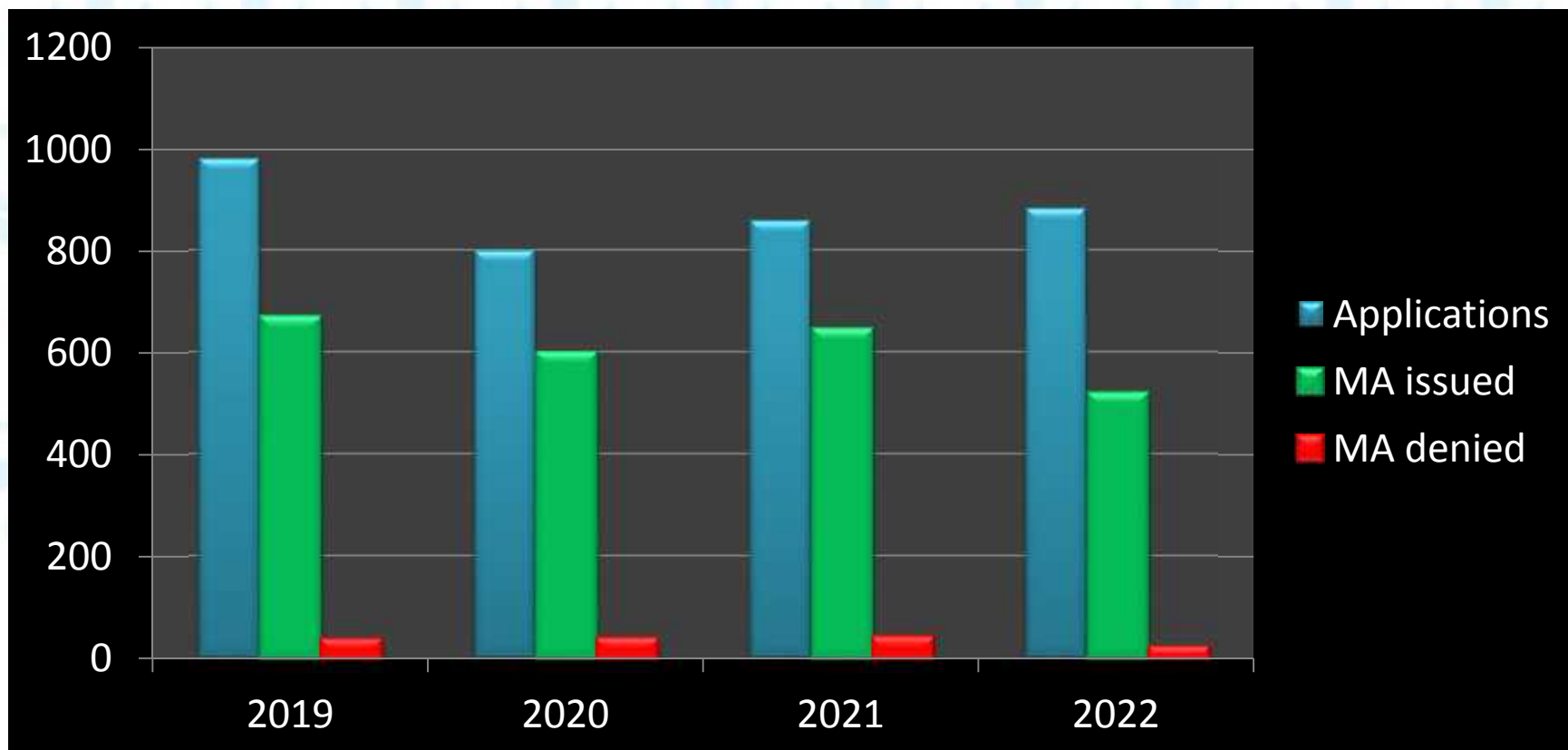


Regulatory Enablers for fast track approvals

- Using the Emergency Use Authorization guideline and Reliance Procedure we authorized 5 COVID 19 vaccines
 - Johnson & Johnson's,
 - AstraZeneca (Covidshild, Oxford Un. Uk and South Korea),
 - Sinopharma of Beijing
 - Pfizer
 - Sinovac



Trend of Application



Regulatory Enablers for fast track approvals

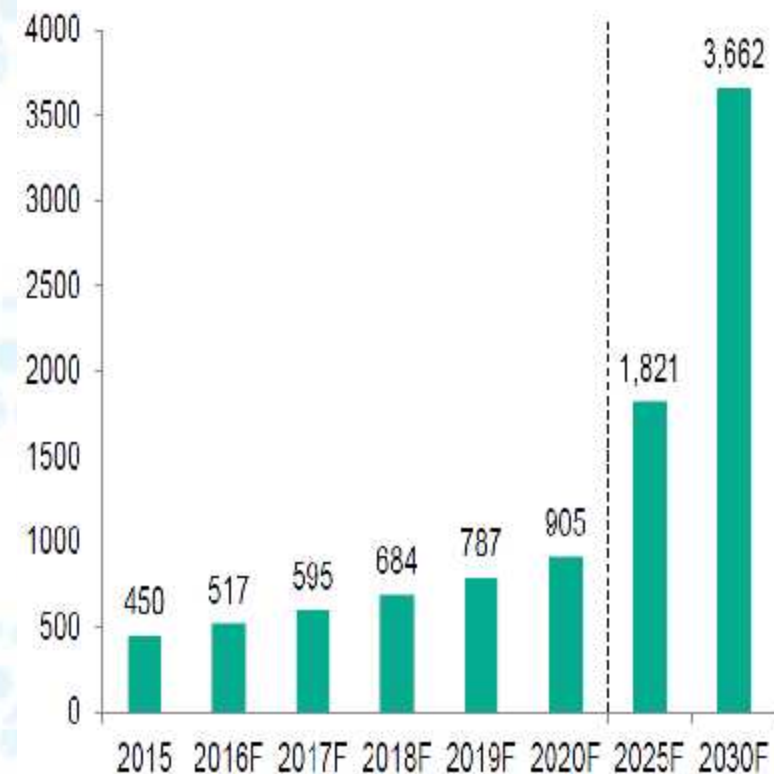
- Technology Assisted Regulation
- The authority has implemented an electronic regulatory information system (eRIS) to make all of its regulatory activities transparent to users.
- Track and Trace (i-verify application)



Supply Chain Resiliency

- In 2015, the Ethiopian pharmaceutical market was estimated to be **\$ 450M** and it has been growing at 15% to reach an estimated value of **\$ 1.8Bn** by 2025.
- According to the market research company Fitch Solutions, the estimated size of the market in 2021 is **\$1.12Bn**
- Public sector purchase by EPSS is estimated to be **75%** of the total pharma.

Pharmaceutical market in Ethiopia
(2015-20F), US\$ million



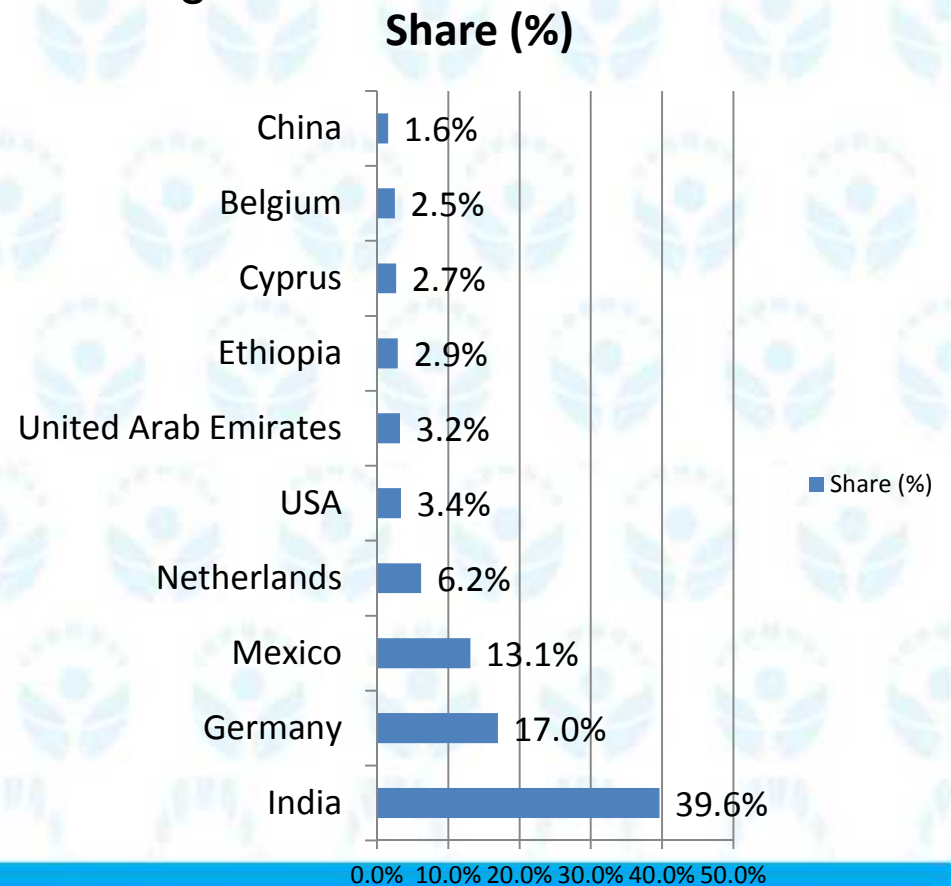
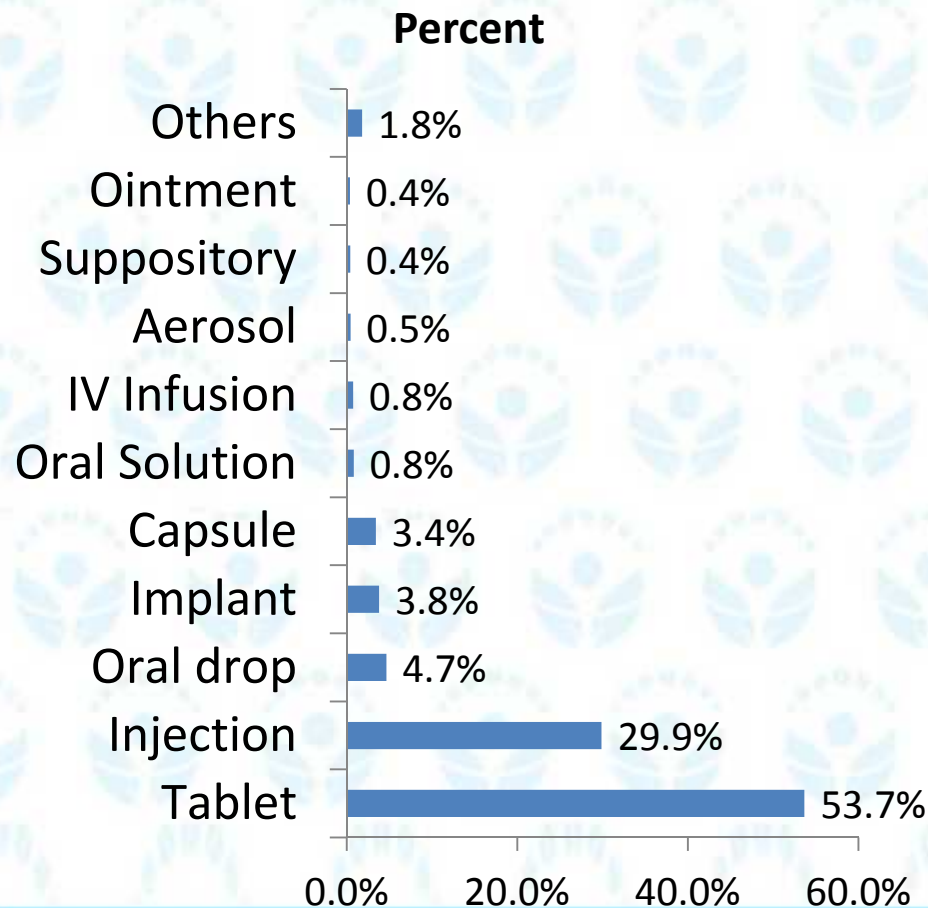
The Ethiopian pharmaceutical market

is highly dependent on import **>90%**.
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Supply Chain Resiliency

- Market Share by Dosage Form

- Market Share by Country of Origin



Supply Chain Resiliency

- Covid-19 laid bare Africa's huge reliance on imported pharmaceuticals, with the continent importing as much as 90% of its drugs.
- Local manufacturing is vital to African economies, a challenge made especially clear with the supply restrictions that have arisen during the Covid-19 pandemic
- Some 60% of total pharma spend in Ethiopia is public and social sector related, making the Ethiopian Pharmaceutical Supply Service (EPSS) the single most powerful buyer in the country.
- Key products purchased in the public and social sector are antivirals and antibacterials.

Supply Chain Resiliency

- One of the prime focuses of the Ethiopian government's national growth agenda is the development of the local pharmaceutical sector as enunciated in the 10 year National Strategy and Plan of Action for Pharmaceutical Manufacturing Development (NSPAPMD).
- The strategic plan aims to boost local manufacturing to provide access to quality-assured medications while also contributing to the economy.
- During COVID 19 pandemic Ethiopia reprocessed the existing industries to manufacture sanitizers and masks.

Supply Chain Resiliency



i-Verify | **EFDA**
ETHIOPIAN FOOD & DRUG AUTHORITY

A MOBILE APPLICATION TO VERIFY IF MEDICINE IS REGISTERED WITH THE PROPER AUTHORITY AND IF IT'S AUTHENTIC.

- Download the iVerify mobile app from **GOOGLE PLAY**
- Type in the name of the drug or move the front packet of the drug to your mobile camera and click **SCAN**
- If you do not receive any information, report the drug as illegal. Click on the **Report** button and type the name of the city and the name of the pharmacy where you found it.
- As additional information, send a photo of the medicine.

The Authority will look into this information and take the necessary action.

Reason for Reporting on i-Verify:

- When the searched item is not found
- When items batch & expiry on i-Verify are different from the actual items
- When the products is expired

OR CALL OUR FREE HOTLINE **8482**

GET IT ON **Google Play** | **Download on the App Store**

- Fight Against Substandard and Falsified Medicines
- Track and Trace (i-verify application)

Regulatory Preparedness for Health Care Emergencies

EFDA is working to reach Maturity level III or above based on WHO GBT

- This helps in the recognition of EFDA's regulatory measures by NRA with similar/lower Maturity level
- Eg. Marketing authorization issued by EFDA may be recognized by other countries

IGAD harmonization initiative :

- Joint assessment of dossier, GMP inspection & Post Market Surveillance
- Facilitate obtaining marketing authorization by member countries
- Ultimate goal of this initiative is "Mutual recognition"

African Medicine Agency :

- Established
- Ethiopia will be signatory member
- The treaty will be ratified soon
- Will create access to more than 1.1 billion market

WHO Collaborative registration procedure

- 46 countries participating including Ethiopia
- 31 African countries
- Prequalified products will be recognized by 46 countries
- e.g
SINOPHARM VACCINE

Regulatory Preparedness for Health Care Emergencies

- Issued Regulatory Preparedness and Mitigation Strategy for Emergency Health Threats on August 2020. (www.efda.gov.et/publications)
- Focuses on dealing with emerging health threats such as coronavirus, ebola and others that could be caused by biological, chemical, environmental and other unknown triggers. The strategy is meant to provide guidance on regulatory interventions during public health emergencies.
- The objective is to ensure sustained access to innovative, safe, quality assured and effective medical products through mitigating medical products shortage during public health emergency situations.

Regulatory Preparedness for Health Care Emergencies

The Authority will undertake the following actions as part of the routine preparedness to ensure adequate readiness to deal with an emergency public health threat.

- Regular interactions with vaccine/antimicrobials/antivirals experts and regulatory network with academia, research institutes and relevant stakeholders and partners;
- Regular discussions with local manufacturers and suppliers of medical products.
- Regular interaction with EPHI through early warning and response system set up by EPHI. There should be notification and information sharing of health measures planned or undertaken against serious cross border health threats;
- Regular interactions and information sharing with international organizations such as WHO, EMA, AMA, AU, ACDC, IGAD and other national regulatory agencies.

Regulatory Preparedness for Health Care Emergencies

- Conduct regular analysis to compare recently imported and locally manufactured products by utilizing trends to forecast imminent shortages and identify alternative solutions.
- Create regulatory flexibility that suits public health emergency mitigation and response
- Prepare and make ready necessary legislative documents that facilitate decisions for emergency use authorization of medical products during emergency situations
- Arrange logistic and supply arrangements including financial and other resources.
- Establish structure within the Authority that deal with emergency and crisis management.
- Harmonize important regulatory requirements with other NMRAs to facilitate speedy access to existing, new and innovative products

Regulatory Preparedness for Health Care Emergencies

Interventions that will be done to respond to public health emergencies

- Strengthen assessment on shortage of medical products and mitigate shortages
- Protect patients from substandard and falsified medical products
- Facilitate to accelerate priority research and innovation
- Pharmacovigilance aspects
- Develop legal and guidance documents
- Communication and information sharing

- For more information, please visit

 <http://www.efda.gov.et/>



The screenshot shows the EFDA website homepage. At the top, there is a navigation menu with links for Home, About Us, News and Events, Services, Publications, Directorate, COVID-19, Announcement, and Contact. The main content area features a 'Welcome to EFDA!' heading. Below this, there are four columns of information:

- Organization:** EFDA is the National Regulatory Body of Ethiopia which is under the Ministry of Health. The Authority is responsible to ensure the quality, safety and efficacy of medicines, food, cosmetics and medical devices.
- Objectives:** To protect the health of consumers by ensuring:
 - Their safety and quality
 - Safety, efficacy, quality and proper use of medicines
 - Safety, quality and performance of medical devices
- Establishment:** EFDA was established under the Ethiopian Central Drug Re-examination establishment statute of Ministry of Health, No. 116/2011, after repealing the drug administration and control proclamation (P.D. 502). EFDA became operational on July 11, 2010. It was set up from the Ethiopian government. It is mandated as the Food, Medicines and Healthcare
- Mission:** To guarantee and protect the public health by ensuring safety, efficacy and quality of health and health related products and services through product quality assessment and registration, licensing and supervision of health professionals, health institutions, pharmaceuticals and food establishments, and promotion of good manufacturing practices.

There is also an 'About The Authority' section with an image of medical supplies and a paragraph of text.

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THANKYOU



Over 20 billion seedlings planted starting from 2018 until september 2022

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