PAVIA Implementation Progress: ETHIOPIA

COUNTRY SPECIFIC ACHIEVEMENTS & CLOSING REPORTS

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Product Safety Director

Presentation Outline

- Key PAVIA achievements
- General PV achievements
- Best practices for other countries
- Closing plans
- Plans for sustainability post-PAVIA
    - ❖ Country PV Linkages with other PV stakeholders
    - ❖Cascading of PV activities
    - ❖Plans for continuation of PV trainings, and capacity building
    - ❖ Plans for continued strengthening of PV regulatory and policy frameworks
    - ❖Plans for sustainability of the PV triangle

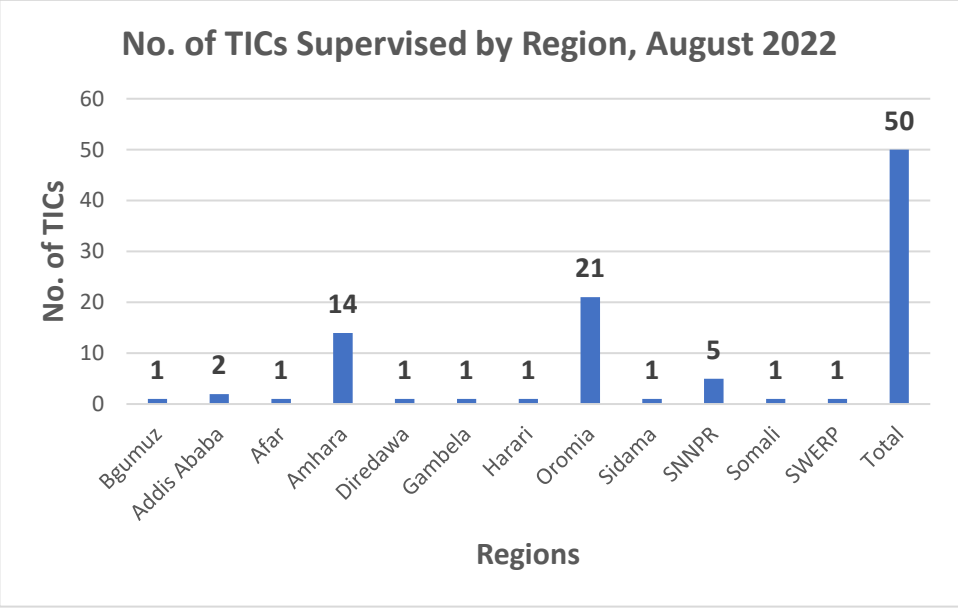
Key PAVIA achievements

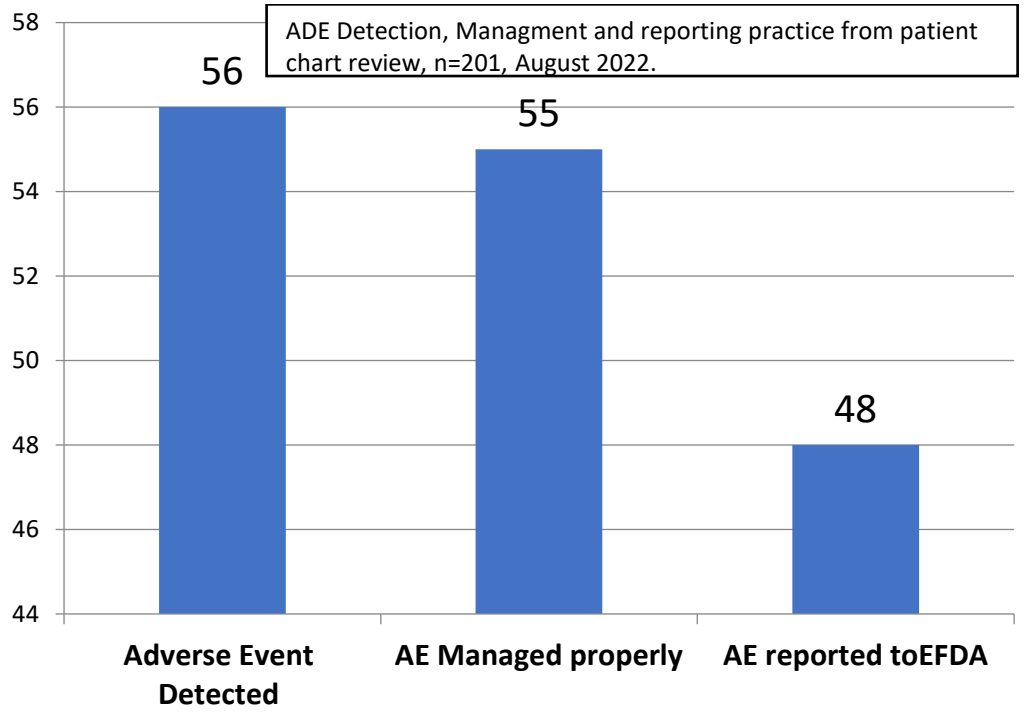
Significant improvement in ADE reporting from TICs has been observed
: Which was achieved by improved

1. aDSM sensitization meetings,trainings

ey PAVIA achievements 2.supportive supervission,

❖In august 50/64 TICs, report was shared with key stakeholders.





Key PAVIA achievements…

Globally Shared Reports

3.Since the start of the project total 654 reports received from TICs (including through RHBs) up to December 2022

Only 41 reports received before the start of the PAVIA project

Key PAVIA achievements…

Globally Shared Report…

11,457


https://vigiflow.who-umc.org/search/csrs
VigiFlow - ET Food, Medicine & Healthcare Admin and Control Authority
Filter
New AEFI
Import
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VigiLyze
Page 1 of 1496
29911 reports match your search with 1 filters applied
Worldwide unique id
Delegated to organisation
Initials
Date of birth
Reaction / event (MedDRA)
Drug name (WHODrug)
Initial received date
Latest received date
Status of report
ET-EFDA-300031980
ET Food, Medicine & Healthcare Admin and Control Authority
M.S
Bedaquiline, Clofazimine, Linezolid
20022023
20022023
Open
ET-EFDA-300031981
G.B
Clofazimine, Linezolid
ET-EFDA-300031979
zinet
Hypersensitivity reaction
15022023
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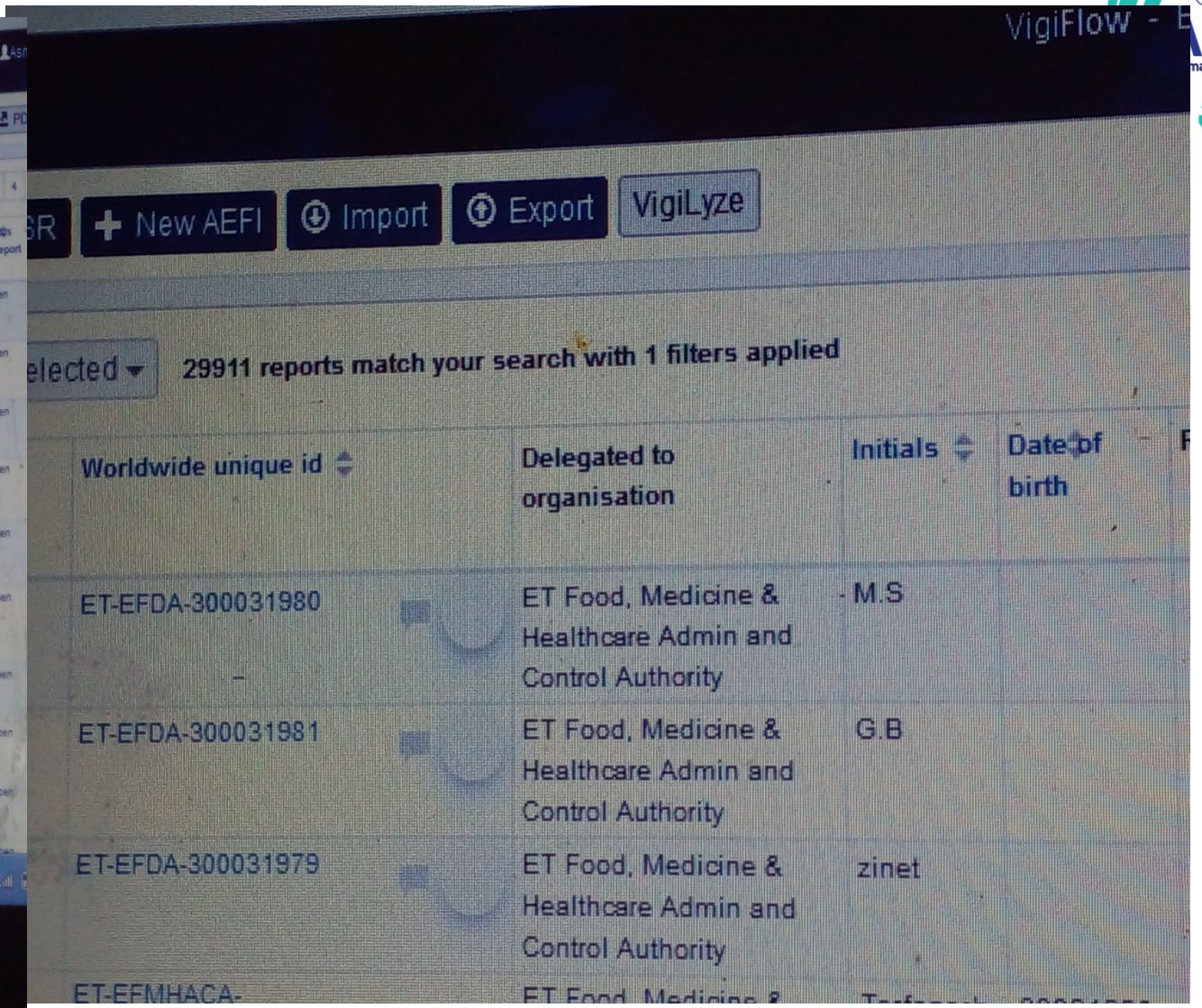
Tesfanesh
30091990
Thrombosis
COVID-19 vaccine Janssen
06022023
ET-EFMHACA-20230206184320673O-6GXY4
Miss
20111994
Itching, Rash
Dihydroartemisinin
ET-EFDA-300031968
A patient
Kounis syndrome, Fatigue, Coronary spasm, Injection site redness, Pseudoallergic reaction, Chest tightness, Headache, Burning sensation, Urticaria, Cardiac troponin T increased, Left ventricular hypertrophy, Anaphylactoid reaction, Dizziness, Myocardial injury, Bronchospasm
02022023
ET-EFDA-300031967
semira
01122000
01022023
ET-EFDA-300031966
15021997
30012023
ET-EFDA-300031962
AS
01012006
Injection site pain, Injection site redness, Injection site swelling, Injection site numbness
Pfizer BioNTech COVID-19 vaccine
28012023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4. Strengthen Collaboration Work with EFDA,NTP and AHRI)

- PAVIA strengthen collaboration and work together of EFDA, NTP and AHRI with improver our Pharmacovigillance system.
- Triangle Members: NTP,AHRI,PV Center, PAVIA CO.
- Meeting regularity = Planned monthly but due to varied schedules regularity not maintained .
- But beyond the regular meeting triangle members collaborate in implementing planned activities. e.g Trainings, SS ,development of guidelines, SOPs etc…
- Integration of aDSM topics in the general pharmacovigilance and pharmaceuticals, PMDT & supply chain management
- Strengthen collaboration with NTP and AHRI contributed to improved reporting of ADEs.

Key PAVIA achievements…

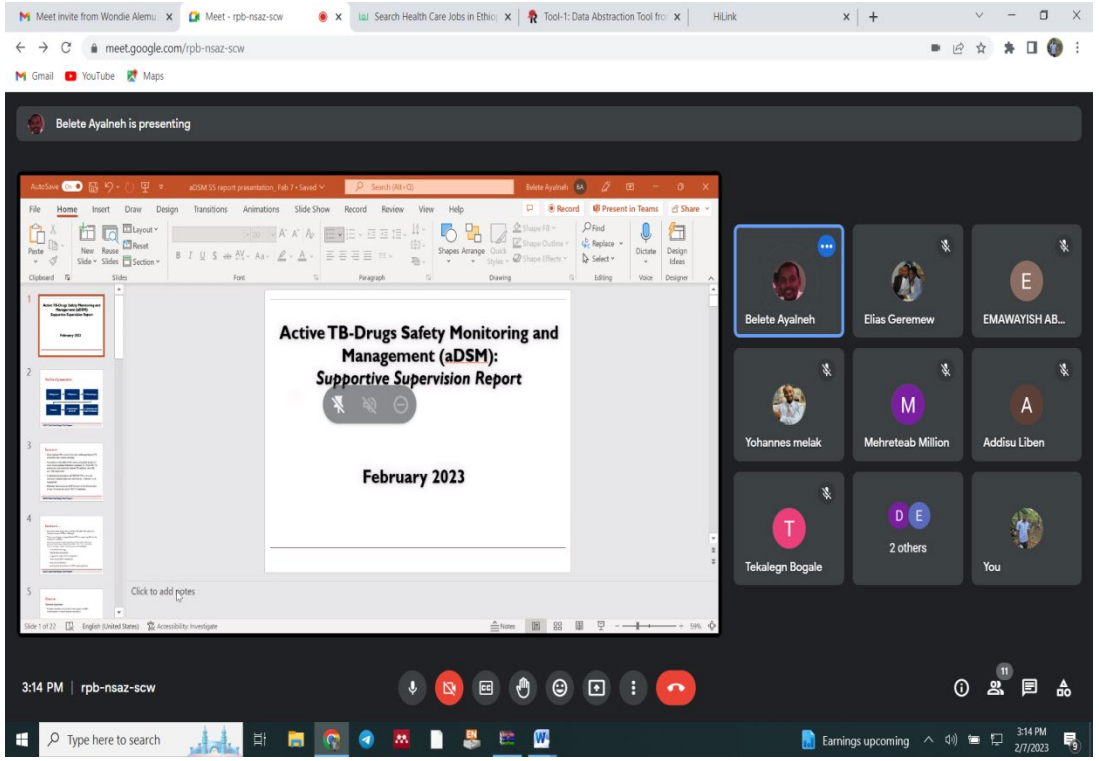
5. Investigation of reported MDR TB drugs SAE cases
6. Additional reporting methods introduced ,Decentralization of PV center and focal persons trained on:

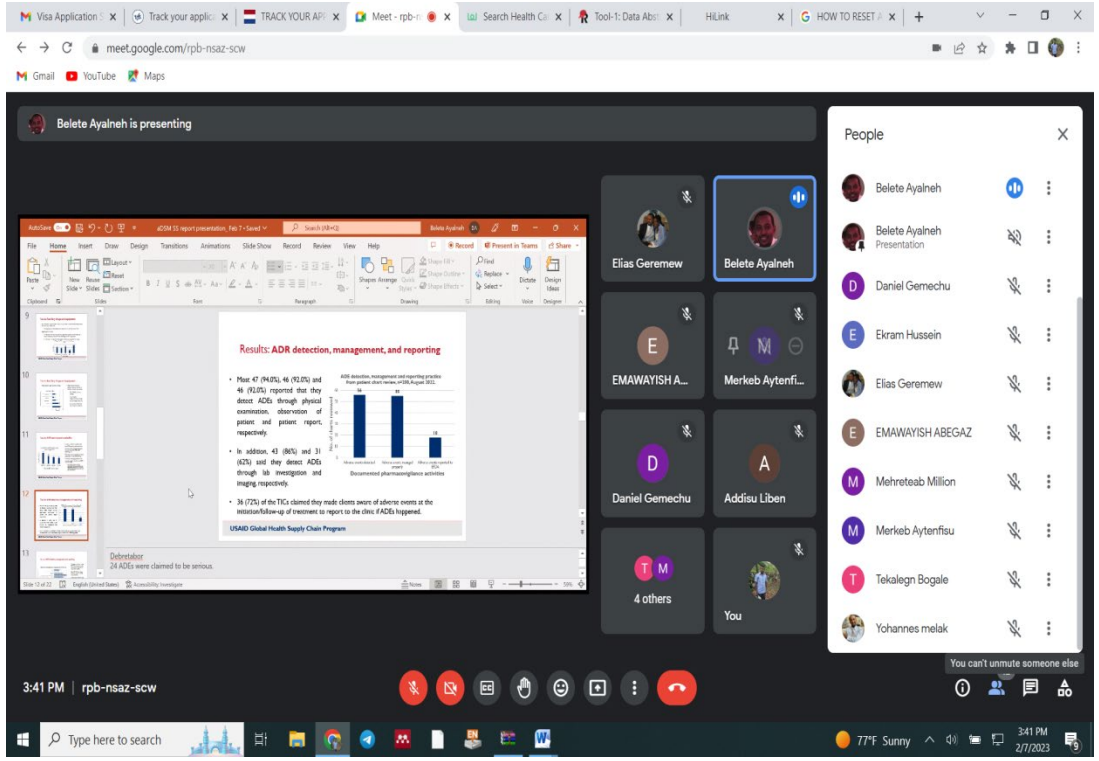
- ❑ E-reporting: www.fmhaca.gov.et, services link, e-Reporting of ADR
- ❑ MedSafety mobile apps,
- ❑ Mail reporting system: pharmacovigilance@efda.gov.et
- ❑ RMP/PSURS/ICSRs from MAH
- ❑ previously existing ADE reporting tools:
  - ✓ Yellow Form (ADE reporting form)/hard copy, manual/
  - ✓ AEFI Reporting Form / hard copy, manual/
  - ✓ AE Line listing form / hard copy, manual/

- *ADE was incorporated in the MDR TB Tracker (*case-based EMR for DR-TB*) which is developed by NTP.*

7. Dissemination of aDSM data analysis result *(different stakeholders including higher officials involved)*

3.aDSM supportive supervision report to stakeholders



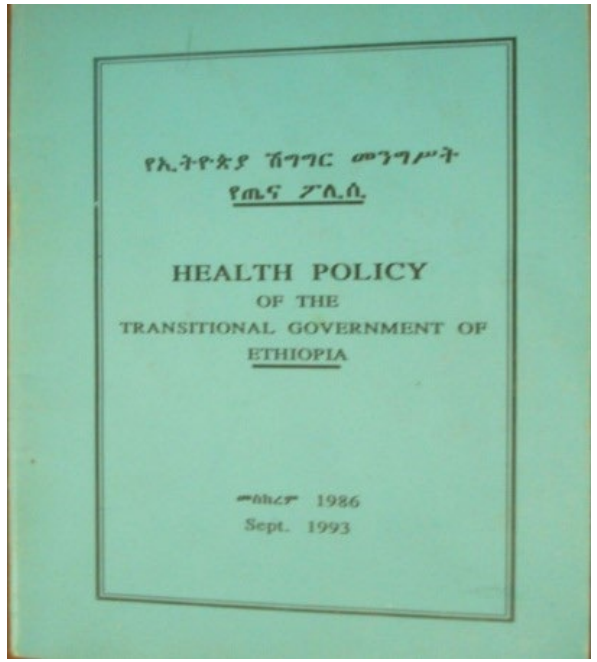


9. Established PV stakeholder platform and aDSM Committee

General Key achievements

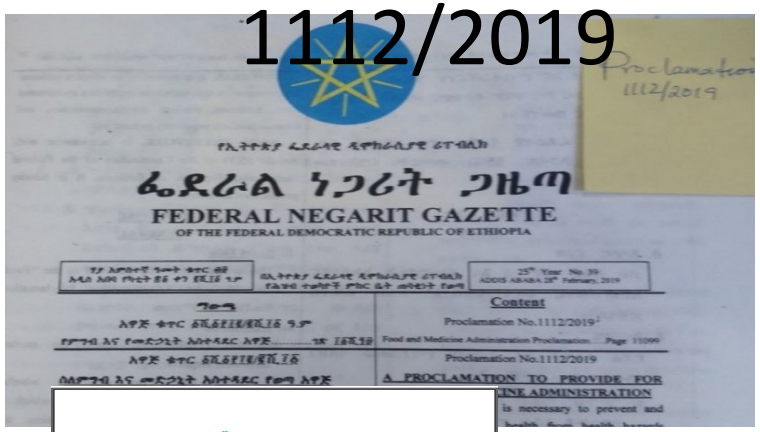
- The National PV road map was Approved
- The National PV directive was Approved
  - Establish a mandatory requirement of QPPV for MAHs
  - Incorporate Mandatory performance and funding of PASS
  - Set out timelines for submission of PSUR, ISCRs, RMP in line with International Standards,
- Patient reporting guideline was developed
- Stakeholder engagement for PV activities ToR was approved
- Integration of PV training to national CPD course

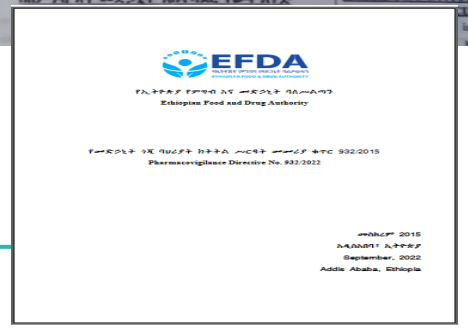
Key achievements…



PV Policy, law and regulations

1112/2019





Rationale:
Need for a strong drugs ***administration and regulation*** to maintain public health and safety:

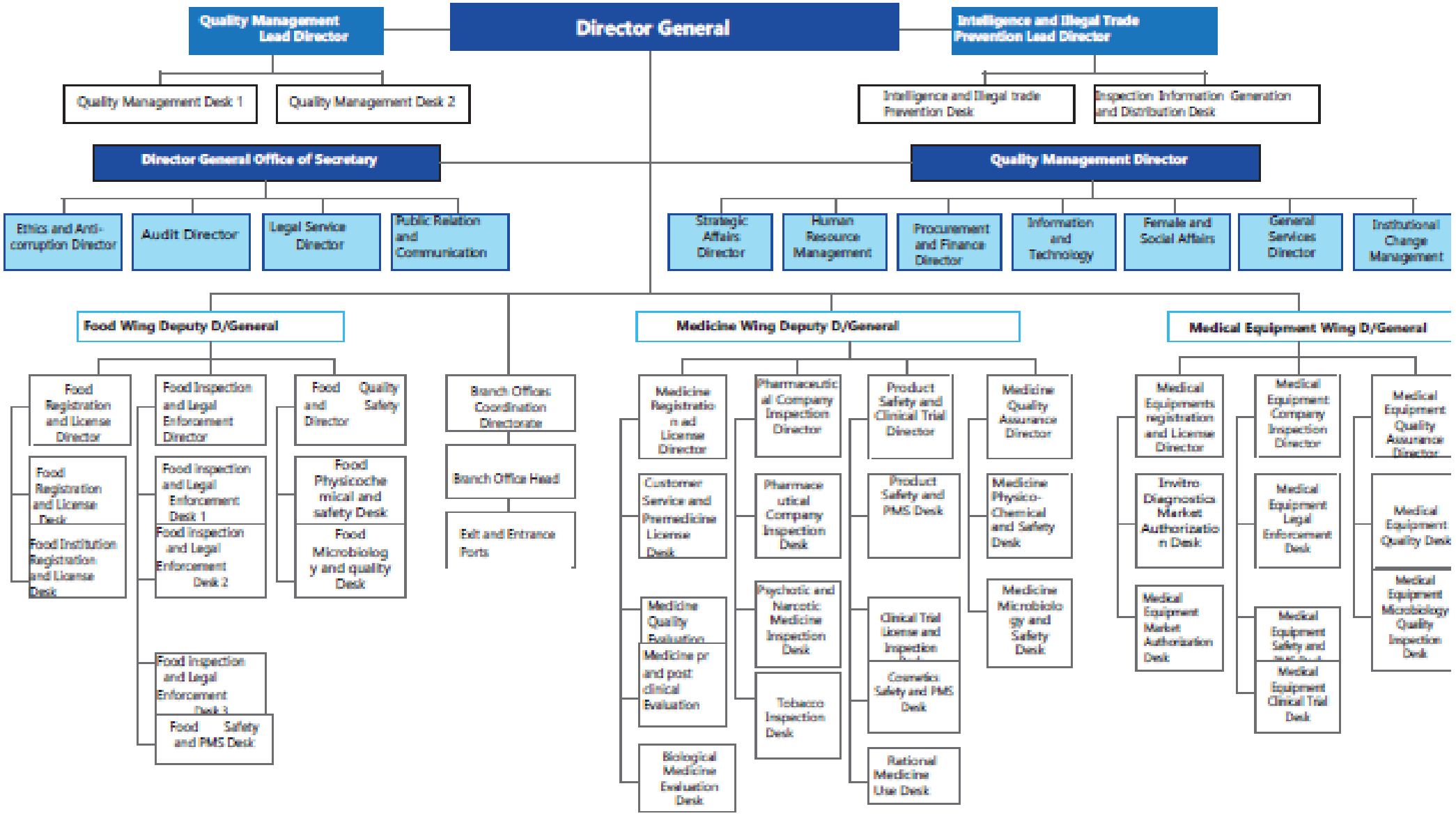
To ensure SEQ + RU

Key Achievements...

Systems, structure and stakeholder coordination...

- New EFDA structure was approved by civil service commission on June 2022.
- Under this New EFDA structure PV and Post marketing surveillance Directorate will be established.
- EFDA branch offices will be expanded from 6 to 11 branches office and under each branch office PV and Post marketing surveillance desk will be established.
- Staff deployment is on progress
- PV stakeholder coordination plate form was established

Ethiopian Food and Drug Authority



Key achievements…

PAC re-established with revised ToR

- ❑ Broadening its scope to all medicine
- ❑ Inclusion of relevant experts
- ❑ Revision of TOR
- ❑ Issuing nomination letter

EFDA is working for Maturity level 3

Necessary QMS documents were prepared:

- ❑ Legal documents such as pharmacovigilance directive
- ❑ PV guidelines
- ❑ Quality Manual
- ❑ SOP
- ❑ Checklist
- ❑ Records were developed

aDSM supportive Research in collaboration with AHRI

Research:

Title and Methods

- Performance of aDSM for PV strengthening in Ethiopia; Experience assessment from MDR-TB management program
  - mixed method involving both quantitative and qualitative
  - Data abstraction tools for patient chart review *plus* questionnaire, therefore
  - level of aDSM performance, prevalence of adverse events (AEs), level of AE detection and management and factors affecting aDSM performance are assessed
  - Involving >10 TICs

Progress, achievements

- Data collected from >1300 Patients' charts
- Data cleaning in progress
- Manuscript writing will be started end of Feb, 2023.

Systematic Review:

'Safety and treatment outcome of bedaquiline and delamanid containing regimens in the treatment of MDR/XDR TB among HIV co-infected patients: a systematic review and planned meta-analysis'

Objective - assess safety risks in TB-HIV co-infected management when new anti-Tb drugs are used

Progress:

- Prospero registered
- Data mining is completed, papers screened, selected
- Drafting the first version

Best practices for other countries

- Development of PV Roadmap
- Legal framework e.g.The National PV directive was Approved
- Strengthen collaboration with NTP and AHRI contributed to improved reporting of ADEs.
- Expansion of health care workers training on PV
  - More than 4500 Health care proffesionals trained on PV
- Preparation of procedures related to PV(Stakeholders ToR, SOP related to aDSM, PV road map…)
- Structural re-arrangement of PV function :-

  New EFDA structure was approved by civil service commission on June 2022.-Under this New EFDA structure PV and Post marketing surveillance Directorate will be established.
- Developed PV training manual, indorsed as CPD course
- AEFI training manual

Closing plans:

- Implementation of prepared PV related procedures
- Strengthening PV stakeholders engagement(research institutions, academia…)
- PHP integration to safety monitoring
- Expansion of the best practices to other public health program medicines and other medicines(Chronic, infectious…)
- Creation of model health institutions taking the TICs as model
- Keep in update of safety reports through the established systems including TICs and focal persons

Plans for sustainability post-PAVIA

- **Country PV Linkages with other PV stakeholders.** Will this continue after PAVIA. yes,
  - Developed stakeholders engagement ToR and approved by stakeholders
  - TORS describes who are stakeholders, how and when to meet, responsibilities
- **Cascading of PV activities.** Will this continue after PAVIA. yes,
  - PV has its own structure staffs and budget
  - It has its own annual and monthly plan/deliverables
  - Provided many capacity building activities,
    - continuous onsite support and developing knowledge and skill transfer among health professionals

Plans for sustainability post-PAVIA

- **Plans for continuation of PV trainings, and capacity building.**
  - Developed PV training manual and included in country CPD course , provided by EPA
  - Standard AEFI training manual was developed
- **Plans for continued strengthening of PV regulatory and policy frameworks.** Will this continue after PAVIA. If yes, how?
  - Revision of PV guideline
  - Work to WHO maturity level 3
- **Plans for sustainability of the PV triangle.**
  - **This will be in larger scale, PV stakeholders as included in ToR**
  - **Working on other PV research activities (AHRI)**
  - **Work with PHP to improve AE reporting rate**
    - **AEFI system assessment, … Integrate AE reporting with program data reporting**

THANK YOU

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