The African Medicines Regulatory Harmonization (AMRH) Initiative

Prof Moji Christianah Adeyeye, FAAPS, FAS
Director General, NAFDAC
Steering Committee Chair, AMRH

NEPAD Planning and Coordinating Agency

NEPAD
TRANSFORMING AFRICA

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OUTLINE

Background & Context

Key Accomplishments, Challenges & Lessons Learnt

How will the AMRH-AMA Vision be financed?

Background & Context

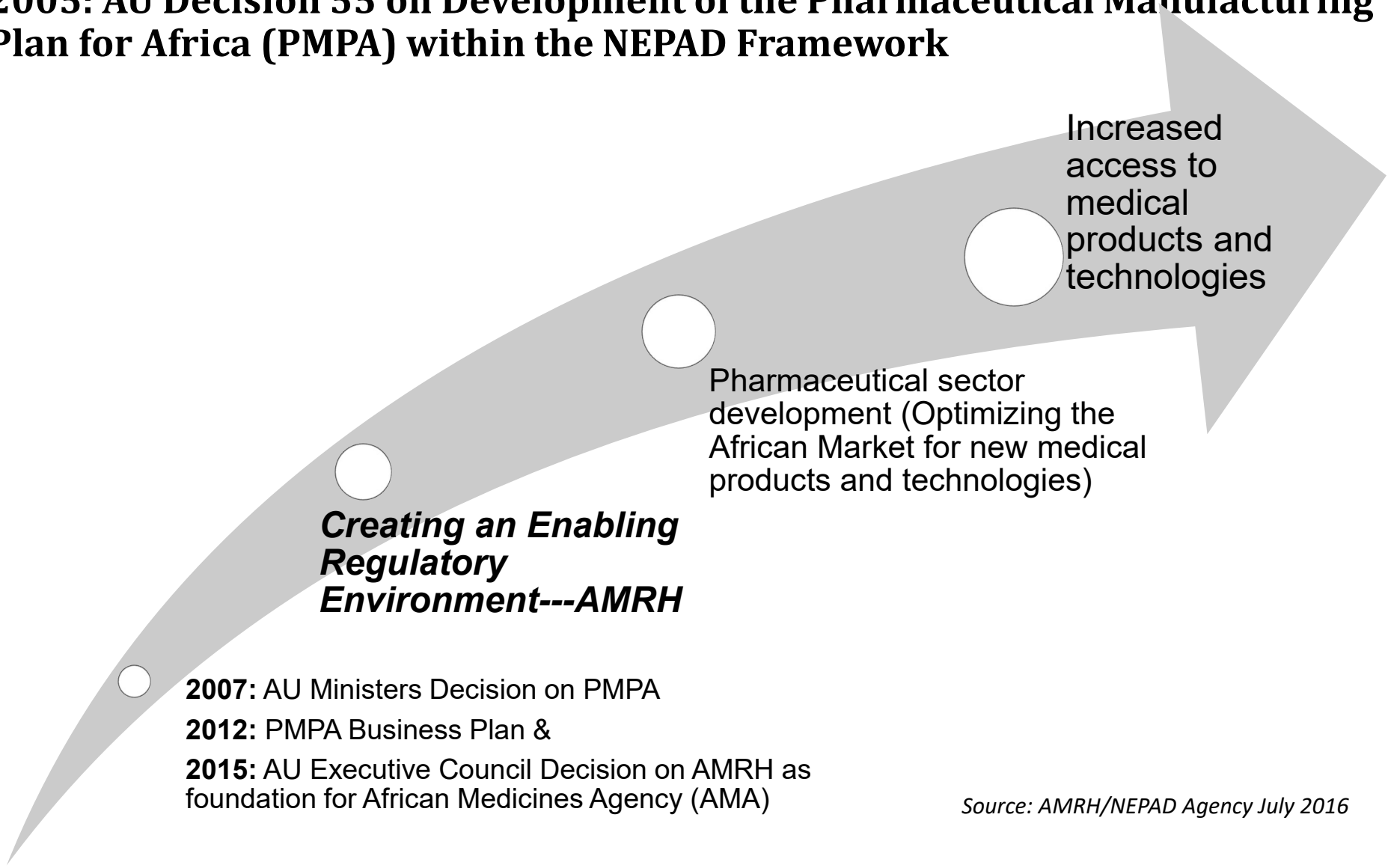
15% | **World population in Africa**

25% | **Global disease burden in Africa**

- **Lack of access to quality, safe and efficacious medicines is a key contributing factor** to these health problems
  - Partly due to general **lack of local pharmaceutical manufacturing or tools to work with,** and **weak medicines regulatory systems including the supply chain control**

Background & Context…

2005: AU Decision 55 on Development of the Pharmaceutical Manufacturing Plan for Africa (PMPA) within the NEPAD Framework



Source: AMRH/NEPAD Agency July 2016

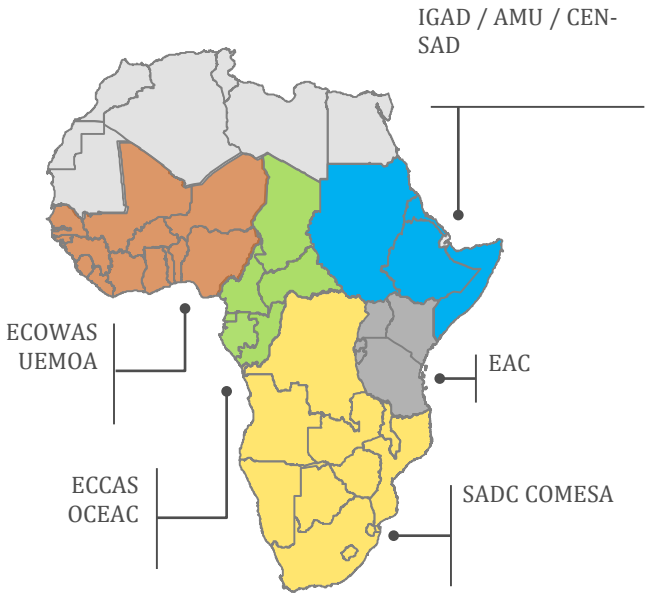
Background & Context…

55| African Union Member States

1.13 billion
Number of people on the African Continent

8
Regional economic communities recognised by African Union

"achieve access to safe, effective, quality and affordable essential medicines and vaccines for all".



AMRH Overview

Is a partnership initiative formalized in 2009 and launched in the East African Community countries in 2012 (Tanzania, Uganda, Kenya, Burundi, Rwanda)

Partnership includes African countries (regulatory authorities) and regional blocs, NEPAD, AUC, PAP, WHO, Gates Foundation, DFID, PEPFAR/USG, GAVI, World Bank

Aims to improve the fragmented regulatory system for product registration in Africa by changing from a country-focused approach to a collaborative regional and simplified one

Stepwise approach - start by harmonizing and streamlining technical requirements for product registration, **leading to increased and timely product access**

Creates a platform to build African regulatory capacity by region

AMRH Overview

The Pathway

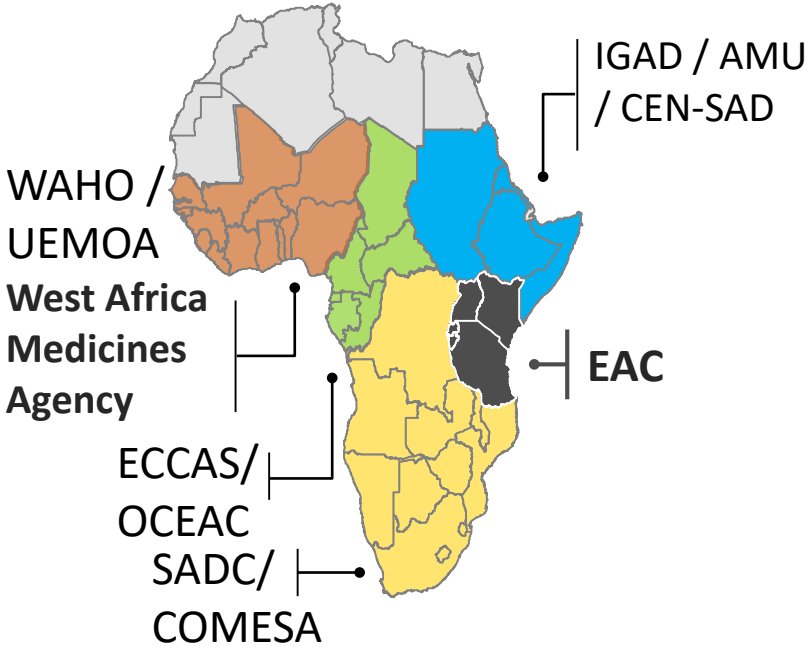
Regional regulatory platforms

- Harmonized standards (technical requirements / guidelines)
- Joint and regional dossier assessments /GMP inspections
- Work sharing / pooling of resources
- Streamlined decision-making processes

- ***Reduced registration cycle time…***
  …starting with generics
  …extending to other product categories *(NCEs, vaccines, diagnostics)*
- ***Extending to other regulatory functions over time*** *(clinical trials, safety surveillance, etc.)*
- ***Extending to other African regional blocs***

Source: AMRH/NEPAD Agency
July 2016

African Union Vision



55 countries → **5regions** → **1 continent**

Source: adapted from AMRH/NEPAD Agency July 2016

AMRH Strategic Direction V2 (2016- 2020)

Vision

African people have access to essential medical products and technologies

Mission

Provide leadership in creating an enabling regulatory environment for pharmaceutical sector development in Africa

Strategic Direction 1: Policy Alignment & Regulatory Reforms

SO: Enhanced policy coherence in RECs and member states for public health and pharmaceutical industry development

Targets

- At least 3 regions have adopted regional policies and legal frameworks for regulation of medicines by 2020
- At least 25 countries have domesticated the Model Law on Medical Products regulation by 2020 – **West Africa Pilot**
- At least 3 regions have implemented Innovative GMP Certification Schemes by 2020

Strategic Direction 2: Regional integration and harmonization

SO: Increased use of harmonized policies and regulatory frameworks by member states

Targets

- MRH projects implemented in 5 RECs by 2020
- AMRH project scope expanded to clinical trials oversight, PMS, PV, medical devices and diagnostics in 5 regions by 2020
- MRH M&E framework implemented in 3 regions by 2020
- At least 2 regional medicines agencies established by 2018

Strategic Direction 3: Human and institutional capacity development

SO: Increased human and institutional capacity for regulation of medical products and technologies

Targets

- 15 regional centres of regulatory excellence operational by 2020
- Curricula on Regulatory Science in alignment with Global Competency Framework by 2018
- 10% increase in the number of regulatory experts in Africa by 2020

Strategic Direction 4: Enabling Environment: Coordination, partnership and resource mobilization

SO: Effective execution of programmes on regulation of medical products and technologies

Targets

- Scientific & Regulators conferences convened biennially
- At least 4 functional Technical/Expert Working Groups (TWGs) by 2018:
  - PRR
  - RCD
  - GMP
  - Clinical Trials & Ethics ; Alignment with AVAREF
- AMRH transitioned into AMA by 2018

Key Accomplishments

Key Accomplishments

Targets

1

- At least 3 regions have adopted regional policies and legal frameworks for regulation of medicines by 2020
- At least 25 countries have domesticated the Model Law on Medical Products regulation by 2020 – West Africa Pilot X
- At least 3 regions have implemented Innovative GMP Certification Schemes by 2020

By end of 2018

- 2 RECs/RHOs (EAC & CEMAC-OCEAC) adopted regional policies frameworks on regulation of medical products
- 14 countries domesticated the AU Model Law
- 2 RECs implementing regional GMP schemes

Key Accomplishments

Targets

2

- MRH projects implemented in 5 RECs by 2020
- AMRH project scope expanded to clinical trials (CT) oversight, PMS, PV, medical devices and diagnostics in 5 regions by 2020
- MRH M&E framework implemented in 3 regions by 2020
- At least 2 regional medicines agencies established by 2018

By end of 2018

- RECs MRH Governance structure operational (Steering Committee, Expert Working Groups, Harmonized Guidelines (registration, GMP, QMS, IMS), standard operating procedures, REC MRH Project Management Tools
- 3 RECs (EAC, SADC, ECOWAS) implementing MRH projects
- PV, CT & Medical Devices added as part of AMRH Programme
- M&E Framework endorsed by AMRH Steering Committee for operationalization in all RECs implementing MRH Projects
- EAC and ECOWAS in the initial stages of establishing regional medicines agencies

Key Accomplishments

Target

- 15 regional centres of regulatory excellence operational by 2020
- Curricula on Regulatory Science in alignment with Global Competency Framework by 2018
- 10% increase in the number of regulatory experts in Africa by 2020

By end of 2018

- 11 RCOREs operational in different fields of regulatory expertise
- RCOREs curricula aligned with Global Competency Framework
- Review to be conducted in 2019

Key Accomplishments

Target

- Scientific & Regulators conferences convened biennially
- At least 4 functional Technical/Expert Working Groups (TWGs) by 2018:
  - Policy and Regulatory Reforms
  - Regulatory Capacity Development
  - GMP
  - Clinical Trials & Ethics ; Alignment with AVAREF
- AMRH transitioned into AMA by 2018

By end of 2018

- 3 scientific and regulators conference conducted since 2013
- February 2017, new AMRH Governance Framework
- Eight continental TWGs at different levels of functionality; AVAREF serves as TWG on clinical trials oversight under the new AMRH Governance Structure
- Treaty for establishment of AMA endorsed by Ministers of Health and Ministers of Justice & Legal Affairs for consideration by the AU Summit in February 2019

Key Accomplishments (cont'd)

Milestone 5

Shorter approval timelines for products assessed through the RECs e.g. ZAZIBONA (median 9 – 10 months) compared to the time to market authorization for products assessed in the individual countries and subsequent improved market access by manufacturers.

Milestone 3

Improved legal frameworks for regulation of medical products using the AU Model Law as a reference guide.

Milestone 4

Improved reliance amongst countries e.g. in the EAC region, a lead country for registration of products, GMP inspections, pharmacovigilance e.t.c; provides technical leadership in the coordination of joint regulatory activities

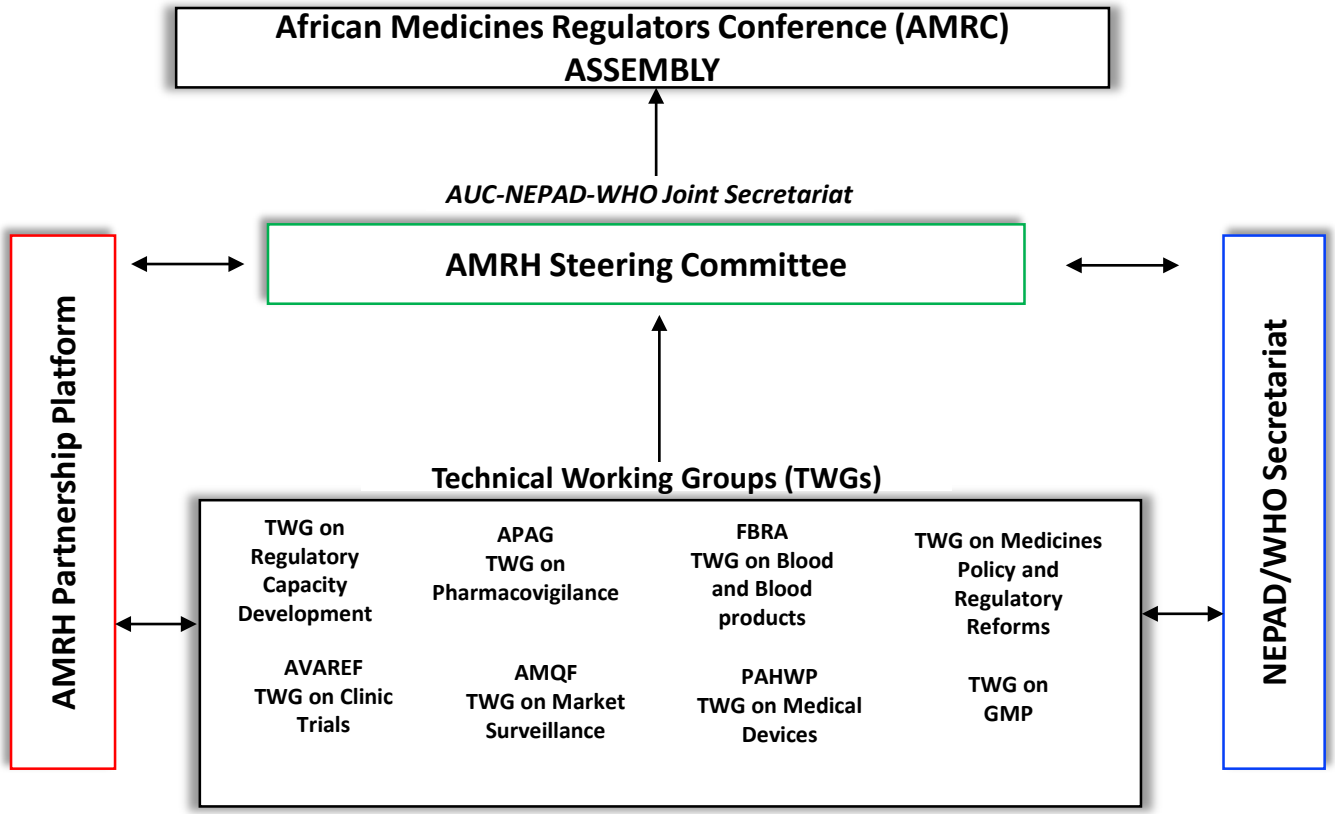
Milestone 1

Established governance framework (systems and structures) for harmonization of regulatory standards at regional and continental levels such as Technical Working Groups and Steering Committees and regional and continental levels

Milestone 2

Regulatory capacity for marketing authorization, GMP inspections and clinical trials oversight strengthened

AMRH Governance Framework….



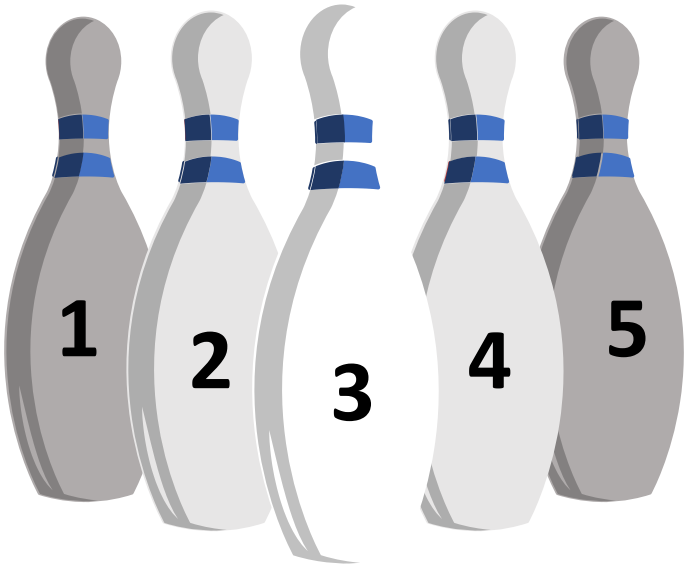
5 Key Challenges

1 REG. CAPACITY

Varying levels of regulatory capacity among countries participating in a regional platform for harmonization of medical products regulation with subsequent delayed national decision making by some countries following approval of jointly assessed products.

2 FRAMEWORKS

Inadequate legal framework for regulation of medical products.



3 GUIDELINES

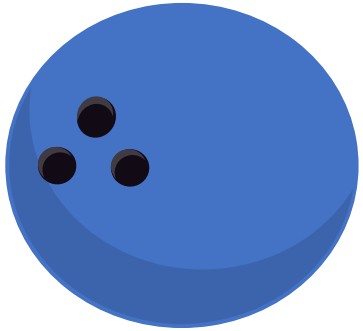
Varying guidelines and standards for registration of medicines, quality management systems and information management systems across RECs.

TECH. CAPACITY 4

Limited technical capacity to manage and coordinate MRH Programs at national, regional and continental levels

RESOURCES 5

Availability of resources to undertake a fully-fledged regional medicines regulatory harmonization project & its sustainability



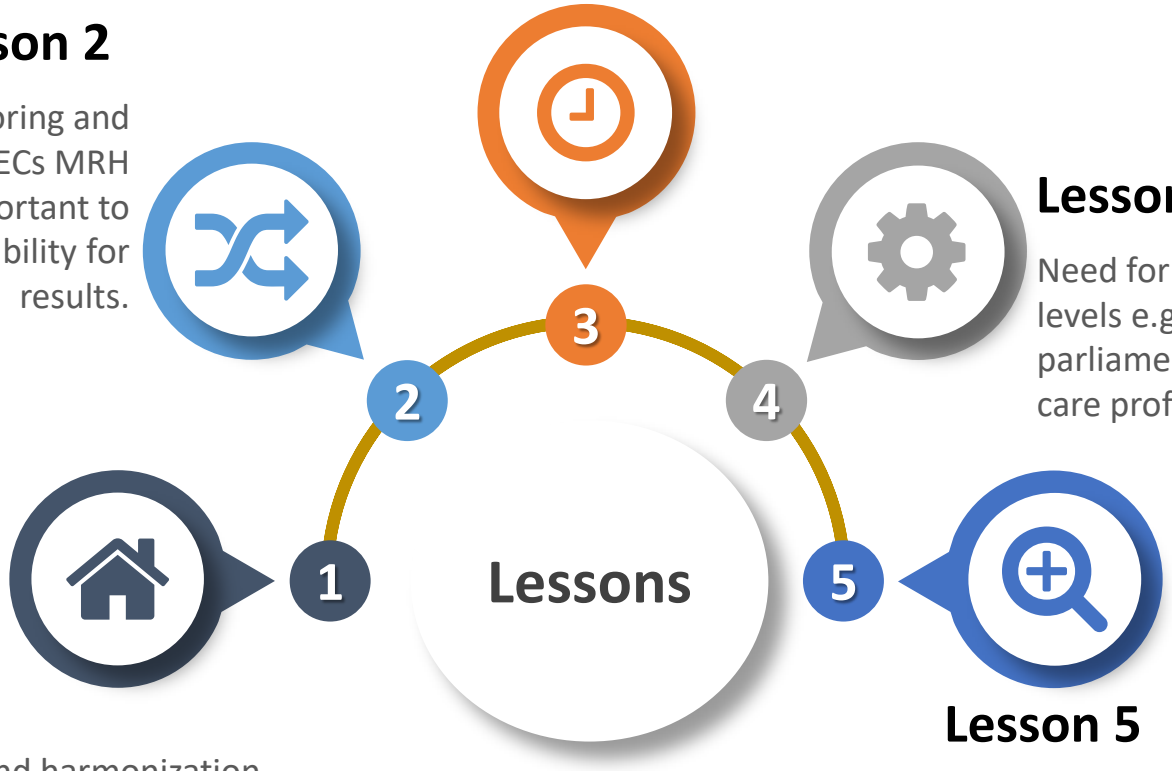
Lessons Learnt

Lesson 3

Clear Governance structures involving national Heads of NMRAs and experts is key for ownership and leadership.

Lesson 2

Management, monitoring and evaluation tools for RECs MRH Programs is important to ensure accountability for results.



Lesson 4

Need for advocacy at all levels e.g. Policy makers, parliamentarians, health care professionals, industry.

Lesson 1

Regional integration and harmonization of policies, guidelines and standards of practice is critical for building national regulatory capacity through work sharing, information sharing, twinning programs e.t.c..

Lesson 5

Need for effective coordination of partners and resource mobilization


The Future
we want for Africa
AGENDA 2063
Unity, Prosperity & Peace
2013, Year of Pan Africanism
and African Renaissance
50
OAU - AU

Thank you!