



African Union
a United and Strong Africa



NEPAD
TRANSFORMING AFRICA

Situational Overview of Regulatory Harmonization in Africa

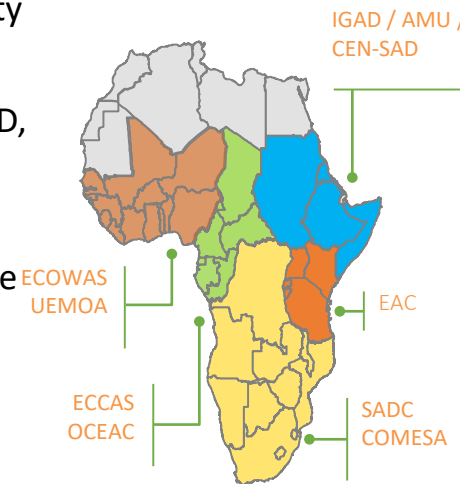
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PRESENTATION OUTLINE:

1. Background & Updates on AMRH and AVAREF
2. The African Medicines Agency
3. Ongoing AMRH Work & Transitional Arrangements
4. NEPAD Agency Mandate & Contribution

Background: African Medicines Regulatory Harmonization (AMRH) Initiative

- 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, BMGF, 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



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**

African Vaccines Regulatory Forum (AVAREF)

- Established in 2006 by WHO to serve as a network of NMRAs and ECs from 19 countries to build their capacity, and improve harmonization of practices in support of product development and regulation of clinical trials
 - Began as informal network, necessary for quick decision-making, whipped up enthusiasm, achieved results, minimized delays implementation
 - Played a crucial role in the successful development of several vaccines
- Formalized in 2010 involving Heads of NMRAs and Chairs of NECs, clear ToRs, slow implementation, changes in profile of participants
- New AVAREF ToRs 2016, New model and governance

AVAREF Progress and Capacity Building Efforts

- Improved efficiency in regulatory reviews of clinical trials
- Harmonized Guidelines and templates for NMRAs and ECs developed
- Joint review and joint inspection of clinical trials
- Expedited review procedure for registration of vaccines
- Regulatory strategy development (PIP of RTS,S vaccine)
- Linkages with other programs and initiatives
- Inter and intra country collaboration
- Parallel submission to NMRAs and ECs adopted
- Set 60 working days CTA regulatory decision target
- Emergency regulatory guidelines in development – table top simulation completed
- Supporting clinical trial designs (scientific advice)

Examples of joint reviews by AVAREF

- Conjugate meningitis A vaccine clinical trial - 2006
- RTS,S malaria vaccine clinical trial - 2008
- Expedited review of conjugate men A and registration, 2011
- Expedited review of inactivated polio vaccine and registration – 2012
- Joint reviews of Ebola vaccine clinical trial application in Geneva 2014, Tanzania 2015, Sierra Leone and Ghana, 2015
- Assisted review of CTA for medicine against eumycetoma in Sudan
- Medicine against visceral leishmaniasis 2017
- RTS,S Pilot Implementation program 2018

National VS Joint Review Timelines

Sponsor/Product	No of countries	Submission Date	Decision Date	Time to decision (WDs)
PATH MenA phase II/III	2/3	May 20, 06	July 20, 06	60 days
J&J Ebola vaccine phase I	4/7	Jan 14, 15	March 5, 15	32 days
DnDi VL Miltefosine/Paromomycin Vs Sodium Stibogluconate/Paromomycin phase III	4	26 July,17	Oct 11, 17 Nov 15, 17 Nov 19, 17 Jan 25, 18	56 – 122 includes sponsor time

2017 National Timelines

All reporting countries – 135 days
South Africa – 91 days

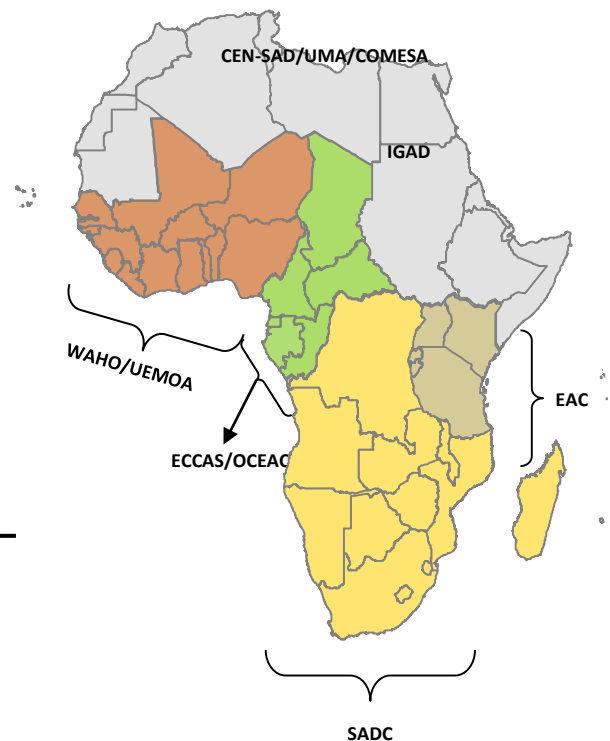
AMRH & AVAREF Progress...

> 85% of Sub-Saharan Africa covered with medicines registration harmonization (MRH) Projects at different levels

REC progress

• REC	• Status	• Comments
• EAC	• Implementation	• Launched March 2012
• CEMAC-OCEAC	• In progress	• Launch Nov. 2016
• WAHO/UEMOA	• Implementation	• Launched Feb 2015
• SADC	• Implementation	• Launched July 2015
• IGAD	• Preparatory Phase	• 2016

Completed or in-process RECs	Countries covered	Total members*	% pop covered
EAC & OCEAC	12 (20%)	11	17%
EAC, OCEAC, ECOWAS	26 (46%)	26	45%
EAC, OCEAC, ECOWAS, SADC	41 (74%)	41	72%



**EAC Pharmacovigilance Project,
AVAREF alignment with AMRH on clinical trials
ethics and regulatory oversight**

The African Medicines Agency

Background...AU Decision EX.CL/Dec.857(XXVI)

- Recognized the need to strengthen the capacity for regulation of medical products in Africa, and the harmonization of medicines regulatory systems as a foundation for the establishment of a single regulatory Agency for Africa within the framework of the Pharmaceutical Manufacturing Plan for Africa.
- Endorsed the establishment of the African Medicines Agency (AMA); and
- Requested the AUC, the NEPAD agency and the WHO in collaboration with other stakeholders to define the scope of the medicines or medical products that would be covered by the work of the AMA, and to work out detailed modalities, institutional framework, legal and financial implications, of the establishment of the AMA.

African Medicines Agency

(A) Specialized Agency of the African Union (AU),

(THAT) Serve as a **catalyst** for stronger regulatory oversight

(BY) Galvanizing (1) **technical support**, (2) **expertise** in various countries and RECs, and (3) **resources at a scale that cannot be matched at national or regional level.**

Main Objective: To improve access to quality, safe and efficacious medical products on the continent

AMA Objectives

Specific Objectives:

- Coordination and strengthening of ongoing initiatives to harmonize medicines regulation, promote cooperation and mutual recognition of regulatory decisions.
- Carrying out regulatory oversight of selected medical products and providing technical guidance to State Parties and RECs.
- Pooling expertise and capacities and strengthening networking for optimal use of the limited resources available.

AFRICAN MEDICINES AGENCY



55

COUNTRIES



8

REGIONS



1

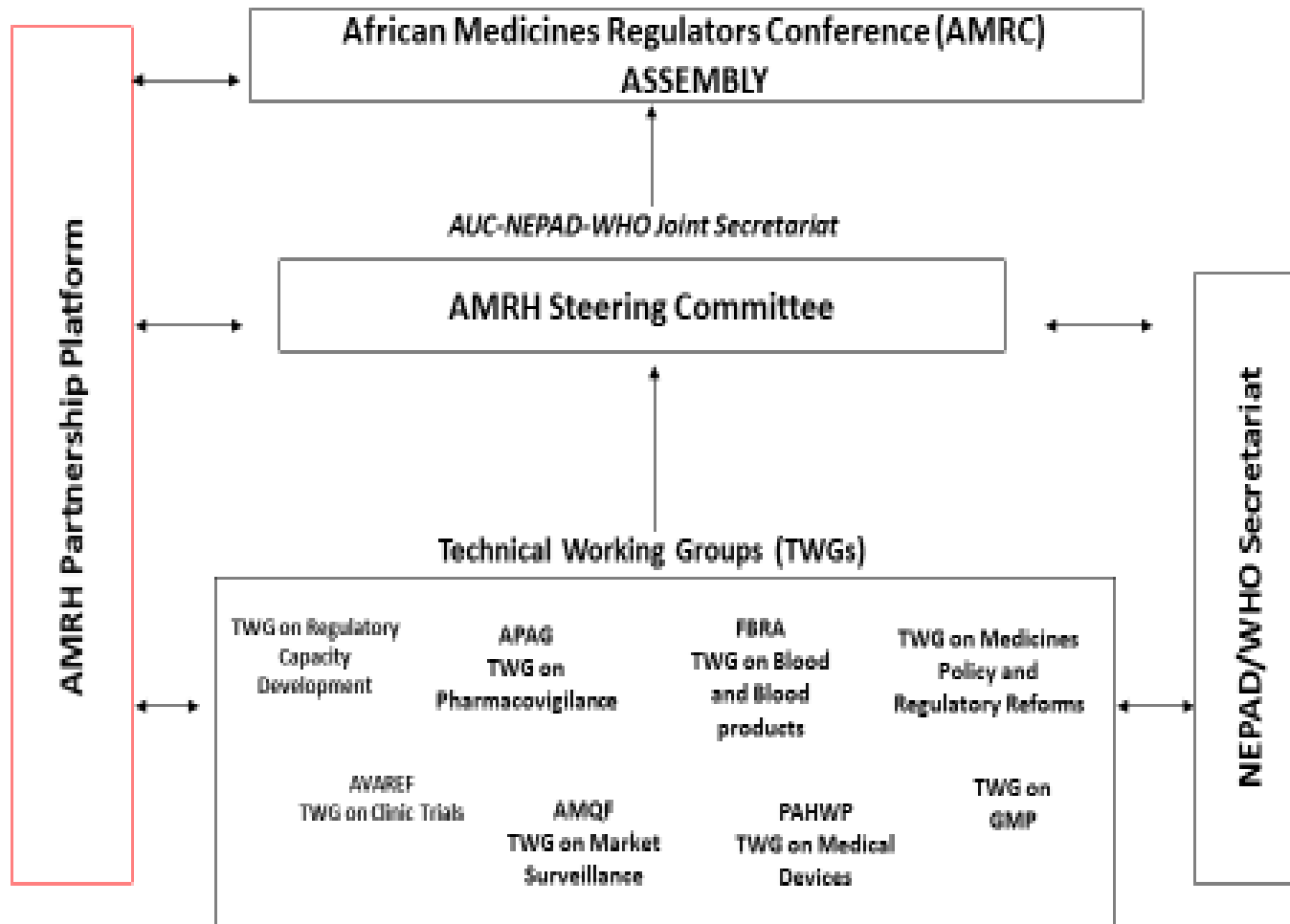
CONTINENT

Ongoing AMRH Work & Transitional Arrangements

Transitioning AMRH structures into the AMA

- Based on the AU Executive Council Decision, {EX.CL/Dec.857 (XXVI)} in January 2015 which endorsed the Milestones for the setting up of a single medicines regulatory agency in Africa within the context of the AMRH Initiative, and as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA) which is being implemented under the NEPAD Framework

AMRH Governance Framework



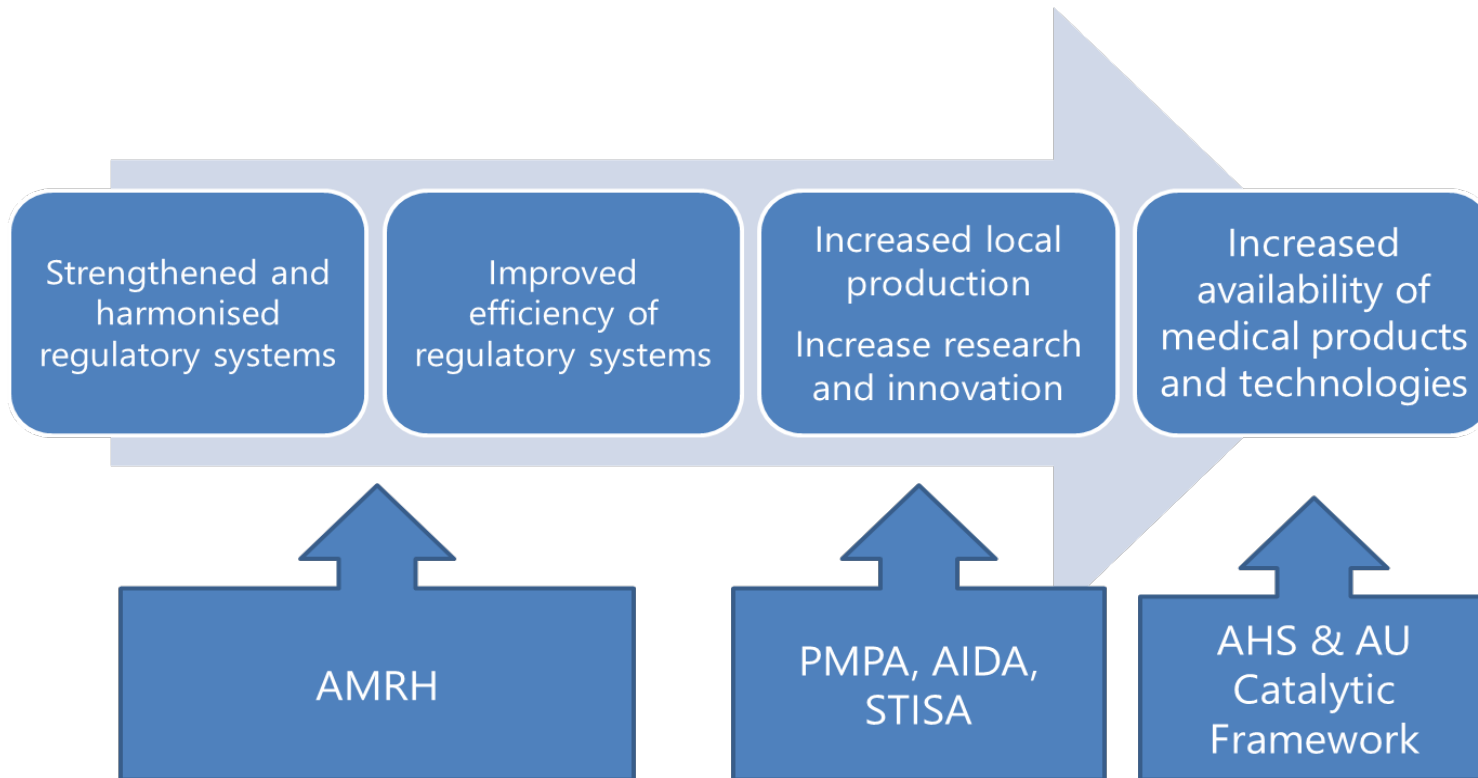
NEPAD Agency Mandate & Contribution

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Contributing to AU & Global Policy Frameworks including health:

- The Abuja Declaration on HIV/AIDS, Tuberculosis (TB), Malaria and other related infectious diseases (2001);
- Africa Health Strategy (2016-2030);
- **Pharmaceutical Manufacturing Plan for Africa (PMPA) --Business Plan (2012);**
- Program for accelerated Industrial Development of Africa (AIDA)
- AU Catalytic Framework to end AIDS, TB and Eliminate Malaria in *Africa By 2030*;
- AU Science, Technology, and Innovation Strategy for Africa (2014-2024) in short STISA:2024
- Continental Free Trade Area (CFTA) - (2012-2017)
- Agenda 2063; and
- Sustainable Development Goals (SDGs).

AMRH/AVAREF contribution to African Union Policy frameworks...





Thank you!