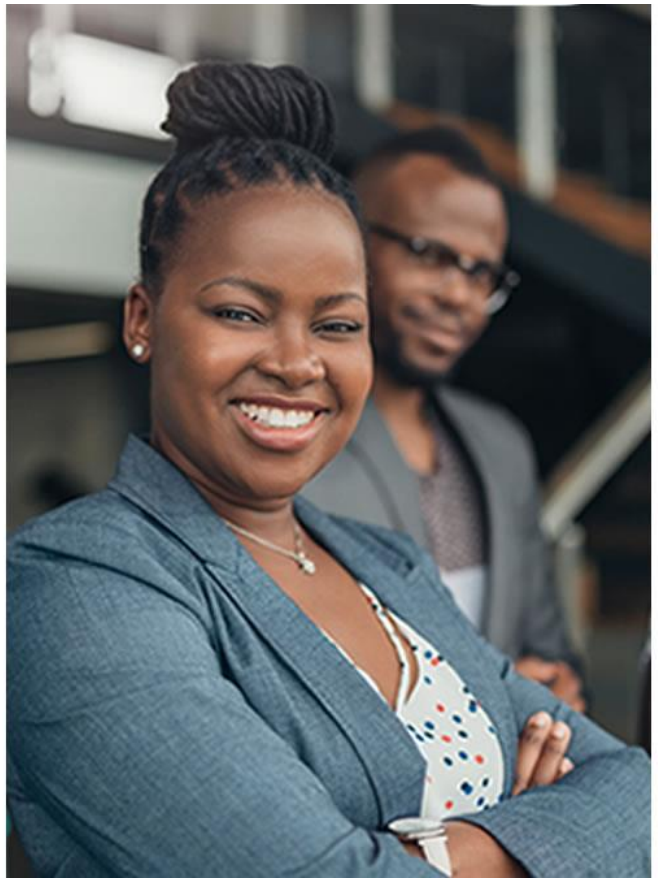
AUDA-NEPAD COVID-19 Response Strategy



A Framework for Medical Products Regulation in Africa in response to COVID-19 Pandemic: The AMRH Initiative

By Margareth Ndomondo-Sigonda; Heald of Health Program, AUDA-NEPAD

OUTLINE

Background

Problem Statement

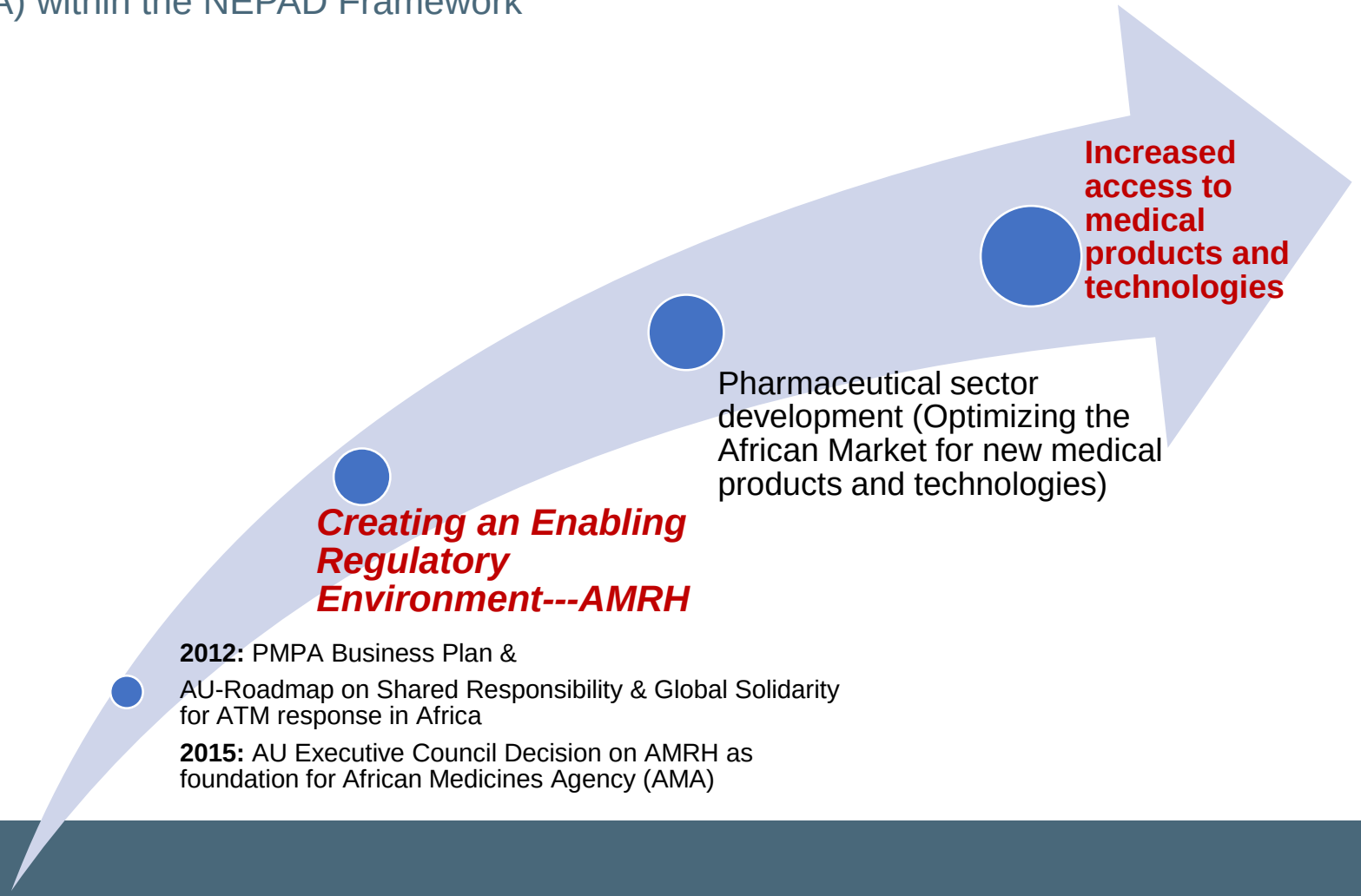
Leveraging on AMRH Achievements

AMRH COVID-19 Regulatory Strategy

Conclusion & Recommendations

BACKGROUND

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



BACKGROUND…

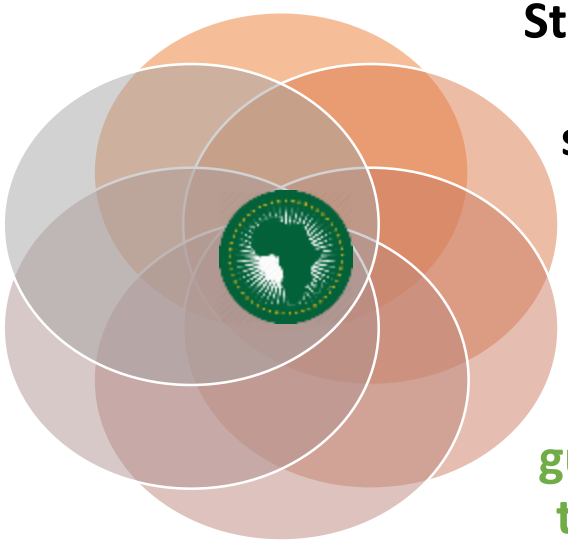
AMRH vision…

Streamlined (harmonized) future

At least 5-7 regional economic communities (RECs) covering the entire African continent[1]

Faster registration

Stronger, institutionalized regulatory capacity & systems strengthening programmes



Resource pooling and information sharing

Single set of requirements, Clear guidelines, Fewer dossiers to prepare (one per REC)

Transparent regulatory processes with clear timelines

Earlier approval of more medical products & vaccines

1. WHO prequalification, Article 58 positive opinions, stringent regulatory approval, certificate of pharmaceutical product (CPP)

Problem Statement

- The emergence of COVID-19 pandemic poses a challenge to low- and middle-income countries to ensure that experimental human models for clinical trials of vaccines and therapeutics are conducted in an efficient way while ensuring compliance with internationally acceptable standards.

- The quality and safety of medical products is at stake due to unscrupulous business community taking advantage of the dire need of the African population to have access to COVID-19 medical products.

- Scientists and researchers experience delays in approval of protocols for clinical trials for COVID-19 medical products which will jeopardise patients' needs.

LEVERAGING ON AMRH ACCOMPLISHMENTS

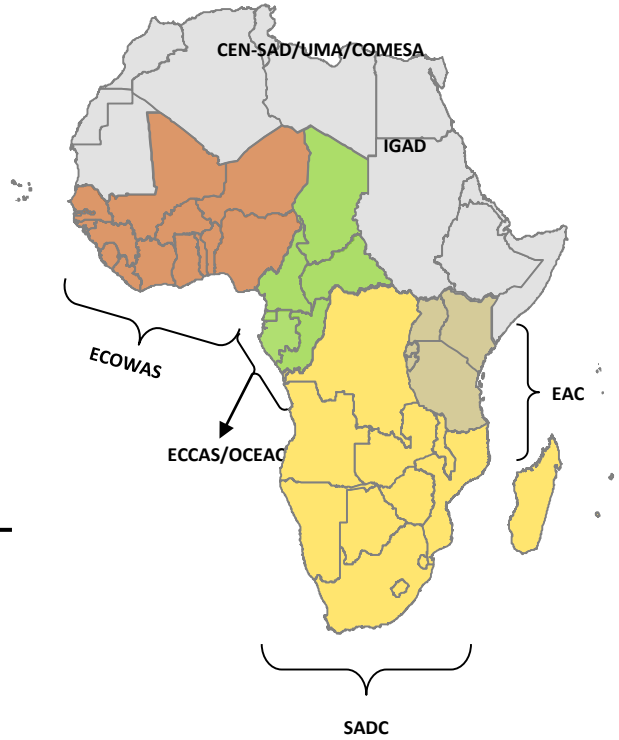
1. RECs MEDICINES REGULATORY HARMONIZATION PROJECTS

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

REC progress

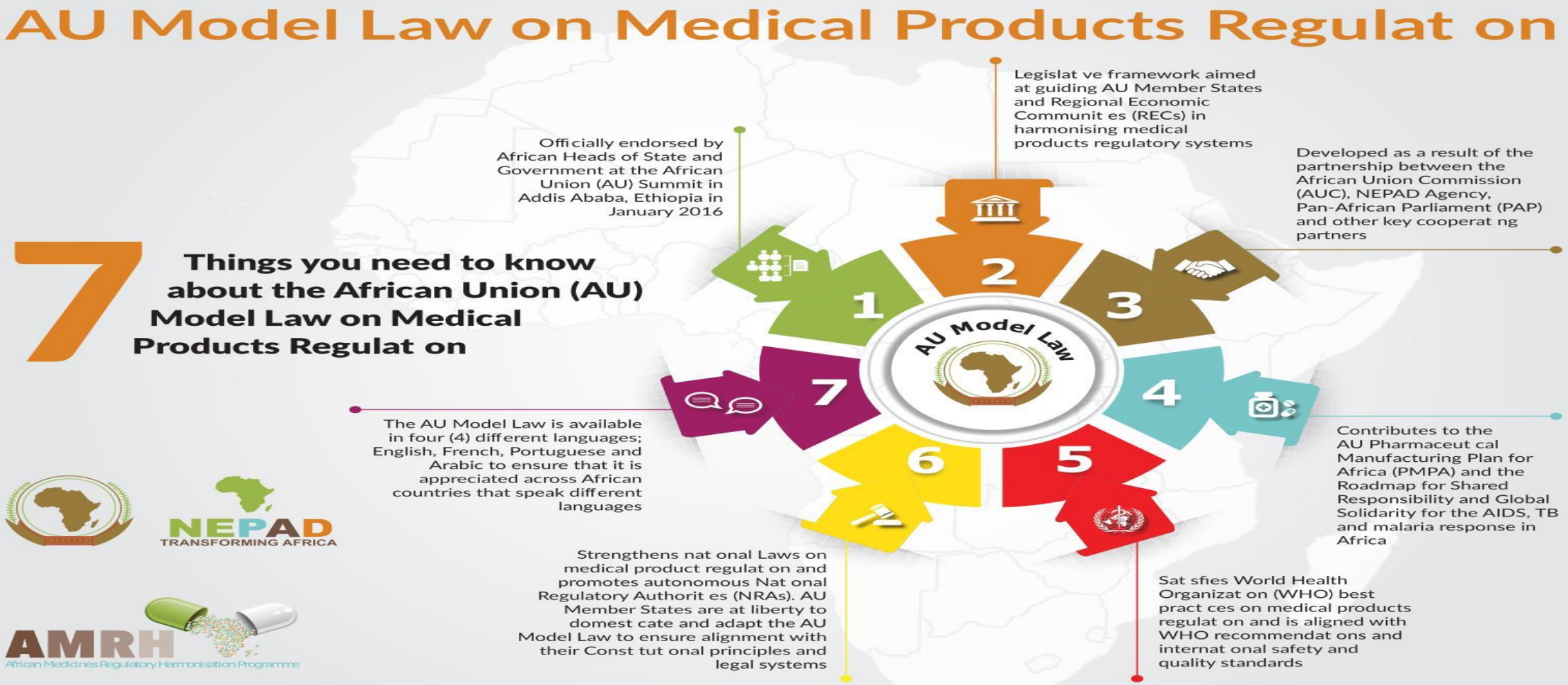
REC	Status	Comments
EAC	Implementation	Launched March 2012
ECCAS	In progress	Launch Nov. 2016
ECOWAS	Implementation	Launched Feb 2015
SADC	Implementation	Launched July 2015
IGAD	Preparatory Phase	2016

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



8-11 months registration approval timelines, expansion of scope to cover other regulatory functions & products e.g. EAC Pharmacovigilance Project,
AVAREF alignment with AMRH on clinical trials ethics and regulatory oversight

2. DOMESTICATION OF THE AU MODEL LAW ON MEDICAL PRODUCTS REGULATION



17 Countries domesticated the AU Model Law on Medical Products Regulation

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

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AFRICAN UNION DEVELOPMENT AGENCY

NEPAD
TRANSFORMING AFRICA

Regional Centres of Regulatory Excellence (RCOREs)

AMRH
African Medicines Regulatory Harmonisation Programme

What is the role of RCOREs?

RCOREs will produce regulatory workforce in Africa by performing the following roles:

1. Providing academic and technical training in regulatory science applicable to different regulatory funct ons and managerial aspects.
2. Contribute to skills enhancement through hands-on training, twinning and exchange programmes among NMRAs.
3. Encourage pract cal training through placement in pharmaceut cal industry.
4. Execute operat onal research to pilot-test innovat ons and intervent ons to inform best pract ces for scale up to other NMRAs.

What is an RCORE?

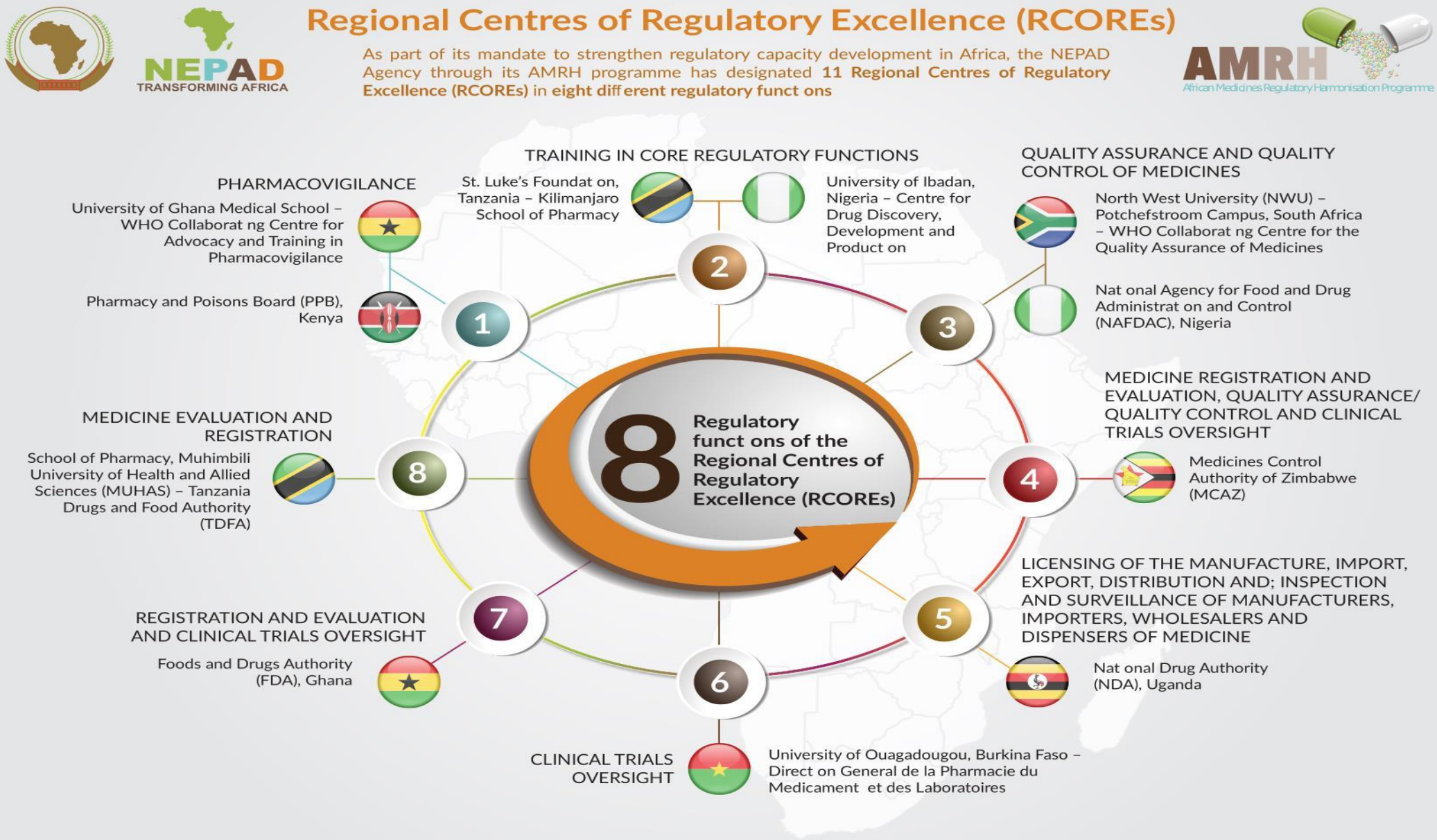
A Regional Centre of Regulatory Excellence (RCORE) is a designated inst tut on or partnership of inst tut ons with specific regulatory science expert se as well as training capabilit es. This init at ve was established by the NEPAD Agency's AMRH programme to fill an exist ng gap and address the regulatory capacity challenges experienced by Nat onal Medicines Regulatory Authorit es (NMRAs) and the pharmaceut cal industry in Africa.

How To Become a Designated AU RCORE

Your country and/or inst tut on can become part of the AU RCORE. Just follow these four steps to get designated:

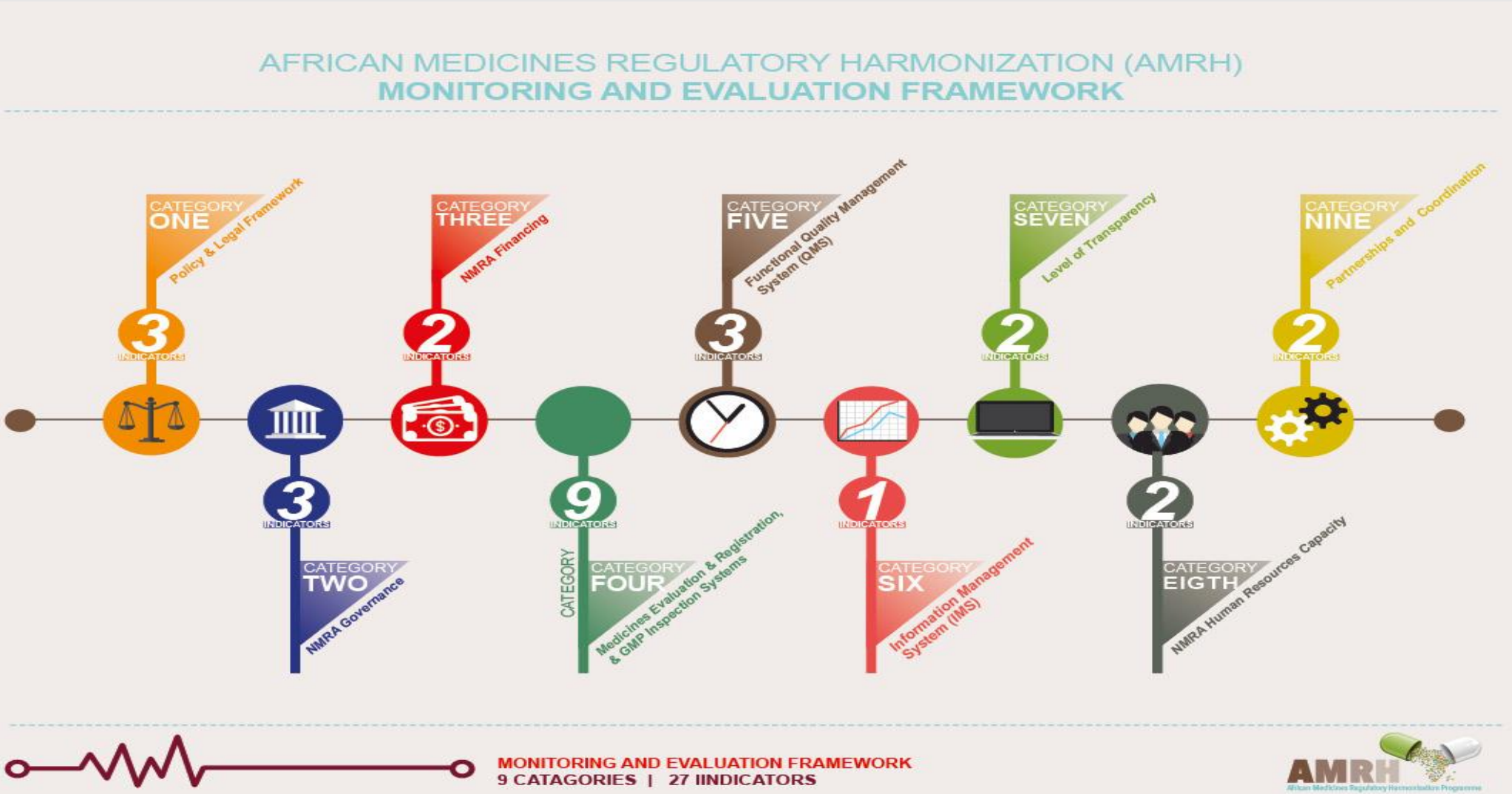
1. **APPLICATION**
   Submit an expression of interest to the NEPAD Agency
2. **ASSESSMENT**
   Assessment of expression of interest, short-list ng and audits shall be conducted accordingly
3. **SELECTION**
   Based on the eligibility criteria, select on will be done accordingly
4. **PERFORMANCE EVALUATION/ REVIEW**
   The performance of the registered RCORE shall be monitored cont nuously

RCORE'S (CONTINUED)



4. AMRH INDICATORS FRAMEWORK

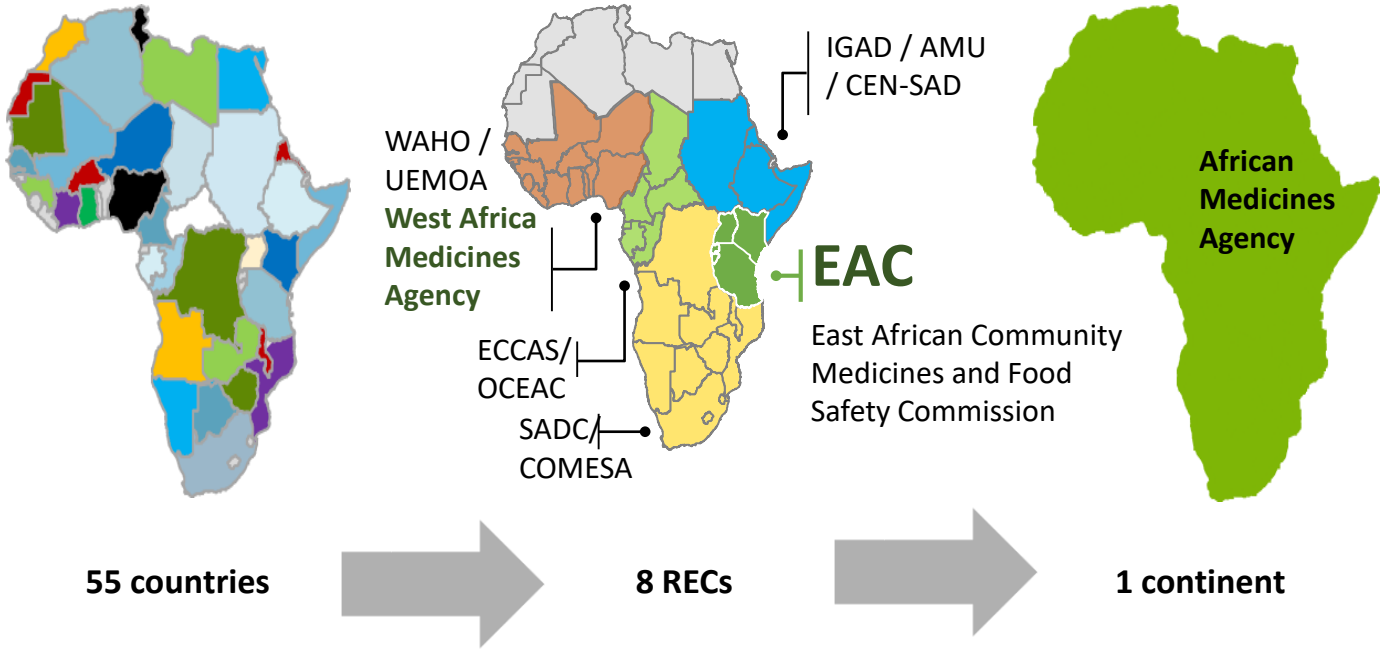
….Linked to AU Health Statistics, to be published



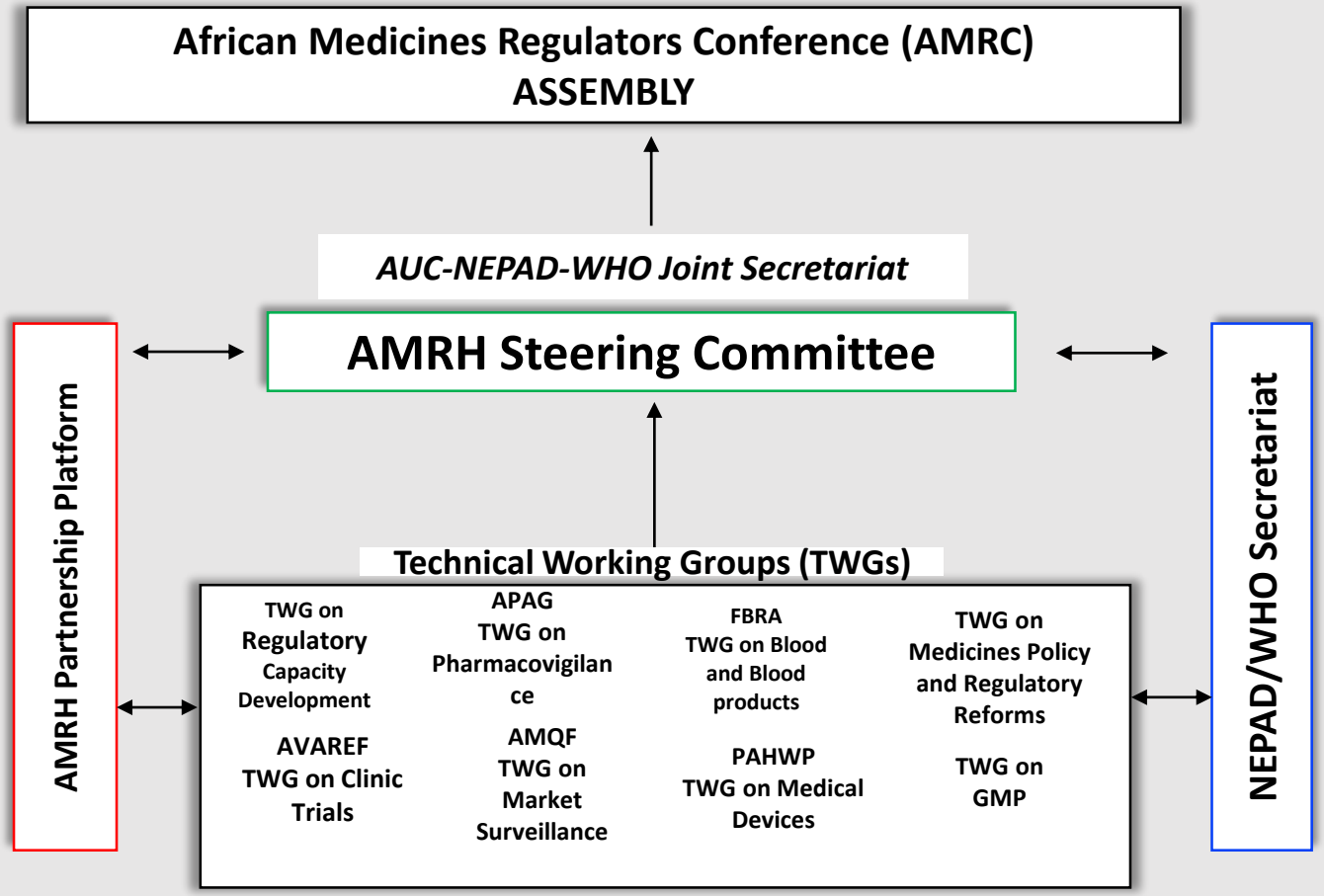
5. AFRICAN UNION AMRH-AMA VISION

AMRH-AMA Milestones:

- AU Executive Council decision in January 2015 EX.CL/Dec.857 (XXVI) AMRH a foundation for AMA
- 11 February 2019, AMA Treaty adopted by AU Assembly
- As of February 2020, 15 AU Member States signed & 1 Ratified the AMA Treaty



6. NEW AMRH GOVERNANCE FRAMEWORK



The African Union Specialized Technical Committee on Health, Population and Drug Control (STC-HPDC) held in Addis Ababa, Ethiopia in April 2015, in recognition of the need of convening all the AU Member States, adopted a decision to '*institutionalize the biennial AMRC as a platform for sharing best practices on regulatory matters and a mechanism for generating technical information to guide AU decision making processes*'.

AMRH COVID-19 Regulatory Strategy

African Vaccines Regulatory Forum (AVAREF)

- AVAREF Technical Coordinating Committee (TCC) and the Steering Committee (SC) had a meeting on 1st April 2020 to discuss pertinent issues on how regulators and ethics committee members can better prepare and respond on COVID 19.
- Agreed on joint review of COVID-19 clinical trials conducted in Africa.
- Aim to address inefficiencies and delays in providing a final response to the sponsor resulting from sequential application to NRA and Ethics Committee without oversight of each other's inputs.
- Guidelines for clinical trials adopted by AVAREF and the AMRC Assembly to be used as basis for review.
- Safety surveillance to be conducted on COVID-19 medical products undergoing clinical trials

AVAREF…

10 Guidelines on Clinical Trials in Africa

- AVAREF Clinical Trials Application Form Checklist
- AVAREF Clinical Trials Application Form
- AVAREF Clinical Trials Assessment Template
- AVAREF Quality Assessment Template
- AVAREF Nonclinical Assessment Template
- AVAREF Statistical Assessment Template
- AVAREF GCP Inspection Guide
- AVAREF GCP Inspection Checklist
- AVAREF Joint Review Guidelines
- AVAREF Strategy and Guidance for Emergency Preparedness

AVAREF Joint Review Experience…

- AVAREF Joint review Process successfully applied to important vaccines against meningitis, malaria, rotavirus, pneumococcal pneumonia and Ebola and has been extended to other therapeutic interventions.
- The process retains local country insights so that participating agencies do not compromise protection of its citizens by a top-down approach.
- Through this approach, AVAREF will make available an online platform (SharePoint) for joint reviews of clinical trial applications for preventive, diagnostic and therapeutic interventions related to the COVID-19 pandemic. Participating countries (national regulatory agencies, national ethics committees and targeted ethics review boards) will post their queries online for real-time response from sponsors/applicants.
- Through virtual meetings, participating countries will conduct joint reviews of clinical trial applications on COVID-19 and also discuss pertinent issues on how regulators and ethics committee members can better prepare and respond to the COVID-19 pandemic.

African Medical Devices Forum (AMDF)

- The Africa Medical Devices Forum leadership (South Africa-Chair & Kenya-Vice Chair) and AMRH Joint Secretariat (AUDA-NEPAD & WHO) convened first meeting on 31st March to deliberate on COVID-19 response and agreed to establish a Task Force to provide the needed expertise to guide the review and approval process by NRAs.
- Four Working Groups have been established working on the following areas:
  - Working Group 1: To develop and update list of tests including names of the test and source
  - Working Group 2: To Develop and update list of medical devices and other products for surveillance, prevention control and case management.
  - Working Group 3: To propose mechanism (s) to receive information on substandard and falsified tests and other devices and dissemination of such information to regulators.
  - Working Group 4: To develop guidance document to NRAs on management of IVDs and medical devices donations for Covid-19.
- The four working groups are expected to conclude their assignments on 13 April 2020, the outcome of which will assist AUDA-NEPAD to guide AUC and AU Member States on approval of importations, procurement and donations for COVID-19 medical products and related supplies.
- The task force is composed of experts from WHO, AUDA-NEPAD, Africa CDC, ASLM, African NRAs, National research institutes, AUC, AMRH Partners and other interested parties.

Conclusion and Recommendations

- Effective regulation of medical products provides guarantee on the quality, safety and efficacy of products circulating in various markets.
- Proliferation of substandard and falsified (SF) products pose a major health threat across the African continent.
- African governments have a noble role to protect the health of their people towards the attainment of the highest possible physical and mental wellbeing.
- COVID-19 response is an opportunity to address the existing regulatory capacity challenges that African countries are facing.
- AUDA-NEPAD in collaboration with AMRH Partners is advocating for implementation and/or ratification of the four key frameworks to assure quality, safety and efficacy of medical products:
  - PMPA, the AMRH Initiative, the AU Model Law on Medical Products Regulation (Model Law) and the treaty for the establishment of the AMA.
  - AU Member States are encouraged to adopt the guidelines for conducting clinical trials which were adopted by AVAREF Assembly and the African Medicines Regulators Conference, in 2017.
  - Joint review of clinical trials for COVID-19 therapies and vaccines is critical for faster and quality approval process
  - AU Member States are encouraged to adopt AMRH Technical guidelines for regulatory review, importation, procurement and donation of medical devices and diagnostics
- African Union Member States are encouraged to uphold the highest levels of ethical and scientific standards when testing for the safety and efficacy of medical products including those aimed at curbing the current COVID-19 pandemic.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Thank you!