The African Medicines Regulatory Harmonization Initiative

5 Year Workplan for AMRH Support to Operationalization of the African Medicines Agency

(2022-2026)

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Table of Contents

1. Background

The African Union (AU) Assembly in 2005 undertook to adopt the pharmaceutical manufacturing plan for Africa (PMPA) Policy Framework to ensure self-reliance on medical products by the African continent. One of the critical components of the PMPA Policy Framework is the provision of an enabling regulatory environment for the local production of medical products that meet internationally acceptable standards of quality, safety, and efficacy. The African Medicines Regulatory Harmonization (AMRH) Initiative was thus established in 2009 to address desperate regulatory systems on the continent working through regional economic communities (RECs). Through the coordination of the African Union Development Agency – New Partnership for Africa's Development (AUDA-NEPAD), Partners agreed on a stepwise approach to address regulatory systems challenges faced by national regulatory authorities (NRAs) on the continent[1].

To ensure country ownership and leadership, the initiative established regional expert working groups and/or technical working groups, steering committees, and heads of agencies fora supported continentally by the following organs: the AMRH Technical Committees (TCs), the AMRH Partnership Platform (AMRH PP), the AMRH Steering Committee, and the African Medicines Regulators Conference (AMRC) and the AMRH Joint Secretariat[2]. While the AMRH Steering Committee (SC) focuses on the technical and strategic priorities of the initiative, the AMRH PP is responsible for the coordination of partners' support, and the AMRH Secretariat undertakes day-to-day management of the Initiative. The AMRC Assembly is a convening of all the 55 AU Member States NRAs, which serves as a platform for sharing best practices on regulatory matters and a mechanism for generating technical information to guide AU decision-making processes[3].

The regional medicines regulatory harmonisation initiatives started with the registration of generic medicines as an entry point while slowly expanding the scope to cover other regulatory functions such as pharmacovigilance and clinical trials oversight, to mention a few. In terms of product categories, the programme slowly expanded the scope from generic medicines to other products such as new chemical entities (NCEs), vaccines, medical devices, blood and blood products.

Following the launch of the East African Community - Medicines Regulatory Harmonization (EAC-MRH) project in 2012, the AMRH Initiative has witnessed significant progress with other regions launching their projects, namely Southern African Development Community (SADC) in 2015, the Economic Community of West Africa States (ECOWAS) in 2015, the Intergovernmental Authority for Development (IGAD) in 2016, and the Economic Community of Central African States (ECCAS) through the Organization for the Coordination of the fight against Endemic diseases in Central Africa (OCEAC) in 2018. Before the launch of the SADC MRH Project, four countries, namely Zambia, Zimbabwe, Botswana and Namibia, initiated the Zazibona collaborative procedure for medicines registration in October 2013. AIDS in January 2015which was endorsed by SADC Ministers of Health & Ministers Responsible for HIV & AIDS in January 2015, has registered significant progress and is now operational across all the countries in the region.

1 AUDA-NEPAD, AUC, PAP, WHO, BMGF, DFID, CHAI, World Bank

[2] The AUDA-NEPAD and WHO serve as Joint Secretariat for the AMRH Initiative.

[3] The African Union Specialized Technical Committee on Health, Population and Drug Control (STC-HPDC) held in Addis Ababa, Ethiopia in April 2015

The regional harmonisation initiatives have invested in developing and implementing harmonised guidelines for product registration, good manufacturing practice (GMP) inspections, pharmacovigilance, post-marketing surveillance, medical devices, and clinical trial control. In addition, regional policy frameworks for quality management systems (QMS) and information systems management (IMS) and standard operating procedures (SOPs) for joint review of dossiers and GMP inspections and manuals have been adopted, resulting in more harmonised and predictable regulatory review processes within these regions. Regulatory collaboration on joint assessment and GMP inspections have been conducted in some regions such as EAC, ECOWAS, SADC and IGAD. While different RECs have adopted/adapted the World Health Organization (WHO) and/or International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) standards, variations exist among RECs. This has precipitated the need for continental standard-setting platforms through the establishment of technical committees (AMRH TCs) in different regulatory functions drawing on the expertise and capacity of national authorities to undertake the work.

Furthermore, the AU Model Law on Medical Products Regulation was adopted in 2016 to strengthen national legal frameworks, including establishing autonomous NRAs and facilitating collaboration and reliance among the agencies. Seventeen (17) AU Member States have domesticated the AU Model Law, namely Benin, Burkina Faso, Burundi, Cote d'Ivoire, Egypt, Eswatini, the Gambia, Lesotho, Namibia, Malawi, Mozambique, Rwanda and South Africa Seychelles, Tanzania, Zambia, and Zimbabwe. Countries such as Burkina Faso, Burundi, Cote d'Ivoire, Egypt, Malawi, Mozambique, Tanzania-Zanzibar, and Rwanda have established semi-autonomous agencies due to the AU Model Law domestication process.

The designation of eleven (11) Regional Centres of Regulatory Excellence (RCOREs) to ensure sustainable production of the regulatory workforce in Africa is another critical milestone under the AMRH initiative. Figure 1 provides a summary of RCOREs' areas of competence.

Source : AUDA-NEPAD, RCORES Publication 2014

The existing RCOREs have proved to be useful platforms for capacity building in regulatory science including developing of approximately 25 curricula and training of more than 360 pharmaceutical and regulatory personnel across Africa. For instance, the Ghana FDA which serves as an RCORE on clinical trials oversight has trained 54 regulatory experts from 9 countries on the continent. The Kenyan RCORE carried out PV and post-marketing surveillance sensitisations (training lasting less than 2 days) to more than 4,000 health care workers during the review period[4].

A body of knowledge for RCOREs was developed as a technical content for instruction in the technical categories and areas that the RCOREs are involved in capacity building. It was intended to serve as a reference resource for regulatory curricula reforms undertaken by the RCOREs, a tool for harmonising training curricula offered by various institutions participating within the RCOREs framework or other interested institutions in the regulatory capacity building space. In addition, the Body of Knowledge was to be utilised in the context of implementing the proposed Africa Medicines Regulatory Professionals Fellowship Programme, to nurture and develop technical and managerial competencies to ensure effective medicines regulation in Africa. This would eventually assist in qualifying regulatory professional into foundational, specialisation, and advanced levels as they pursue their career in different regulatory specialties e.g., pharmacovigilance, clinical trials oversight, GMP, just to mention a few. The long-term goal is to ensure that the regulatory science curricula is in alignment with the WHO Global Curricula and Competency Framework for Regulators currently under development once concluded. The RCOREs programme will be revived to allow for advancement and recognition of regulatory professionals on the continent.

[4] USAID MTaPS Program, Evaluation of the Regional Centers of Regulatory Excellence, 2014-2019

The AMRH initiative has further advocated to strengthen NRAs capacity to attain WHO Maturity Level 3 through tracking implementation of institutional development plans. To date, Africa has 4 NRAs that have reached maturity level 3 namely Ghana, Nigeria and Tanzania as vaccines exporting countries, and Egypt as vaccine producing country. The aim is to develop further the collaboration with WHO and RECs to assess NRAs using the GBT and support implementation of IDP including training programs for NRAs focusing on non-vaccines manufacturing countries. NRAs in vaccine producing countries will receive support from PAVM regulatory workstream and in close collaboration with AMRH.

As part of alignment of regulatory systems strengthening (RSS), harmonisation efforts and regulatory networks across the continent, the AMRH SC has approved ten TCs to provide technical support. They include the African Medicines Quality Forum (AMQF) on quality assurance and post marketing surveillance; the Pan African Harmonization Working Party for medical devices and diagnostics (PAHWP) now the African Medical Devices Forum (AMDF); the African Vaccines and the African Vaccines Regulatory Forum (AVAREF) for clinical trials and ethics oversight. Others are the Africa Pharmacovigilance Advisory Group (APAG); the African Blood Regulators Forum (ABRF); Medicines Policy and Regulatory Reforms (MPRR); Regulatory Capacity Development (RCD), Good Manufacturing Practice (GMP), the Regulatory Information Management Systems (RIMS), and a technical committee on products evaluation and registration.

The RCD-TC recommended the designation by the AUDA-NEPAD of 11 regional centers of regulatory excellence (RCOREs) in 2014 while the MPRR-TC was instrumental in the development and subsequent adoption of the AU Model Law on Medical Products in 2016. Twenty-five (25) knowledge products in the form of guidelines, studies and/or evaluation reports have been produced by the various TCs. They include the AU Model Law on Medical Products Regulation (2016), Guidance document for domestication of the African Union Model Law on Medical Products Regulation (2021), Guide for RCOREs (2014), RCOREs Booklets, Guide for Management of MRH Projects by RECs (2021), Ten (10) AVAREF Clinical Trials Guidelines of 2019 (i.e. Application Form Checklist, Clinical Trials Application Form, Clinical Trials Assessment Template, Quality Assessment Template, Nonclinical Assessment Template, Nonclinical Assessment Template, Statistical Assessment Template, AVAREF Good Clinical Practice (GCP) Inspection Guide, GCP Inspection Checklist, Joint Review Guidelines, Strategy and Guidance for Emergency Preparedness).

Others are Guidelines for Issuance of Market Authorization for Medical Devices and In-Vitro Diagnostics (2020), Guidelines for Registration of Medical Devices Establishments (2020), Guidelines for Import Control for Medical Devices and In-Vitro Diagnostics (2020), Guidelines for Inspection of Manufacturing Sites for Medical Devices and In-Vitro Diagnostics (2020), and the AU Guidance on Emergency Expedited Regulatory Authorization and Access to COVID-19 Vaccines in Africa (2021). Studies and/or evaluation reports include the Consultancy Report for Scoping of a Continental Regulatory Information Management System Solution and Information Sharing Platform for the Member States in the African Union (2020), Africa Medical Products Regulatory Harmonization Training Curriculum (2021), RCOREs Evaluation Report (2014-2019) and the AU Body of Knowledge for the African Medicines Regulatory Professional Fellowship Programme (2014).

In terms of assets, there are existing grants funded by the Bill and Melinda Gates Foundation (BMF) in support of the AMRH and AU-3S programs coordinated by AUDA-NEPAD and AVAREF Project coordinated by WHO. The AMRH Grant is $2m covering the period between 09 July 2020-30 June 2023 and the AU-3S BMGF Grant is $10m for the period 21 November 2019-30 November 2024. In addition, the GIZ grant to AMRH Programme is Euro 695,753.00 for the period November 2021 to 31 July 2023.

2. The AMRH - a foundation for the AMA & vaccines regulatory excellence in Africa

The development, adoption by the AU Assembly and subsequent coming into force of the Treaty for establishment of the African Medicines Agency (AMA) is a result of the foundation built by the AMRH Initiative as part of PMPA framework[5]. The creation of AMA is the final component of the AU vision of a strengthened medicines regulatory ecosystem on the continent. This vision is anchored within a decade long journey to move Africa from 55 countries, each with its own disparate regulatory system, to an integrated, harmonised, efficient networked system built around the RECs and NRAs, which is interlinked into AMA. Each of these actors (NRAs, RECs, and AMA) are expected to play a critical and unique role built on a clear division of labour, which ensures optimal use of resources, non-redundant activities, and best-informed decision making at all levels. The program will contribute to the development of additional expertise for specific categories of products at continental level based on assessments that will be conducted.

The AU ambitious target to reach the goal of 60% local vaccine production by 2040 through the partnership for African Vaccines manufacturing (PAVM) framework is another opportunity for strengthening regulatory systems on the continent. The PAVM aims to address the key enablers of the vaccine manufacturing ecosystem through 8 bold programs such as creation of an African vaccines pooled procurement mechanism; establishment of a vaccine manufacturing deal preparation and financing facility, and a vaccine technology transfer and IP enablement unit; embedding vaccines regulatory excellence in NRAs and RCOREs; and setting up vaccine research and development (R&D) centres and a coordinating unit. Other programs include forming regional capability and capacity centres; and advocating for enabling trade policies for vaccines while having a body drive continental strategy delivery and oversight.

Vaccine manufacturing requires appropriate regulatory oversight from regulators who have sufficient competence across a range of areas including inspections, clinical trial and market authorisation review capabilities, pharmacovigilance systems and laboratories for testing and batch release. In addition, R&D centres need to be able to access regulators for advice in relation to product development as well as for approvals of clinical trials and novel products. The AMRH and the AMA Initiatives recognise the broader work needed to realise this vision across the different areas of the vaccine manufacturing ecosystem (including tech transfer, talent development, financing, demand, and other market dynamics).

The AUDA-NEPAD is leading the regulatory workstream of the PAVM framework working under the AMRH and subsequently AMA once operational. Areas of focus include strengthening and/or reactivation of the AMRH Technical Committees (TCs) on clinical trials oversight, GMP inspections, AMQF for strengthening quality control laboratories, and Regulatory Capacity Development TC responsible for designation of RCOREs. Continental technical guidelines will be developed based on identified needs. In addition, training and talent building will be strengthened through RCORE while vaccine manufacturing frontrunner NRAs will be supported to attain WHO ML3/WLA.

[5] AU Executive Council Decision, {EX.CL/Dec.857 (XXVI))} of January 2015

3. Implementation arrangements

The AMRH Project to operationalise the AMA and its plan to support vaccines manufacturing on the continent will be implemented through the existing AMRH governance structure with focus on strengthening key entities namely NRAs, RECs, AMRH Technical Committees (TCs), AMRH Partnership Platform, AMRH Steering Committee, and the AMRC Assembly supported by the Secretariat.

The purpose of the AMRH governance framework is to provide strategic direction on regulatory systems strengthening and harmonisation interventions on the continent, ensure convergence and alignment at regional and continental levels while fostering ownership and leadership by Member States, collective responsibility, mutual accountability, and sustained impact[6]. Some of the core principles of the AMRH governance include the need to organise regulatory activities across groups of countries within regional structures such as RECs and/or Regional Health Organizations (RHOs). In addition, resources for the regulatory system strengthening should be used only for value-adding activities ensuring pooling of resources at the regional level and economies of scale through work sharing; NRA reliance on regulatory work already undertaken by competent regulatory authorities and WHO; and harmonisation of regulatory standards and requirements between NRAs. Furthermore, a need for performance framework that enables performance management of all key partners, including remedial actions for non-compliance is recognised.

The RECs currently engaged under the AMRH Programme include the EAC, ECCAS, ECOWAS, IGAD and SADC while the West African Health Organization (WAHO) and the Organization for Coordination of the Fight Against Endemic Diseases in Central Africa (OCEAC) represent the RHOs.

3.1. The roles and responsibilities of various entities

The AMRC is an assembly of all Heads of NRAs in AU Member States and serves as a platform for the overall decision-making in the AMRH governance framework. It produces recommendations to be taken as technical, policy and strategic guidance to AU Policy Organs.

The AMRH SC provides strategic and technical guidance on the feasibility, analysis and modalities (options) in implementing regulatory systems strengthening and harmonisation initiatives for medical products in Africa and leads in the execution of plans and priorities established by the AMRC. The AMRH SC is also responsible for providing oversight and guidance in the management of the AMRH PP.

The AMRH TCs are responsible for providing technical opinion, advice and guidance on different regulatory functions as defined under the WHO Global Benchmarking Tool (WHO GBT). The guidance can be in the form of developing continental technical guidance on medical products regulation and harmonisation under specific thematic areas; facilitating joint review of dossiers and clinical trials applications; providing advice on safety and quality of medical products circulating on the African market, just to mention a few. The AMRH TCs are also responsible for supporting implementation of activities at national and regional levels, domestication of continental guidelines, and promotion of collaboration between national level and REC level stakeholders.

[6] AMRH Governance Framework was adopted by the AMRH Steering Committee in 2017

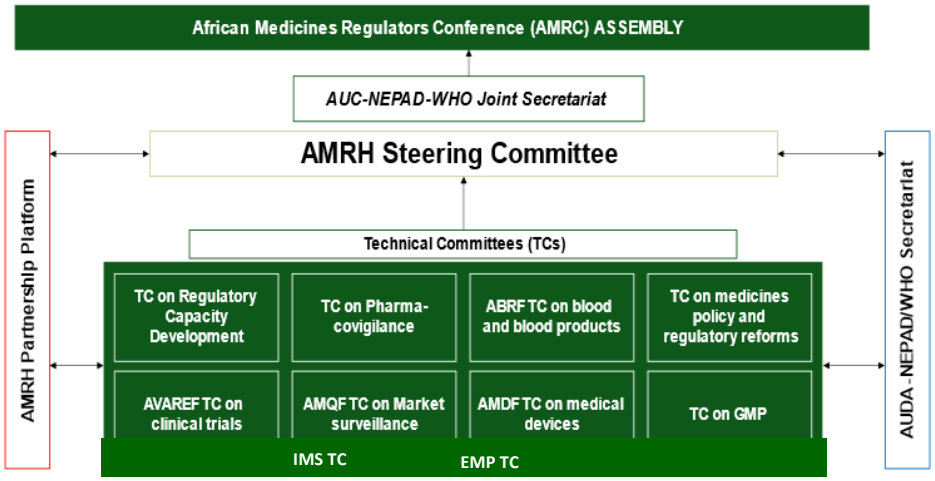
The AMRP PP is established to increase collaboration among stakeholders supporting regulatory systems development in Africa; foster mutual responsibility, accountability, and shared impact; and ultimately minimise duplication and coordinate efforts at all levels of implementation. To date, more than 44 partners constitute the AMRH PP to provide either financial, technical or policy advocacy support which is thematically organised through Joint Action Groups (JAGs).

The RECs Secretariats are responsible for coordination of regulatory harmonisation programmes and projects; day-to-day management of initiatives at regional level; monitoring and evaluation of performance; and reporting to AMRH Steering Committee. In the future, it is anticipated that REC responsibilities will include i) coordination of assessments and inspections for products under its jurisdiction once AMA is operational and has a clearly defined scope of products, ii) coordination of nomination of regulatory experts from NRAs within their respective regions to participate in AMRH and subsequently AMA TCs, iii) rely on AMRH and/or AMA technical standards and product recommendations, and support members states to implement the standards and to authorise the products, iv) track and maintain the regulatory metrics including performance timelines for both their own REC products as well as AMRH and/or AMA products, and publish these at least annually on their website. RECs will be strengthened to efficiently coordinate regional MRH initiatives and ensure alignment with AMRH and AMA eventually.

The NRAs are responsible for the day-to-day country level management and monitoring of regulatory and agreed activities, engagement in regional networks for harmonisation of regulatory systems to ensure effective and efficient performance of regulatory functions.

3.2. The AMRH Governance Framework

Figure 1 below provides an overview of the AMRH Governance structure.



Source: AUDA-NEPAD Publication, 2019

The existing assets and knowledge products under the AMRH structures will be used to support AMA operationalisation. The AUDA-NEPAD will work with various stakeholders to ensure effective execution of the project deliverables. These stakeholders include the AUC, WHO, AMA DG, RECs, NRAs, industry, and partners.

The existing key performance indicators will be strengthened to ensure that all the various entities deliver as a collective through regular monitoring arrangements and subsequent follow-up. A mid-term review will be conducted to evaluate progress while an external review will be conducted at the end of the project period.

A communication plan will be embedded in the project to ensure the visibility of the action and the contribution of the various stakeholders. This will be done through knowledge and information sharing on AMRH Support to AMA operationalisation and increased media engagement for programme visibility and understanding at national, regional, and global levels.

3.3. Workstreams for project implementation

13 workstreams have been identified to guide AMRH Secretariat in providing technical support for vaccines manufacturing and the AMA operationalisation processes as follows:

3.3.1. Donor/partner engagement and coordination

The AMRH Partnership Platform (AMRH PP) will be strengthened while leveraging on the World Health Organization's (WHO's) Coalition of Interested Parties (CIP). A mapping exercise has been conducted to determine partners support at country, regional and continental levels. 44 partners are currently in the database with 18 partners individually engaged namely the Africa-CDC; WHO; EC; Enabel; UNDP; CEPI; BMGF; GIZ; Susan Thompson Buffett Foundation (STBF); BfArm; PTB; Welcome Trust; Paul-Ehrlich-Insitut (PEI); FIND; MTaPS;

French Development Agency; PATH; EDCTP. Ongoing engagements with the European Medicines Agency (EMA) are being undertaken to determine and agree on areas of support.

Partners engagement will be an ongoing process to bring in those that are not part of the AMRH PP, to expand the scope of partnership and strengthen collaboration to ensure effective coordination. The terms of reference for the AMRH PP including the partners engagement framework will be reviewed considering new developments. Funders and technical partners platforms will be established within the AMRH PP to bring together partners with common areas of interest i.e. financial or technical support. For technical support, each partner will then commit to support particular thematic areas through the joint action groups (JAGs).

Key results areas (KRAs) for this workstream include:

KRA 1.1 Partner Support Coordinated
KRA 1.2 Partnership platform meetings convened.
KRA 1.3 Technical and financial support mobilised

3.3.2. Policy and Legal Frameworks

The MPRR-TC will be revived to provide technical oversight on the policy and legal frameworks workstream which is key for strengthening the national and regional regulatory systems, the AMA operationalisation as well as support to the PAVM framework for vaccines regulatory oversight. Given the need for NRAs to update their policies and laws to allow for recognition of or reliance on RECs and AMA technical standards, scientific opinions and recommendations, this TC will have to provide technical support to AMA from the very beginning.

Currently, the regional regulatory harmonisation processes across Africa are at varying stages of maturity, generally focusing on joint review of products dossier applications with the bulk of applications being handled at national level. The existing RECs MRH initiatives will be reviewed to identify gaps and areas that need strengthening to ensure alignment of regulatory policies and legal frameworks at national and regional levels to enhance effective participation of countries. The role of Heads of Agencies, RECs MRH initiatives, and their relationship with AMA will be reviewed for consideration by the Conference of the State parties (COSPs). Countries will be supported to define legal provisions at national level required for the uptake of AMA guidance and recommendations. The NRAs will be supported to attain WHO ML3 and/or WLA status.

Key results areas (KRAs) under this workstream include:

KRA 2.1: Relationship between AMRH structures and AMA governance structure defined
KRA 2.2: Regional harmonisation initiatives strengthened
KRA 2.3: Countries supported to define legal provisions at national level required for the uptake of AMA guidance and recommendations
KRA 2.4: Advocacy on policy and legislative reforms strengthened
KRA 2.5: Technical committee on MPRR operational

3.3.3. Regulatory Capacity Development (RCD)

There is a critical gap in skills within the regulatory sciences field on the African continent, and an acknowledged need to develop a long-term strategy for the training and professional development of African regulatory professionals. The existing regulatory staff often lack continuous training and professional development opportunities and may therefore not be adequately prepared to cope with new innovations and advances in research and development of new medical products and technologies. It is also true that many NRAs are unable to retain highly qualified and experienced regulatory staff due to low salaries and limited professional development opportunities.

Strong functional NRAs rely on having qualified and experienced regulatory professionals to effectively carry out their duties. These professionals must also be equipped with the latest tools and techniques in health product regulation across different territories. The RCOREs and other academic institutions offering regulatory science courses have proved to be useful platforms in meeting this need.

The Technical Committee on regulatory capacity development (RCD-TC) will be revived to provide technical oversight on development of regulatory workforce on the continent. A consultant will be engaged to review the role of RCOREs in advancing regulatory science on the continent. In addition. A mapping of regulatory expertise will be conducted to identify gaps and needs and define roles. This exercise will facilitate the establishment of and/or review of the existing pool of regulatory experts in different fields and create a data base of the same.

A process for designation of new RCOREs for vaccines, and medical devices will be initiated through publication of expression of interest. Development of training materials and subsequently conducting trainings programs will be done as required including the steering of the RCORE network.

A review of existing regulatory science curricula will be conducted to identify gaps and propose the most appropriate curricula in alignment with the WHO competency framework for regulators. Emphasis will be put on linking education, training, and research with career development with a view to combine an academic base with experiential learning aligned within a competency framework. This is key for creating a regulatory ecosystem that engages with a broad range of stakeholders to ensure that expertise in the ever-expanding field of regulatory science filters into teaching and research in a symbiotic way.

A mechanism for recognition of regulatory professionals including a certification system through a continuous personal development (CPD) programme will be established for individuals engaged in regulatory affairs for human and veterinary medicines and medical devices on the continent. Engagement with regulatory professional certification bodies such as TOPRA[7] or RAPS[8] will be done to determine whether to be associated as African Chapter or establish a new entity 'the African Regulatory Affairs Professional Association'

[7] An EU base entity 'The Organization for Professionals in Regulatory Affairs' all over the world
[8] A US bases Regulatory Affairs Professional Society

encompassing professionals from regulatory authorities, academia and industry operating in Africa. The aim is to promote the regulatory science profession in Africa through skills development, professional training and events. The African organisation may operate as a sister association to either TOPRA or RAPS having access to training and professional development courses, undertaking twining arrangements especially between academia on areas such as MSc programs and training and exchange ideas around key regulatory topics. It is envisaged that the Association will have its own statutes, legal identity, Board, and Advisory Committee and have linkage with other regulatory associations across the globe.

Key results areas (KRAs) under this workstream include:

KRA 3.1: Regulatory Capacity Development (RCD) Technical Committee established and operational

KRA 3.2: New RCOREs designated and existing ones strengthened

KRA 3.3: Pool of Regulatory Expertise database developed

KRA 3.4: Revive the African medicines regulatory professional fellowship programme to accommodate new advances in vaccines, medical devices, and other products

KRA 3.5: The African Chapter for regulatory professionals established and operational

3.3.4. Evaluation of medical Products (EMP)

The AMRH goal is to have harmonised and functioning medicines regulatory systems within the African continent in accordance with national and internationally recognised policies and standards. In order to implement this, it is critical that all technical matters including drafting of technical guidelines and procedures be done by nominated experts in from AU recognised RECs drawn from respective Partner/Member States.

Currently, Technical Committees support REC and national drug authorities (NRAs) review processes for medical products dossier applications and standard setting. Different RECs have adopted different guidelines for registration of medical products which require harmonisation at continental levels with the advent of the AMA. A TC on evaluation of medical products (EMP TC) will be established to assist in harmonising technical requirements and regulatory review processes across the continent for specific group of medical products. This will be done by working closely with RECs expert working groups to ensure their participation and contribution to the continental TC work.

Continental guidelines and joint review procedures will be developed by the EMP TC for consultation with the industry and other key stakeholders before adoption. The TC will develop Common Technical Document (CTD) format for application for registration of priority products in alignment with internationally acceptable standards such as WHO and/or ICH. Harmonised technical requirements and guidelines for issuing scientific opinions on recommendations for registration of medical products or emergency use authorisation of human medicines at NRA level will also be developed by the EMP-TC.

In addition the TC will develop harmonised technical requirements and guidelines for emergency use and ultimately Emergency Use Authorization (EUA) of human medicines and vaccines at NRA level; identify and develop a list of priority medicines that will be jointly assessed; develop standard operating procedures (SOPs) for assessment of applications

for registration of priority medical product on the continent, develop procedures for joint assessment of medical products application dossiers for consideration and subsequent approval by the appropriate AMRH and/or AMA Governance structures.

The TC will further coordinate the development of a continuous and sustainable training program for NRAs assessors on the assessment of application dossiers; facilitate domestication of the agreed technical documents for registration of medical products including guidelines, and SOPs for assessment of application dossiers; facilitate development of technical guidance and procedures for joint review of product dossiers for a group of priority complex medical products; facilitate and advocate for use of the WHO collaborative registration procedures and reliance models to facilitate approval of medical products, information sharing and capacity building. It will further provide scientific advice and guidance through collaboration with other AMRH TC to facilitate decision making process by the appropriate AMRH and/or AMA Governance structures.

A consultant will be engaged to support the operationalisation of the EMP-TC. AUDA-NEPAD will continue to facilitate debate around the roles and responsibilities of the registration TC vs the proposed Scientific Advisory Committee (SAC) as a body to provide independent scientific opinion to guide the AMA Governing Board on recommendations from the technical committees (TCs). The review will determine whether SAC should serve as an overarching regulatory committee, or advisory to the AMA DG. Considerations will be made to avoid conflicts between EMP TC and SAC especially if the TC recommendations are not accepted by SAC and the risk of duplication, and/or an added lay of bureaucracy/delays.

Key results areas (KRAs) for this workstream include:

KRA 4.1 EMP-TC established and operational.

3.3.5. Strengthen the National Quality Control Laboratories (NQCLs

National Quality Control Labs (NCQLs) are responsible for routine testing of medical products including vaccines and biologicals for release onto the market, for testing products including those that are potentially defective, and for identification of Substandard/Falsified (SF) products. Some may also work on pharmacopeial standards and monographs as well as research. Currently most NQCLs are focussed on physical and chemical properties of the product from medicines perspective. Vaccine lot testing and release is the function which needs to be added to these laboratories through an appropriate upgrade plan.

With the establishment of the AMA, the Partnerships of African Vaccine Manufacturing (PAVM) initiative and the need to build African regulatory systems in general, and for vaccine regulatory processes, there is a need to build vaccine regulatory excellence. The AMRH Initiative is supporting the PAVM regulatory workstream to establish Reliance Vaccine Regulatory Laboratory Network in the African continent.

There are 16-17 countries which have announced new vaccine manufacturing initiatives and their NRAs would need support for vaccine regulatory oversight. There is a need to

develop a clear vision and framework for biologics laboratory network for the continent, with laboratories operating to appropriate standards, collaborating, relying on each other, and not duplicating work. The aim is to ensure that laboratories are appropriately coordinated through the existing AMRH governance structures specifically the African Medicines Quality Forum Technical Committee (AMQF-TC). Under the AMQF TC, a Vaccine Subcommittee has been established to oversee vaccine related regulatory work.

Each region needs access to laboratory expertise and these laboratories can work together to form a network serving the needs of regulators at continental, regional and national level. The Reliance NRAs network of 5 most mature agencies along with their NQCLs would be upgraded to support the frontrunner vaccine producing country NRAs through Reliance Framework. Laboratories in vaccine producing countries would be upgraded as their NRAs embark on journeys to next maturity level. African NRAs and manufacturers need access to a WHO prequalified laboratory to ensure the quality of their products circulating in various markets.

There are several laboratories at varying capacity for medicines, vaccines and biologicals testing and lot release. A mapping exercise will be conducted to determine the existing laboratory capacities and gaps with a view to provide the needed support in advancing vaccine manufacturing on the continent and operationalisation of the AMA. Consideration will be made to repurpose and upgrade the existing laboratories to be WHO Prequalified and/or ISO Certified and serve as continental and/or regional laboratories to be accessible to all member states and work with national regulators to carry out lot testing and batch release for Vaccines. Collaborative work will be encouraged to diminish NRA barriers to access the certified laboratories. Efforts will be made to ensure that the established network of WHO PQ laboratories is strengthened, and support is provided to identified laboratories to be WHO Prequalified and/or ISO Certified.

The African Medicines Quality Forum (AMQF) TC operations will be supported to provide oversight on strengthening laboratory capacities at national, regional, and continental levels. The NQCLs will be strengthened to support vaccines manufacturing, post marketing surveillance (PMS) programmes and the African Medicines Agency designated laboratory.

National and regional post marketing surveillance (PMS) programmes will be strengthened. Joint regional PMS programmes and cross border operations by NRAs and law enforcement agencies will be documented and promoted as means to curb sub-standard and falsified (SF) medical products including the IGAD PMS study[9]. Regional post marketing experts working groups will be established where they do not exist while the AMQF sub-committee of SF and sub-regional networks will be operationalised to coordinate at continental level.

Key results areas (KRAs) under this workstream include:

KRA 5.1: African Medicines Quality Forum (AMQF) operations supported

KRA 5.2: National Quality Control Labs' (NQCL) capacity strengthened

- NQCLs mapped, WHO prequalified/ISO certified labs identified, and a framework for lab networks developed

[9] IGAD PMS Survey on the quality of Oxytocin and Amoxicillin (2019).

- Network of laboratories on biologicals and vaccine lot testing and release created
- Laboratories supported to attain WHO PQ and/or ISO certification

KRA 5.3: Post-marketing surveillance programmes strengthened to curb sub-standard and Falsified (SF) medical products

3.3.6. Clinical trials regulatory oversight

The AVAREF TC is responsible for strengthening the capabilities and capacity of ethics and regulatory oversight of clinical trials to ensure ethical and scientific conduct of product development in African countries. In addition to approving pneumococcal and malaria vaccines among others, AVAREF has published 10 guidelines for regulation of clinical trials and contributed to the development of AU Guidance on Emergency Expedited Regulatory Authorization and Access to COVID-19 Vaccines in Africa. AVAREF TC will continue to provide technical support on assessment of clinical trial applications or clinical data to both NRAs and AMA while expanding its scope in support of vaccines manufacturing regulatory oversight.

Given the existing multiple entities supporting the conduct of clinical trial (CT) of medical products on the continent and the need to ensure effective coordination, a consultant will be engaged to assess interlinkages of existing systems and structures. These include the African Vaccines Regulatory Forum (AVAREF), the Pan African Clinical Trials Alliance (PACTA), Pan African Clinical Trials Registry (PACTR), and the Clinical Trials Community Programme, just to mention a few. Gaps will be identified with a few to determine the need to strengthen the capacities for ethical and regulatory oversight and the interaction between sponsors, ethics committees, NRAs and Clinical Trial Registries with a view to increase transparency, promote communication among bodies involved in regulation of clinical trials and increase efficiency of clinical trial oversight processes. The assessment will also consider the need for strengthening PACTA to consolidate various gains attained so far and further enhance coordination of human resource capacity, best practices, common technical requirements and the efficiency and transparency of the ethical/regulatory processes as a cornerstone for addressing public health emergencies.

The consultant is expected to further review ToRs for existing CT-TC to ensure alignment with AMA and PAVM objectives, review implementation of the AU Guidance on Expedited Approval of COVID-19 Vaccines by NRAs; facilitate the development of programs to facilitate collaborations among the existing CT platforms and structures at regional and continental levels.

Key results areas (KRAs) under this workstream include:

KRA 6.1: Relationship between AMRH, AVAREF, AMA & PACTA Structures defined and strengthened.

KRA 6.2: Clinical Trials Networks Coordinated at AU Level.

3.3.7. Regulation of medical devices and in-vitro diagnostics

The mission of the AMDF TC is to study and recommend ways to harmonise medical devices and diagnostics regulation in Africa. The overall mandate of the AMDF is to identify technical needs, develop technical documentation in line with international guidelines and best practices and recommend to the Steering Committee for adoption. In executing its roles and responsibilities, the TC will provide technical advice on matters related to regulation of Medical Devices (MDs) and In-vitro Diagnostics (IVDs), develop, and disseminate scientific materials to inform policy and decisions to the member states, RECs and AMRH Steering Committee. The TC will also develop technical guidelines for both pre, placing and post market activities and establish, promote, and strengthen platforms for communication, collaboration and sharing of information between regulators and stakeholders. Furthermore, the TC will advocate on the need for NRAs to strengthen regulation to improve access to medical devices and vitro diagnostics of good quality, safe with acceptable performance. Sub-TWGs made up of experts to work on specific regulatory areas/functions will be strengthened. The TC will support in implementation of work plans, technical guidelines and standards on medical devices and in vitro diagnostics regulation at national and regional level and assist in developing proposals for funding and sustaining AMDF's activities. The TC will monitor progress on the implementation of medical devices and diagnostics regulatory activities undertaken by NRAs through RECs.

Key results areas (KRAs) under this workstream include:

KRA 7.1: Harmonization, mutual recognition, and reliance of medical devices regulations in Africa advanced and promoted.

KRA 7.2: Technical capacity of national regulatory agencies in medical devices and IVDs strengthened.

KRA 7.3: An RCORE on medical devices and IVD designated.

3.3.8. Regulation of blood and blood products

It is currently not envisaged that blood and blood products will be within the initial scope of AMA, this TC will therefore remain under AMRH until such a time that AMA (through a decision by the COSP and GB) has added blood and blood products to its scope. The purpose of the ABRF is to facilitate access to quality, safe, and affordable blood products for all people of Africa through continental enhancement of the work of the RECs to advance technical and regulatory harmonisation and cooperation among the Member States.

The scope of the ABRF is to promote information sharing and reliance for strengthening and harmonising regulatory systems for blood products; to provide advocacy and communications targeted to policy makers and the general public to enhance understanding and support of the need for blood regulation; and to strengthen capacity of national blood regulators through external assessment against the WHO Global Benchmarking Tool and cooperation in addressing identified gaps and deficiencies.

The roles and responsibilities of the ABRF are to develop technical guidelines on strengthening and harmonising regulatory systems for blood products; disseminate knowledge materials and training resources relevant to blood regulation; promote information sharing, regulatory convergence, and reliance among Regulatory Authorities through harmonisation of regulation of blood products; and support implementation at national and regional level of regulatory harmonisation for blood products. Other roles are

to oversee projects developed at the RECs in blood product quality and safety consistent with the vision of AMRH, relying on the expertise and input from RECs and from ABRF Working Subgroups, and ensure their dissemination and advocacy through all RECs and to develop innovative regulatory pathways for blood products including common data collection, risk assessment, compliance methods and common tools to address new and emerging threats and recommend mechanisms for funding and sustaining the Forum's activities.

Key results areas (KRAs) under this workstream include:
KRA 8.1: Access to quality, safe, and affordable blood products facilitated

3.3.9. Pharmacovigilance (PV)

The AU Smart Safety Surveillance Project (AU-3S) coordinated by the AUDA-NEPAD, is aimed to strengthen pharmacovigilance capabilities and capacity in countries in Africa with the establishment of reporting mechanisms, an adverse event database, competencies around signal detection and risk benefit evaluation, with the involvement of experts. The Project is being piloted in 4 countries namely Ethiopia, Ghana, Nigeria, and South Africa with initial scope of COVID-19 vaccines. It is subsequently planned to be expanded to other biological products in due course and geographic regions. The AU-3S Steering Group constituted by heads on NRAs of the pilot countries will be provide guidance on the direction of the programme in support of vaccines manufacturing and AMA operationalisation.

Assessment of existing PV initiatives will be conducted by a consultant to facilitate alignment and develop a PV Framework for Africa. Collaboration with the European and Developing Countries Clinical Trials Partnership (EDCTP) funded programmes on PV (and clinical trial oversight and registration in Africa) will be pursued to ensure alignment with continental PV initiatives. These include the Pharmaco Vigilance Africa (PAVIA) Project implemented in Eswatini, Ethiopia, Nigeria, and Tanzania; PROFORMA Project implemented in Ethiopia, Kenya, Rwanda, and Tanzania; just to mention a few.

Key results areas (KRAs) under this workstream include:
KRA 9.1: Africa Safety Advisory Committee operational.
KRA 9.2: Continental Safety Surveillance (SS) / Pharmacovigilance initiative operationalised.
KRA 9.3: SS/PV Projects in Africa aligned.
KRA 9.4: Capacity for SS/PV strengthened.

3.3.10. Inspection of manufacturing sites & API database

A Technical Committee for good manufacturing practices (GMP-TC) has been revived to provide technical support to AU Member States to build their GMP inspectorate capabilities, provide technical advice on the development and implementation of sustainable GMP standards in alignment with ICH and PIC/S guidelines. This will be done in collaboration with national regulatory authorities (NRAs), regional economic communities (RECs), pharmaceutical industry, and partners in support of the AU Pharmaceutical Manufacturing Plan for Africa (PMPA) and the Partnership for African Vaccines Manufacturing (PAVM) initiative through the AMRH Initiative and eventually the African Medicines Agency (AMA) once operational.

Specifically, the role of the GMP TC is to support NRAs in identifying regulatory gaps related to GMP inspection, develop continental guidelines for GMP inspection including vaccines and biologics, facilitate joint inspections of manufacturing sites for priority products in support of AMA functions. The GMP-TC among others is also responsible for reviewing existing active pharmaceutical ingredients (API) data available to African NRAs and define use case for a continental API database, developing and validating user requirements for a minimum viable product (MVP) and/or offer available digital solutions for adoption. Working with Information Management Technical Committee (IMS-TC) through the regulatory information management systems (RIMS) platform, a database will also serve as a repository for sharing inspection reports for all manufacturing sites and contract research organisations (CROs). The TC is further responsible for developing a shared platform for information sharing among the partner/member states and reporting progress on implementation of its Plan of Action to the AMRH Steering Committee.

The GMP-TC will develop guidelines/practical 'playbook' for inspectors to drive standardised approach for inspection of medicines and vaccine manufacturing plants; coordination of pre- and post-recommendation inspections (GMP, GLP, GCP) for selected medical products to be covered by AMA including vaccines.

A consultant/an expert will be engaged to support development and implementation of the GMP TC workplan; drafting of guidelines, procedures, and protocols for GMP; supporting and coordinating the development of databases; coordinating partners support on GMP-TC; and supporting GMP-TC in-house and external meetings.

Key results areas (KRAs) under this workstream include:

KRA 10.1: A functional GMP-TC assessed based on agreed and costed workplan with clear key performance indicators (KPIs).

KRA 10.2: Guidelines and SOPs for joint GMP GLP, GCP, GVP inspections of manufacturing and clinical trial sites developed.

KRA 10.3: Pre- and post-recommendation inspections (GMP, GLP, GCP, GVP) for selected medical products including vaccines coordinated.

KRA 10.4: A community of practice (CoP) on GMP expertise established and operational.

KRA 10.5: cGMP best practice documented and shared widely.

KRA 10.6: Training materials and programmes for GMP GLP, GCP, GVP inspections developed and operational.

KRA 10.7: A consolidated continental database for API, GMP inspection reports and CROs established.

KRA 10.8: A Joint Action Group (JAG) for GMP-TC support (technical and financial) established.

3.3.11. AMRH communication on AMA

The AMRH knowledge and information in support of AMA Operationalization will be shared with internal and external stakeholders. This is designed to promote the ongoing regulatory systems strengthening and harmonisation (RSS&H) efforts on the continent but also to support visibility of partners involved in regulatory strengthening. Media engagement for

programme visibility and understanding at national, regional, and global levels will be strengthened.

Advocacy will be conducted to increase AMRH and AMA visibility while advocating for more ratification on the AMA Treaty.

Key results areas (KRAs) under this workstream include:

KRA 11.1: Knowledge and information on AMRH Support to AMA Operationalization shared.
KRA 11.2: Strengthened media engagement for programme visibility and understanding at national, regional and global levels.
KRA 11.3: The AMRH Website developed and maintained.
KRA 11.4: # of knowledge products on RSS&H shared.
KRA 11.5: # of media engagements at national, regional and global levels on AMRH support to AMA.
KRA 11.6: Additional # of countries ratified the AMA Treaty

3.3.12. Regulatory Information management Systems (RIMS)

The TC on Information Management Systems (IMS) will be supported to facilitate the operationalisation of RIMS at national, regional, and continental levels.

The IMS TC supports the IMS technical aspect of medical products regulations in alignment with the regulatory harmonisation initiatives. It is responsible for supporting and developing robust information management systems and work sharing platforms for RECs, NRAs, RCOREs, TCs and all other Partners and stakeholders as an essential component of regulatory convergence and reliance. Given its importance to the operations of AMA, the TC will provide technical support to AMA in establishing information management systems.

The TC will design and develop a continental IMS for medical products regulation that will facilitate the flow of quality data and effectively manage compliance to norms and standards. It will provide support and monitoring of the implementation of IMS activities; implement and operationalise a common Information Management System for regulation of medical products linked to the continental, regional and national platforms; and develop technical documents that would ensure quality implementation and sustainability of IMS. The TC will conduct continual review and update of existing systems; contribute to the sharing of data to enhance productivity within the RECs, NRAs, RCOREs and TCs Strategic Agenda; and develop and facilitate implementation of ICT technical standards, SOPs, guidelines, and any other relevant documents on strengthening and harmonising regulatory systems among the RECs in the continent. The TC will also promote and strengthen communication and collaboration between RECs, NRAs, RCOREs, TCs and AMRH Steering Committee and other stakeholders involved in Continental Regulatory Harmonization Projects; and promote the generation of knowledge materials for dissemination to RECs and other relevant stakeholders. It will identify gaps in the information management system implementation process in RECs, NRAs, RCOREs and TCs and make recommendations to the AMRH Steering Committee and identify ICT risks and recommend mitigation measures.

Key results areas (KRAs) under this workstream include:

KRA 12.1: AMRH Website and Information sharing portal developed and maintained.
KRA 12.2: Technical committee on IMS operational.
KRA 12.3: Various RIMS systems integrated to allow information-sharing, work-sharing, and collaboration.
KRA 12.4: Support development of e-CTD platform in at least 1 REC.
KRA 12.5: RIMS systems integrated to allow information-sharing, work-sharing, and collaboration among the NRAs.
KRA 12.6: RIMS embedded into AMA once operational.

3.3.13. Overall coordination/PMO

AMRH support to the operationalisation of AMA will be effectively coordinated through a strengthened Secretariat and support for consultants. A total of 16 staff will be supported through funding from different partners. Consultants will be engaged based on identified need. Regular meetings of the Secretariat & Consultants will be convened to ensure alignment of deliverables for each KRA. Regular updates on AMRH support to AMA and progress made will be shared with key stakeholders and an annual report will be published every year.

The AMRH Steering Committee, African Medicines Regulators Conference (AMRC) Assembly, the biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA) and the AMRH Week will be convened as per schedule. The AMA Governance Structures including the AMA DG, the Governing Board, and the Conference of the States Parties (CoSP) will be engaged with a view to offer technical support on AMA operationalisation.

Key results areas (KRAs) under this workstream include:

KRA 13.2: AMRH support to the operationalisation of AMA effectively coordinated

- # of PMO meetings held according to agreed schedule.
- Performance reports on the various workstreams.
- AMRH Secretariat, AMRH Steering Committee, AMRC Assembly, SCoMRA and AMRH Week meetings convened as per schedule.
- AMA DG, Governing Board and CoSP engaged as scheduled.

KRA 13.1: AMRH Secretariat strengthened

- # of staff recruited.
- # of consultants engaged.

3.4. Workplan, Budget & Partners Support

A workplan including workstreams (groups), key results areas, activities and budget is provided in **Table 1** below. The total budget for the project over five years is **$ 84,883,114.41 (€ 78,941,296.40).** The detailed budget is attached as an **Annex 1** to this workplan.

Table 1: Budget Summary

Results Area	Budget ($)
1. Donor/partner engagement and coordination	540,500.00
2. Policy frameworks, and REC and NRA support	40,732,690.00
3. Regulatory Capacity Development	4,113,780.00
4. Evaluation of Medicinal Products	4,048,410.00
5. Strengthen the NQCL to support vaccines manufacturing and post marketing surveillance (PMS)	5,367,530.00
6. Clinical Trials Oversight	2,167,100.00
7. Regulation of medical devices and in-vitro diagnostics	2,353,000.00
8. Regulation of blood and blood products	733,605.00
9. Pharmacovigilance	1,037,300.00
10. Inspection of manufacturing sites	3,128,870.00
11. Communication	455,500.00
12. Regulatory Information Management System (RIMS)	1,793,350.00
13. Overall coordination, governance and knowledge sharing	18,411,479.41
Grand Total	**84,883,114.41**

3.5. Sustainability

The project will be anchored on existing initiatives and structures established on the continent for strengthening regulatory systems and harmonisation. Member states and RECs have formed the structures to ensure the integration of projects' interventions into national and regional systems for continuity and sustainability. The policy reforms supported under the project will lead to countries adopting policies and legal frameworks that will continually guide practice at the national level. Furthermore, the interventions will technically support the operationalisation of AMA, a technical body of the African Union responsible for strengthening regulatory systems. The AMA will continue with the technical work that TC will lead and ensure that it leads to systems strengthening. Furthermore, the AMA will be partially funded by the Member States and has the mandate to mobilise resources using different means, which is essential for sustaining efforts on regulatory systems strengthening. The capacity strengthening initiatives implemented under the project will support building a cadre of experts across the continent that will continue with regulatory systems strengthening and harmonisation beyond the project's life.

3.6. Logical Framework

Results	*Results chain*	*Indicator*	*Baseline (value & reference year)*	*Target (value & reference year)*	*Current value* (reference year) (* to be included in interim and final reports)*	*Sources of data*	*Assumptions*
Impact (Overall objective)	Improved availability of safe, efficacious, and quality assured medical products for the African population	**Impact indicator 1:** Percentage increase in medical products approved by NRAs after joint assessments	(…)*	(…)	(…)	Mid-term and end-term Mid-term and end-term evaluation to be conducted to collect data. Data on this indicator will be disaggregated by regional and continental joint assessments, and per RECs. Data will be reported through RIMS. Responsibility: RECs and AMA	*Not applicable*
		Impact indicator 2: Median timelines taken by NRAs to process an application from the time it is received to decision	7 – 8 months (2014)	(…)	7 – 8 months (2014)	Mid-term and end-term Mid-term and end-term evaluation to be conducted to collect data. Data on this indicator will be disaggregated by regional and continental joint assessments, and per RECs.	

Results	Results chain	Indicator	Baseline (value & reference year)	Target (value & reference year)	Current value* (reference year) (* to be included in interim and final reports)	Sources of data	Assumptions
						Data will be reported through RIMS. Responsibility: RECs and AMA	
Outcome (s) (Specific objective(s)	**Outcome 1:** Enhanced policy coherence and regulatory harmonisation for medical products and technologies in Africa.	1.1 Number of countries that have domesticated the AU Model Law on Medical Products Regulation	17 (2019)	25 (2028)	17 (2019)	Annual Data to be collected from NRAs using the R-IMS by national focal points. Dashboard reports to be compiled on R-IMS Responsibility: AUDA-NEPAD; RECs; NRAs	Timely legislative review processes in the countries
		1.2 Number of countries that have ratified the AMA treaty	22 (2022)	30 (2028)	22 (2022)	Annual AMA reports will be updated based on the countries that have deposited their instruments of ratification to the AUC Responsibility: AUC; AMA	Timely legislative processes for ratification of the treaty in the countries
		1.3 Number of countries adopting harmonised policies and guidelines	(…)	(…)	(…)	Annual Disaggregated data will be collected per regulatory	Improved capacity of and interest by NRAs to

Results	Results chain	Indicator	Baseline (value & reference year)	Target (value & reference year)	Current value* (reference year) (* to be included in interim and final reports)	Sources of data	Assumptions
		for regulation of medical products				function from NRAs using R-IMS on adoption of guidelines by countries. The analysed data will be compiled into AMRH, RECs and AMA reports. Responsibility: AUDA-NEPAD; RECs; AMA; NRAs	adopt harmonised guidelines
		1.4 Number of countries using reliance mechanisms for regulatory decision making	(…)	(…)	(…)	Annual NRA reports to RECs; REC annual reports; AMA reports. The data on reliance will be disaggregated as follows: other NRAs' decisions, and regional, continental and global platforms. Responsibility: NRAs	NRAs have adopted legal provisions to enable reliance
	Outcome 2: Improved regulatory capacity for medical products and technologies.	2.1 Number of countries attaining WHO-ML3 status	4 (2022)	8 (2028)	4 (2022)	Annual A tracker will be developed to monitor implementation of IDPs in collaboration with WHO, RECs and NRAs.	NRAs have adequate resource and capability to implement IDPs

Results	Results chain	Indicator	Baseline (value & reference year)	Target (value & reference year)	Current value* (reference year) (* to be included in interim and final reports)	Sources of data	Assumptions
						Responsibility: WHO; RECs; AMRH; AMA	
		Number of countries that have semi-autonomous NRAs	(…)	(…)	(…)	Annual Country laws and reports from established structures of the NRAs Responsibility: NRAs; RECs	Countries will adopt the AU Model Law on Medical Product Regulation
		Number of regulatory professionals in Africa	(…)	(…)	(…)	Annual Data will be collected from the Africa-wide regulatory professionals certification system and the pool of regulatory experts, RCORES and R-IMS. Annual dashboards will used to report on the indicator. Responsibility: AUDA-NEPAD	An Africa-wide certification system for regulatory professional rolled-out

Results	Results chain	Indicator	Baseline (value & reference year)	Target (value & reference year)	Current value* (reference year) (* to be included in interim and final reports)	Sources of data	Assumptions
Outputs	**1.1 Output 1 related to Outcome 1** Partner support to regulatory harmonisation and operationalisation of AMA coordinated	Amount of resources mobilised from partners to support regulatory harmonisation and AMA operationalisation	$1,000,000 (2022)	$72,942,646 (2028)	$1,000,000 (2022)	Annual Signed financing agreements by AUDA-NEPAD, REC reports, AMA reports. This data will be disaggregated at the national, regional and continental levels. Responsibility: AUDA-NEPAD; RECs, AUC, NRAs, AMA	Partner coordination mechanisms streamlined at the national, regional and continental levels for collective impact, alignment and accountability
		Number of partners supporting regulatory harmonisation and AMA operationalisation	44 (2022)	50 (2028)	44 (2022)	Bi-annual Data to be sourced from the partner database, AMRH Partnership Platform reports and AMA reports. Data will be disaggregated as per type and area of support. Responsibility: AUDA-NEPAD; AUC; AMA; RECs; NRAs	Partner coordination mechanisms streamlined at the national, regional and continental levels for collective impact, alignment and accountability
	1.2 Output 2 related to Outcome 1	Updated Model Law adopted by the AU Summit	0 (2022)	1 (2023)	0 (2022)	Once-off	Member States buy-in to the need to update the Model Law

Results	Results chain	Indicator	Baseline (value & reference year)	Target (value & reference year)	Current value* (reference year) (* to be included in interim and final reports)	Sources of data	Assumptions
	Countries supported to define legal provisions at national level required for regulatory systems strengthening and harmonisation					AU Summit decision on the Model Law Responsibility: AUC	
		Number of countries supported to draft national laws in alignment with the AU Model Law on Medical Products regulation	17 (2022)	30 (2028)	17 (2022)	Annual RECs will be supported to develop a tracking tool for the domestication of the Model Law. The data will be reported and consolidated by AUDA-NEPAD reports. Responsibility: AUDA-NEPAD	Country readiness and willingness to domestication of the AU Model Law on Medical Products Regulation
		Number of countries supported to ratify the AMA Treaty	22 (2022)	30 (2028)	22 (2022)	Annual RECs, AMRH and AMA reports. Responsibility: AUDA-NEPAD; RECs; AMA	Country readiness and willingness to ratify of the AMA Treaty
	1.3 Output 3 related to Outcome 1 Regulatory harmonisation initiatives strengthened	Number of joint assessments undertaken	(…)	(…)	(…)	Bi-annual RECs reports and RIMS. The data to be disaggregated at	Increased buy-in and willingness by manufacturers for their applications to undergo regional processes

Results	Results chain	Indicator	Baseline (value & reference year)	Target (value & reference year)	Current value* (reference year) (* to be included in interim and final reports)	Sources of data	Assumptions
						regional and continental levels Responsibility: RECS; AMA	
		Number of joint inspections undertaken	(…)	(…)	(…)	Bi-annual RECs reports and RIMS. The data to be disaggregated at regional and continental levels Responsibility: RECS; AMA	Increased buy-in and willingness by manufacturers for their applications to undergo regional processes
		Number of RECs that have systems for tracking IDPs	0 (2022)	5 (2024)	0 (2022)	Annual RIMS and REC reports Responsibility: RECs	Countries willingness to share data at the regional level and connect to electronic data sharing portal
	1.4 Output 4 related to Outcome 1 Harmonisation of product registration systems and processes strengthened	Number of continental harmonised guidance documents adopted	0 (2022)	(…)	0 (2022)	Annual Continental guidelines, procedures and requirements (this data will be disaggregated per regulatory	Continental TCs operational

Results	Results chain	Indicator	Baseline (value & reference year)	Target (value & reference year)	Current value* (reference year) (* to be included in interim and final reports)	Sources of data	Assumptions
						function and regulated products of focus[10]) Responsibility: AUDA-NEPAD; AMA	
		Number of regional harmonised guidance documents adopted	(…)	(…)	(…)	Annual Regional guidelines, procedures and requirements (this data will be disaggregated per REC and per regulatory function and regulated products of focus[11]) Responsibility: AUDA-NEPAD	REC TCs operational
		Number of countries that have adopted harmonised guidance documents	(…)	40 (2028)	(…)	Annual National guidelines, procedures, requirements and standard operating procedures. Data to be disaggregated for continental	Increased countries' buy-in to continental and regional harmonisation procedures

[10] Product registration; quality control and PMS; clinical trials oversight; inspection of manufacturing sites; regulation of medical devices and in-vitro diagnostics; regulation of blood and blood products; pharmacovigilance.

[11] Product registration; quality control and PMS; clinical trials oversight; inspection of manufacturing sites; regulation of medical devices and in-vitro diagnostics; regulation of blood and blood products; pharmacovigilance.

Results	Results chain	Indicator	Baseline (value & reference year)	Target (value & reference year)	Current value* (reference year) (* to be included in interim and final reports)	Sources of data	Assumptions
						and regional guidelines and collected by RECs and reported through RIMS. Responsibility: RECs; NRAs	
		Number of NRAs participating in joint assessments at continental and regional level	(…)	(…)	(…)	Annual Progress reports from by RECs and submit to AUDA-NEPAD for consideration by AMRH structures; AMA reports Responsibility: RECs; AMA	Increased countries' buy-in to continental and regional harmonisation procedures
		Number of applications jointly assessed	(…)	(…)	(…)	Annual RECs and AMA reports. Data to be disaggregated at the continental and regional levels Responsibility: RECs; AUDA-NEPAD; AMA	Continental and regional joint assessment processes functional
		Number of joint inspections conducted	(…)	(…)	(…)	Annual RECs and AMA reports. Data to be disaggregated at the continental and regional	Continental and regional joint inspection processes functional

Results	Results chain	Indicator	Baseline (value & reference year)	Target (value & reference year)	Current value* (reference year) (* to be included in interim and final reports)	Sources of data	Assumptions
						levels, and based on regulatory functions (GMP, GCP) Responsibility: RECs; AUDA-NEPAD; AMA	
		Number of continental technical committees operational	(…)	(…)	(…)	Annual AMRH reports. Data to be disaggregated per regulatory function. Responsibility: AUDA-NEPAD; AMA	Effective participation by experts from NRAs in TCs
		Number regional expert working groups / TWGs operational				Annual REC reports. Data to be disaggregated by regulatory function. Responsibility: RECs	
	2.1 Output 1 related to Outcome 2	2.1.1 Number of RCOREs operational	8 (2022)	15 (2027)	8 (2022)	Annual RCORE performance assessment reports.	Availability of resources for RCOREs to undertake their functions

Results	*Results chain*	*Indicator*	*Baseline (value & reference year)*	*Target (value & reference year)*	*Current value* (reference year) (* to be included in interim and final reports)*	*Sources of data*	*Assumptions*
	Regulatory expert trained and certified in core regulatory functions					AMRH Secretariat will undertake annual assessment of RCORE performance Responsibility: AUDA-NEPAD; RCORES	
		2.1.2 Number of additional modules added to the African medicines regulatory professional fellowship programme	(…)	(…)	(…)	Annual Body of knowledge and regulatory science curricula Responsibility: AUDA-NEPAD	The WHO regulatory competency framework finalised for alignment of the continental body of knowledge
		2.1.3 Number of regulatory experts trained	(…)	(…)	(…)	Bi-annual Training reports and RCORE reports. The data to be disaggregated to those trained in RCOREs and those trained in other institutions Responsibility: AUDA-NEPAD; RCOREs	RCOREs functional and providing training

Results	Results chain	Indicator	Baseline (value & reference year)	Target (value & reference year)	Current value* (reference year) (* to be included in interim and final reports)	Sources of data	Assumptions
		2.1.4 Number of regulatory experts participating in twinning and mentorship programmes	(…)	(…)	(…)	Bi-annual RECs and AMRH reports Responsibility: AUDA-NEPAD; RECs	Availability of experts to participate in the twinning programme
	2.2 Output 2 related to Outcome 2 Increased availability of regulatory professionals in Africa	2.2.1 Number of regulatory professionals certified under the Africa-wide certification system	(…)	(…)	(…)	Annual Reports from the certification body AUDA-NEPAD to track progress	Africa-wide certification system finalised
		2.2.2 Number of regulatory experts registered on the pool of regulatory experts	(…)	(…)	(…)	Annual Pool of regulatory experts annual progress report Responsibility: AUDA-NEPAD	Pool to consider registering professionals once the Africa-wide certification system is operational
	2.3 Output 3 related to Outcome 2 Increased knowledge and information sharing on regulation of medical products and technologies	Number of knowledge products produced on regulatory systems strengthening and harmonisation	25 (2022)	(…)	25 (2022)	Bi-annual RECs, AMRH and AMA reports. To be disaggregated at continental and regional level	Enhanced capacity for research, publication and communication of results at the national, regional and continental levels

Results	Results chain	Indicator	Baseline (value & reference year)	Target (value & reference year)	Current value* (reference year) (* to be included in interim and final reports)	Sources of data	Assumptions
	among NRAs and RECs across the continent					Responsibility: RECs; AUDA-NEPAD; AMA	
		Number of knowledge sharing platforms available for the regulators across the continent	5 (2022)[12]	6 (2024)	5 (2022)	Bi-annual RECs, AMRH and AMA reports; websites and other electronic knowledge sharing platforms Responsibility: RECs; AUDA-NEPAD; AMA	Effective participation by regulators on available knowledge sharing platforms
	2.3 Output 4 related to Outcome 2 Institutional capacity for NRAs and REC-MRH strengthened	Number of countries supported to implement IPDs towards attaining WHO ML3	0 (2022)	18 (2028)	0 (2022)	Bi-annual REC and AMRH reports Responsibility: RECs; AUDA-NEPAD; WHO	NRAs' willingness to undertake benchmarking using the WHO tool.
		Number of NRAs participating in twining programmes	(…)	(…)	(…)	Annual RECs and AMRH reports Responsibility: RECs; AUDA-NEPAD	Availability of NRAs to participate in the twinning programme

[12] AMRC, AMRH website, SCOMRA, AMRH Week, Annual meeting of Quality Control expert

Results	*Results chain*	*Indicator*	*Baseline (value & reference year)*	*Target (value & reference year)*	*Current value* (reference year) (* to be included in interim and final reports)*	*Sources of data*	*Assumptions*
		Number of RECs and NRAs that have functional RIMS	(…)	(…)	(…)	Annual RECs and AMRH reports Responsibility: RECs; AUDA-NEPAD	RIMS functional
		Number of RECs and NRAs implementing e-CTD	(…)	(…)	(…)	Annual RECs and AMRH reports Responsibility: RECs; AUDA-NEPAD	RECs' and NRAs' readiness to adopt electronic systems

Key: (…)* - Baseline data to be captured over the project period