NEWSLETTER

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AMRH
African Medicines Regulatory Harmonisation Programme

In This Issue

SCoMRA IV Creating Bridges for Medicines Regulatory Systems Strengthening in Africa

The 4th Scientific Conference on Medical Products Regulation in Africa (SCoMRA IV) held in Victoria Falls Zimbabwe 30th to 1st October 2019 brought together over 300 delegates from 41 countries, the African Medicines Regulatory Harmonisation Programme (AMRH) is creating bridges in Africa and abroad with the aim to improve access to Quality, Safe and Affordable Medicines to African citizens. The overall goal of SCoMRA IV was to stimulate discussion on progress made over the last decade of regulatory harmonization and alignment of regulatory networks, identify regulatory challenges facing Africa and lessons learnt, and propose a path forward for the next decade with a special focus on the new African Medicines Agency (AMA).

The conference brought together key stakeholders, regulators, policymakers, academia, the scientific community, private sector and civil society from across Africa, providing a platform for stakeholders to brainstorm on their role of ethical and regulatory approval of clinical trials of new medicines. This year's theme was "A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?' Margareth Ndomondo-Sigonda AUDA-NEPAD Head of Health Program said developing pharmaceutical manufacturing plants in Africa will increase the continents access to medicines.

“The pharmaceutical sector in Africa has huge potential, one of the key elements is to ensure the promotion of local production of pharmaceuticals in the continent in order to provide an enabling regulatory environment,” Sigonda said. The Zimbabwean minister of Health and Child Care, Mr Obadiah Moyo, said lack of locally produced goods puts the whole continent at risk as it faces high rates of diseases. Moyo said 80 per cent of Zimbabwean medicine is imported into the country. “We are threatened by substandard medicines, it is important to build capacity for medicine and harmonize our regulations so we are able to independently manufacture our own drugs,” said Minister Moyo.

Over 90 per cent of generic medicines in Africa is still being imported from mainly India and Europe. University of Cape Town Organic Chemistry professor Kelly Chibale, said new generic medicines take between 5-10 years from its date of manufacture to be introduced in Africa. “There is an urgent need to move towards more innovative approaches based on the science and the supporting data for regulatory decision making in Africa,” he continued to say, “Africa is not seen as an ideal environment for pharmaceutical companies due to the unpredictable nature of registration of medicines in Africa, our leaders need to start demanding local clinical data.”

The key recommendations from the opening ceremony were; (i) increased collaboration between regulators, researchers, academia and the industry is critical for improved capacity on regulation and drug discovery on the continent (ii) there is a need to strengthen research capacity and regulatory oversight focused on the young generation in order to achieve long-term sustainable benefits; (iv) re-thinking the review process to be underpinned by science and data for regulators to make science based decision that are driven by data should take priority (v) acquiring the necessary skills to leap frog and take advantage of innovations in medicines discovery and development is vital. SCoMRA has been held every two years since 2013, SCoMRA IV was a special one as the African Medicines Regulatory Harmonization (AMRH) Initiative is celebrating its 10th year anniversary leading medicines regulatory systems strengthening and harmonization work in Africa since its inception in 2009. SCoMRA IV also came at the opportune time when the continent is looking into the establishment of the African Medicines Agency (AMA) as an offshoot of the AMRH Initiative following the adoption of the AMA Treaty by the AU Assembly in February this year, and subsequent signing by five AU Member States. SCoMRA IV was organized in partnership with Medicines Control Authority of Zimbabwe (MCAZ), the Zimbabwe Ministry of Health and Child Care, the Southern African Development Community, World Health Organisation, The World Bank, the Bill and Melinda Gates Foundation, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and other key Development Partners.

Regulatory Harmonization a Key Driver to Achievement of Universal Health Coverage in Africa

In supporting the continent in moving towards the realization of Universal Health Coverage, the African Union Development Agency (AUDA-NEPAD) and PATH held a Medical Products Regulatory Harmonization Capacity Building Workshop in Johannesburg, South Africa from 26 - 27 November 2019. The workshop was aimed at providing key capacity building sessions on regulatory harmonization and the impact that comes with the implementation of regulatory harmonization in Africa. A modeling study done by PATH showed that accelerating access to two products (amoxicillin dispersible tablets and heat-stable carbetocin) due to regulatory harmonization could save more than 23,000 lives in Eastern and Southern Africa.

The workshop was attended by civil society representatives, members of parliament, media and policy makers. Participants were drawn from South Africa, Kenya, Zambia and Zimbabwe and they were sensitized on the importance of regulatory harmonisation with case studies from Medicines Control Authority of Zimbabwe (MCAZ) and the ZAZIBONA Collaborative Medicines Registration Procedure. They were taken through the African Union Model Law on Medical Products Regulation, African Medicines Regulatory Harmonisation (AMRH), Pharmaceutical Manufacturing Plan for Africa (PMPA), African Medicines Agency (AMA) and the relationship of how these entities (AU-Model Law; AMA; AMRH) fit together.

One of the lauded initiatives from the workshop was the ZAZIBONA Collaborative Medicines Registration Procedure which has seen countries among the SADC region collaborate in a work sharing initiative for medicines assessments and GMP inspections. The participating countries had common challenges which included huge backlogs & long registration times, high staff turnover, limited capacity to assess certain types of products and inadequate financial resources. ZAZIBONA was formed to solve these problems based on a

memorandum of agreement signed by the Heads of Agencies (NMRA Agreement to participate) and SADC Ministers of Health approved/ endorsed the initiative. The participants from the EAC region expressed their wish on their governments emulating the ZAZIBONA initiatives other than putting more effort into developing policies that may take time for each EAC country to agree to.

Key among the outputs of the workshop was the acknowledgement by participants that the workshop was a much-needed element in acceleration of strong regulatory harmonization in Africa. Some participants present, expressed their lack of knowledge on regulatory harmonization despite it coming into effect in 2016. The place of advocacy in actualizing strong regulatory systems in Africa was also realized as the missing link between policy formulation and implementation at continental and regional to level. The workshop highlighted that more such capacity building sessions need to be conducted to ensure that various health stakeholders within the AU member states are speaking one language on advocating for regulatory harmonization. Regulatory approvals are essential in ensuring safety and efficacy of health products. However, across Africa's, regulatory processes differ from country to country resulting in delays in introduction and scale-up. That is why as a member of the civil society, I am excited to see the collaboration between PATH and AUDA-NEPAD geared towards building the capacity of key stakeholders like me to grow in their understanding of the health benefits of regulatory harmonization and its potential impact," said Charles Kilel, Community Engagement Officer at KEMRI/WRP, and a participant at the workshop.

AUDA-NEPAD in collaboration with PATH has proposed to embark on a partnership to support capacity building and build knowledge around the need for regulatory strengthening, and to ensure that Africa member states adopt as a whole or in part, the AU model law towards ensuring we maximize on our regulatory resources. These efforts will catalyze achievement of good manufacturing plan for Africa, PMPA, and subsequently Africa's agenda 2063. To achieve these goals, strong partnerships, through concerted efforts must be built within health sector players and other key players who influence, benefit from or are affected by the outcomes of such efforts.

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Critical Milestone for Regional Harmonised Registration Procedure in West Africa

The West African Medicines Regulatory Harmonization Project was initiated in 2015 as part of collaboration between the West African Health Organization (WAHO) and the West African Economic and Monetary Union (WAEMU), which served as joint Secretariat for the project. A Steering Committee composed of heads of national medicines regulatory agencies (NMRAs) was established to provide oversight and direction to the project with technical support provided by seven (7) technical working groups. The African Medicines Regulatory Harmonization partners namely; African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD); Bill and Melinda Gates Foundation, the World Bank and the World Health Organization (WHO) provide the needed support in the coordination, policy and political advocacy; fiduciary oversight and technical backstopping; respectively.

The 7th WA-MRH Steering Committee during its meeting held in Dakar, Senegal from 9-10 December 2019, registered key milestones achieved under the project since its inception. To date; the region has in place 133 guidelines, standard operating procedures (SOPs) and manuals to guide the operation of the initiative including a harmonized common technical document (CTD) for registration of medical products. 329 staff of NMRAs have been trained in the use of CTD, Dossier Evaluation Procedures, Corrective Action and Preventive Action (CAPA), Good Manufacturing Practices (GMP), Quality Management Systems (QMS) and Quality Control (QC). Staff of 105 Local Pharmaceutical Manufacturers have also been trained to use the CTD.

The NMRAs include the Food and Drug Authority of Ghana (FDA Ghana), the National Agency for Food and Drug Administration and Control (NAFDAC) Nigeria, Liberia medicines and Health Products Regulatory Authority (LMHRA), Pharmacy Board of Sierra Leone, and Medicines Control Authority (MCA) of The Gambia. The 10 other NMRAs are currently strengthening their Quality Management Systems to obtain the ISO 9001: 2015. Ten (10) NMRAs out of the fifteen (15) in the region are fully autonomous, namely Benin, Burkina Faso, Cabo Verde, Cote d'Ivoire, The Gambia, Ghana, Guiné-Bissau, Liberia, Nigeria and Sierra Leone. WAHO has committed to continue its advocacy to ensure the others become autonomous.

The region strives to reduce further the current standard timelines for country registrations that range from 171 to 261 days. The Director General of WAHO, Prof Stanley Okolo, who also serves as Co-Chair of the WA-MRH Steering Committee challenged all the NMRAs during the meeting, "to accelerate availability of safe and efficacious medicines to the population by ensuring that the regional collaborative procedure timeline is reduced to 59 days, as doing so should ensure rapid access to medicines for the population" he said.

The SC meeting was Co-Chaired by the Head of NMRA of Niger; Dr Sani Barira Dan Nouhou, based on the rules of procedure for the Economic Community of West African States (ECOWAS). The SC meeting also took note of the significant milestone reached by the project through the harmonized medicines registration process for the region. A decision was made by the 6th WA-MRH SC in July 2019 to select the NMRAs of Burkina Faso, Ghana, and Nigeria as the lead NMRAs for the take-off of the single regional harmonized process, with the NMRA of Ghana (Food & Drug Admin Ghana) coordinating. That landmark decision creates a favourable enabling environment for medicines manufacturers wishing to access a market population of nearly 380 million, and represents the first visible practical step in the primary objective of the ECOWAS's plan to locally manufacture most of the drugs needs of the region.

In line with the decision of the 6th WA-MRH SC, WAHO in its capacity as the WA-MRH Secretariat invited Expressions of Interest from pharmaceutical manufacturers wishing to use the joint regional procedure for registering medical products in seven (7) therapeutic areas. The response has been particularly encouraging with 13 medical products' applications received from five pharmaceutical manufacturers. Three products have been screened by the lead coordinating NMRA, and assessed and reviewed by the Expert Working Group for medicines evaluation while the other 10 applications are currently being screened by the lead coordinating NMRA. While the region is not exempt from 70 % medicines imports dependency as is the case for the rest of the African continent, the joint regional procedure for registration of medicines provides a window of opportunity to change the narrative. The procedure provides guarantee to increased availability in the market of quality medicines hence contributing to achievement of Sustainable Development Goal 3, particularly SDG 3.8 and 3.9b regarding "access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all". The regional procedure will further facilitate research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries", a process that can only be helped with pharmaceutical industrialisation in the region.

SADC Focal Persons Trained on the AMRH Indicators and Data Collection Tool.

One of the African Union Development Agency (AUDA-NEPAD Agency's core mandate is to monitor and evaluate the implementation of priority programmes and projects to provide evidence -based feedback that enable programme and project managers to base their decision on performance and results. African Union AU) Member States and Regional Economic Commissions (RECs) are making significant efforts to strengthen and harmonise the medicines regulatory systems by implementing the Medicines Regulatory Harmonization (MRH) Projects under the AMRH initiative. However, they are faced with resource and capacity constraints and lack of harmonized tools that meet international standards to collect, collate, analyse and report on AMRH programme results. These are compounded by failure to leverage on existing M&E tools already developed and used by better-resourced regulatory authorities and the World Health Organization (WHO).

The AMRH Initiative and its overall leadership acknowledges the importance of research, monitoring and evaluating of MRH projects in the RECs and Member States and therefore initiated a process to develop an M&E tool for the programme in 2016. In 2017, the tool was duly drafted and later piloted in the East African Community Medicines Regulatory Harmonization Project (EAC-MRH). The tool has been reviewed by the AMRH Steering Committee.

In order to operationalise this tool, it was critical that M&E Focal Persons be nominated at both the National Medicines Regulatory Agency (NMRA) and regional economic community (REC) levels. The nominated person (s) are responsible for routine data collection including proper collection and verification of data for accuracy and quality assurance. In addition, they ensure data credibility, reliability and authenticity through internal interrogation of data before sharing with external audience.

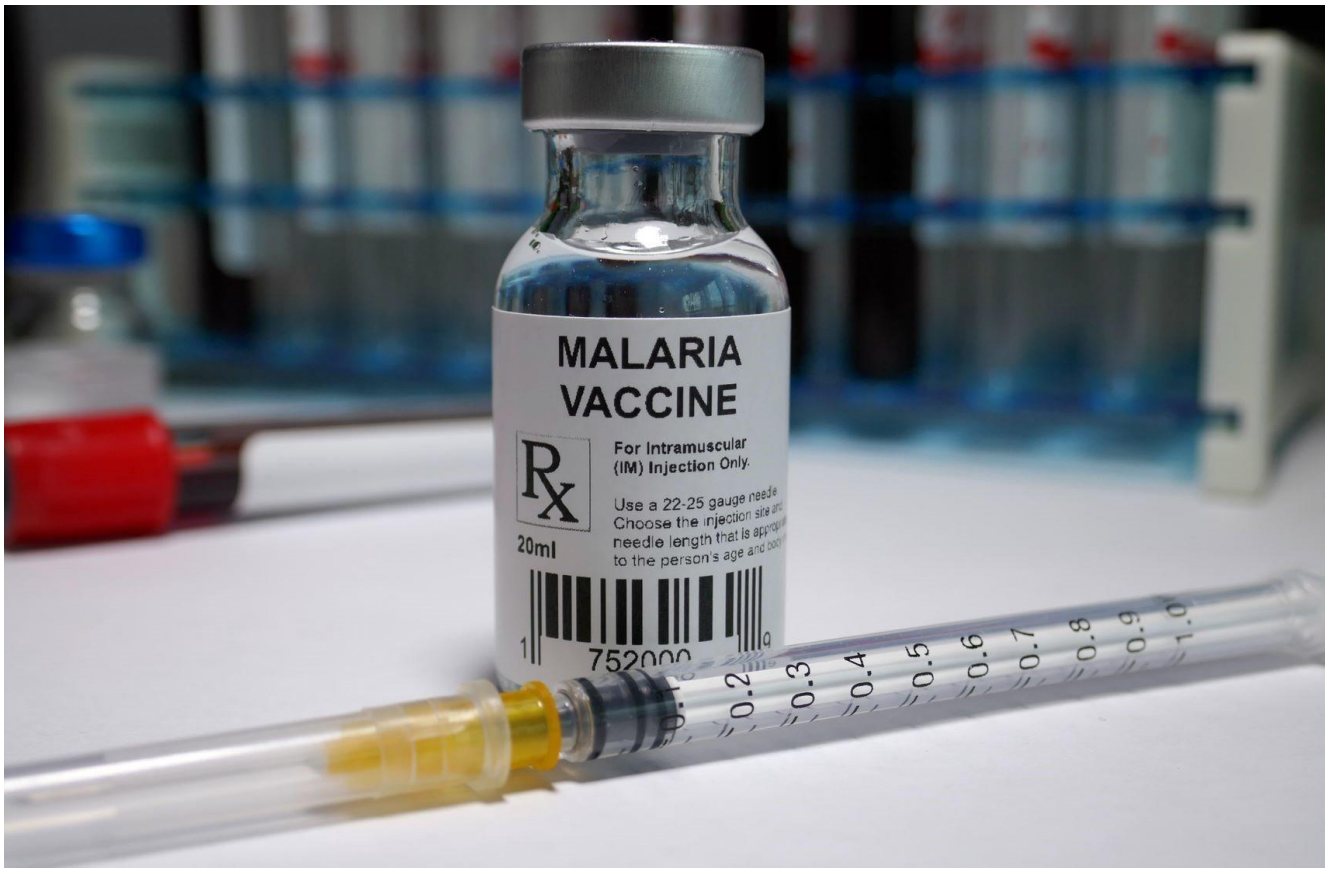
For the SADC MRH Project, 14 M&E Focal Persons have been nominated in the SADC region. AUDA-NEPAD has organised a virtual meeting to sensitize these Focal persons on the AMRH M&E tool and Terms of Reference of the M&E Focal points in August 2019. To further raise awareness on the AMRH M&E indicators, a data collection workshop took place in November 2019 in Johannesburg, South Africa. The following are the outputs of this workshop;

1) Data collected for the SADC-MRH project.

2) Community of Practice created amongst SADC-MRH M&E Focal Persons.

3) More awareness and understanding of AMRH indicators created.

A similar exercise was conducted with the ECOWAS M&E Focal points in August 2019. Approved data from NMRAs are being submitted to the SADC and ECOWAS MRH Secretariats and AUDA. EAC and IGAD have also had a Virtual meeting on sensitisation of the AMRH indicators and Data Collection tool as well. Approved Data for EAC and IGAD is expected to be available before the end of March 2020. ECCAS/OCEAC, are in the process of nominating M&E focal points. Approved data will further be analysed, and report made available to NMRAs and RECs.



AfCFTA a Window of Opportunity for Pharmaceutical Manufacturing Plan For Africa

A high - level stakeholders meeting to discuss an African Continental Free Trade Area (AfCFTA) anchored Pharmaceutical Project took place on 21 November 2019 in Addis Ababa, Ethiopia.

The meeting was attended by the Hon, Minister of Health of Seychelles, Mr, Jean Paul Adam, The Executive Secretary of IGAD, Mr. Mahboub Maliim and Mr. Stephen Karingi the Officer in charge of the UNECA as well as representatives from UNAIDs, United Nations Population Fund (UNFPA), International Finance Corporation (IFC), Islamic Bank , World Health Organization (WHO), United Nations Conference on Trade and Development (UNCTAD) and UNDCO. The objective of the meeting was to gain support from member states (the small island countries), IGAD secretariat and private sector for the adoption of a pharma project that's anchored within the AfCFTA, and to ensure alignment with the Pharmaceutical Manufacturing Plan For Africa (PMPA) objectives and ongoing initiatives.

The meeting adopted a roadmap of next steps towards the implementation of a pooled procurement pharmaceutical initiative which seeks to improve access to quality affordable maternal newborn and child health commodities and medicines to small island developing countries and the horn of Africa. The African Union Development Agency (AUDA-NEPAD) shared the progress of the implementation of the PMPA and its planned work packages on the status of ratification of AMA Treaty, and appreciated the stakeholders' commitment to support accelerated ratification of the AMA treaty and establishment of the Fund for African Pharmaceutical sector Development (FAP-D).

AUDA-NEPAD Head of Health Margareth Ndomondo Sigonda in her keynote address stated that AfCFTA creates a window of opportunity to realize the vision of the PMPA which is to develop a competitive and enduring integrated pharmaceutical manufacturing industry in Africa able to respond to the continent's need for a secure quality, affordable, accessible, safe and efficacious medicines.

SADC Concludes Draft Guideline to Harmonise Product Information and Labelling Requirements

Southern African Development Community (SADC), as a region has harmonized medicines registration guidelines in the common technical document (CTD) format that were approved in January 2015. The harmonization of product information and labelling requirements within the region has been outstanding. Harmonizing regulatory standards to create one regional market and mutual recognition is one of the strategies included in the draft Strategy on Regional Manufacturing of Essential Medicines and Health Commodities (2016-2020), which supports the pharmaceutical component in the SADC Industrialization Strategy and Roadmap 2015 – 2063. Moreover, this supports the priority areas of creating an enabling regulatory environment and strengthening medicines regulatory capacity in the approved SADC Pharmaceutical Business Plan 2015 – 2019.

To this end SADC member states subject matter experts and other key stakeholders held a Regional Stakeholder Consultative Meeting on SADC Product Information and Labelling Guideline in Cape Town, South Africa on 9-11 December 2019. The consultative meeting followed a workshop with industry and regulators that was held as an initial step in developing a regional guideline on product information and labelling. This fulfils the need for stakeholder engagement in drafting regulatory guidelines.

The initial engagement resulted in drafting instructions for the product information and labelling guideline that were approved by the SADC regulators forum. Subsequently, these drafting instructions were utilized for formulating the current draft guideline.

The consultative meeting considered all comments received in writing prior to the meeting and orally during the meeting. Through group discussions and plenary submissions several recommendations were made on several topics:

- Accessibility of the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC): it was recommended that all products should have a PIL; OTC products should be exempt from having an SmPC; pharmacist initiated products should have a PIL and SmPC; these should be available with the product and through other means; bulk products should have 1 PIL and 1 SmPC.

- Guidance on font size, type and line spacing for PIL and SmPC: It was recommended that EU guidance should be used for SmPC and PIL as well as product label.

- QR Code and Serialization: It was recommended that in the guideline instead of mentioning specifically the use of QR Code and/or GS 1, the guideline should mention that there should be a label/"software" that allows for the tracking and tracing of the product throughout the supply chain. In addition, it can be stated that the label/" software" should provide access to the PIL and SmPC. It was also noted that a roadmap needs to be developed that will assist local manufacturers comply with this recommendation.

- Recommended Implementation Model for Guideline once finalized: There was a discussion that the implementation of the guideline should be through the SADC variation guideline which is under development. On the implementation timeline it was proposed that all SADC member states should approve implementation of the guideline within a period of 6 -12 months following adoption by SADC. It was also proposed that industry should implement the guideline 12-18 months following approval for implementation by the last country in SADC.

IS a Continental Information Management System for Medicines Regulation in Africa feasible?

The AMRH Initiative has initiated a process to develop a continental Information Management System (IMS) for increased reliance, work and information sharing among NMRAs, RECs and in the MRH programmes. A key objective of the MRH programme is for RECs to ensure that Member States NMRAs have a common IMS for regulation of medicines that can communicate to each other and linked to the REC Secretariat.

Current IMS challenges in Africa include; inadequate information technology (IT) capacity within some regulatory agencies to develop; maintain proper IMS, poor IT platforms, infrastructure, legal frameworks; poor record keeping.

So why develop a continental IMS?

Currently, the AMRH continental scientific Technical Committees (AVAREF, AMQF, ABRF and AMDF) are in the process of developing online platforms for work and information sharing highlighting the need for electronic data management at continental level. It is also envisaged that both continental and regional IMS solutions would enable e- submission of dossiers by industry and reviews, validation etc by regulators including assessments and inspection. To avoid duplication and in order to facilitate decision making and information sharing amongst Member States and stakeholders, an integrated R-IMS will have to be developed for the continent. Information sharing will enhance the gains of medicines regulatory harmonization and accelerate the authorization of new medical products on the Africa continent.

A fully functional regional integration of systems requires a regional platform to enable work and information sharing among the member states. The absence of this platform has been identified as a major gap and a bottleneck to achieving this objective. Furthermore, most RECs have initiated or in the process of developing a regional IMS to facilitate information sharing. While this presents an opportunity to achieving the objective, there is need to ensure that the various regional IMS systems are developed such that they are interoperable and can facilitate information sharing among countries in the region and across countries in all RECs on the continent.

It is against this backdrop that the African Union Development Agency (AUDA – NEPAD) is establishing a Continental Technical Committee on IMS to develop and coordinate the implementation of a roadmap for the development of a continental platform for Regulatory Information Management System. The first meeting of the RIMS Technical Committee was held in Accra, Ghana in November 2019. Key outcomes of this meeting were;

⇒ To facilitate the development of a continental IMS that will control the flow of quality data and effectively manage compliance.
⇒ Contribute to the sharing of data to progress productivity outcome within the NMRA`s Strategic Agenda. Motivation to build paper free Organizations.
⇒ Ensure the implementation of Continental Regulatory Information Management System (RIMS) in NRA`S & RECs.
⇒ Identification of Prototype RIMS Requirements;
⇒ Develop necessary documentation for the implementation of continental system.
⇒ Review existing systems and design a Continental regulatory information management system (Continental RIMS).

Current system challenges faced by some NMRA`s on IMS were identified and recommendations to address these challenges were agreed. Key recommendations include;

◊ Developing an IMS system that will allow direct data exchanged with REC system through Application Programming Interface (API).
◊ Development of a temporary web portal to share regulatory information at the continental level (Pilot Project).
◊ Constant training of users both internal and external on the use of the Continental System.
◊ To build capacity among member states.
◊ To submit Product Application online by Stakeholders.
◊ The IMS system should be interoperable with REC IMS systems.
◊ The need to have data harmonization around the continent.

In the meantime, the experts agreed that the AMRH Web site is to be developed and used as a temporal step to share key documents as the development of Continental RIMS progresses.

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