As Africa embarks on the trajectory of economic transformation, the pharmaceutical manufacturing industry is promising creation of jobs, economic benefits, improved social and human outcomes as well as stimulating other economic activities across its complex value chain. A vibrant pharmaceutical manufacturing sector in Africa has the potential to contribute to improved access to medicines, better public health outcomes and economic growth.

The 55th Decision of the AU {Assembly / AU/Dec.55(IV)} taken during the Abuja Summit in January 2005 requested the AU Commission to develop a Pharmaceutical Manufacturing Plan for Africa (PMPA) within the framework of the New Partnership for Africa’s Development NEPAD. Subsequently; the African Union Ministers of Health made a decision in 2007 to develop a PMPA business Plan which was later endorsed by the 19th AU Assembly complemented by AU Roadmap on Shared Responsibility and Global solidarity for the AIDS, TB and Malaria response in Africa {Assembly AU/ Dec.442 (XIX)} which among others, emphasizes the need to accelerate and strengthen regional medicines regulatory harmonization initiatives and lay foundations for a single African regulatory agency.

In recognition of the need for a conducive regulatory environment for local production and trade in pharmaceuticals on the continent, the African Medicines Regulatory Harmonization (AMRH) Initiative was established since 2009, under the coordination and leadership of the NEPAD Agency. Through the AMRH Initiative, the East African Community (EAC) and the Economic Community of West African States (ECOWAS) in collaboration with the West African Economic and Monetary Union (WAEMU) have successfully launched the Medicines Regulatory Harmonisation (MRH) programme in March 2012 and February 2015 respectively. The Southern African Development Community (SADC) is in the process to start implementation of the MRH Project in 2015. Progress is also being made in brokering collaboration between Economic Community of Central African States (ECCAS) and the Organization for Coordination of the Fight Against Endemic Diseases in Central Africa (OCEAC) on implementation of AMRH Programme in the Central African region.

AMRH is aimed at increasing access to quality and safe essential medicines to the African populations, by accelerating and deepening medicines regulatory harmonization on the continent.
NEPAD's role in establishment of African Medicines Agency (cont.)

All these efforts provide a foundation for establishment of the regional and continental medicines regulatory agencies. While the East African Community has embarked on the process of drafting a bill for establishment of the East Africa Community Medicines and Food Safety Commission (EACMFSC), the West African region is next on the line.

Furthermore, at the First African Ministers of Health meeting jointly convened by the African Union and World Health Organisation (WHO) held in Luanda, Angola, from 10 to 17 April 2014; the milestones towards the establishment of the African Medicines Agency (AMA) were endorsed. The Ministers committed themselves to prioritize investment for regulatory capacity development; to pursue the efforts towards convergence and harmonization of medical products regulation in RECs and to allocate adequate resources for AMA. They further endorsed the establishment of the AMA Task Team to spearhead the process.

More recently in January 2015, the Executive Council Decision, [EX.CL/Dec.857(XXVI)] endorsed the Milestones for the establishment of a single medicines regulatory agency in Africa within the context of the African Medicines Regulatory Harmonization Programme, which is part of the framework of the PMPA.

The overall aim of PMPA is to provide a mechanism for improving health outcomes through access to medical products and technologies to the African population while strengthening regulatory systems; boosting research and development; promoting intra-African trade and supporting the local pharmaceutical industry. The Council requested the African Union Commission (AUC), the NEPAD Agency and the World Health Organization (WHO) in collaboration with other stakeholders to elaborate AMA’s legal and institutional framework including financial implications for its establishment.

The AUC, NEPAD Agency and WHO as a joint Secretariat for establishment of AMA is responsible for coordination of the work of the AMA Task Team which was established in November 2014. The first AMA Task Team meeting held in Addis Ababa, Ethiopia on 25-26 November 2014 brought together more than 30 experts who reviewed among others; the regulatory pathway in the African context and harmonization approaches and the Luanda Decision on AMA. Specifically, the Task Team reviewed the key milestones towards AMA establishment, the Terms of Reference of the task team to facilitate the establishment of AMA and adopted a 4-year Plan of Action (2015-2018) for the task team to be supported by AUC, NEPAD Agency and WHO joint Secretariat.

NEPAD Agency is supporting the development of the legal and institutional framework for AMA and is responsible for stakeholders’ consultation process as part of the 4 year plan agreed by the AMA Task Team.
Promoting best practice in pharmacovigilance (PhV) is increasingly becoming crucial to ensure medicines safety and protection of public health. Adverse drug events (ADEs) from poor product quality, adverse drug reactions (ADRs), and medication errors contribute significantly to morbidity and mortality in developing countries. The lack of relevant policy and regulations in Sub-Saharan Africa (SSA) reflects fundamental limitations for enforcing medicine safety monitoring. Of the 46 SSA countries, 74% have a PhV center or unit with a clear mandate and formal organizational structure, 39% have national PhV guidelines, 39% have a safety advisory committee, and 45% have a drug information service. However, country coordination of all stakeholders is minimal - only 28% have a platform or strategy to coordinate PhV activities at the national level.

An analysis of pharmacovigilance activities in 55 low and middle-income countries conducted in collaboration with the World Health Organization showed several challenges in implementing PhV, the major challenges being lack of training and stable funding.

Harmonizing pharmacovigilance systems is currently an evolving phase of the African Medicines Regulatory Harmonisation (AMRH) Programme. By design the AMRH Initiative works through Regional Economic Communities (RECs) to advance the harmonisation of requirements for approval of medicines. The initial phase of the programme focused on harmonising requirements for medicines registration. There is increasing demand by RECs and countries to identify and promote harmonization activities for clinical trials oversight as well as pharmacovigilance.

NEPAD Agency with the support of USAID/SIAPS convened a meeting of the Regional Centres of Regulatory Excellence (RCOREs) in Pharmacovigilance in Accra, Ghana from 14th to 15th May 2015. The main objective of the meeting was to align the efforts of the two RCOREs in Pharmacovigilance; namely, Pharmacy and Poisons Board of Kenya and the WHO Collaborating Centre for Pharmacovigilance and its consortium of partners with the work that is currently being undertaken by WHO, Uppsala Monitoring Centre (UMC), USAID/SIAPS and other partners in the African region. The meeting also sought to bring all capacity building efforts together to avoid duplication and improve synergies among technical partners and national authorities. It also reviewed progress made in attaining the vision of national functional pharmacovigilance systems in Africa.

Mapping of the existing PV infrastructure in Africa including the trained personnel, training facilities and institutions, tools, methods and expertise will be conducted to bring all capacity building efforts together to avoid duplication and improve synergies among technical partners and national authorities.
Ministers of Health approve the finalisation of the AU Model Law on Medical Products Regulation

The African Union (AU) Specialised Technical Committee (STC) on Health, Population and Drug Control has approved the finalization of the AU Model Law on Medical Products Regulation for presentation to the STC on Justice and Legal Affairs for technical review and endorsement. The STC, which is a meeting of Ministers responsible for Health, Population and Drug Control, approved the draft Model Law in April 2015. The Model Law has been developed to fill the legislative gap in AU Member States that hinder effective regulation of medical products and prevent harmonisation of these regulations at the regional level. The Model Law will provide a comprehensive guide to member states and RECs in their endeavour to harmonise medicines regulation and provide an enabling medical products regulatory environment. The Model Law was drafted with input from a Continental Technical Working Group on Policy and Regulatory Reforms, comprising legal experts and regulators representing Regional Economic Community (REC) and African Medicines Regulatory Harmonisation (AMRH) Partners.

NEPAD Agency, African Union Commission and Pan African Parliament (PAP) in collaboration with partners convened regional stakeholder consultations in East, South, Central, West and North Africa. The consultations which brought together stakeholders from Ministries of Health; National Medicines Regulatory Agencies; Ministries responsible for Customs, Trade and Industry; Ministries responsible for Justice, National and Regional Parliamentary Committees responsible for Health; pharmaceutical industry associations; Civil Society Organizations and International interest groups were aimed at ensuring a transparent and participatory process in the preparation of the Model Law by enabling key stakeholders in the AU member states and partners to discuss and provide feedback on the draft.

The next step for this progressive Model Law is to present it to the Ministers of Justice and Legal Affairs for technical review and endorsement in November 2015 for eventual submission to the AU structures for adoption.

Following designation of the Regional Centres of Regulatory Excellence (RCOREs) in May 2014, NEPAD Agency undertook to develop a Guide for RCOREs with a view to provide essential information on designation, the requirement to maintain the designated status and performance assessment based on agreed set of criteria and activities. The overall goal is to have a unified standard for running the RCOREs Programme.

In order to address the human resources limitation in the regulation of medicinal products and technologies for human use in sub-Saharan Africa, European and Developing Countries Clinical Trials Partnership (EDCTP) has developed a fellowship programme that aims at developing skills and expertise of regulatory personnel as well as their subsequent retention within the National Regulatory Authorities (NRAs). The EDCTP fellowship scheme focuses on strengthening human resources for regulation of medicinal products and technologies for human use, through long-term training duration period (2-3 years) and mentorship of sub-Saharan African regulators. The scheme targets postgraduates with an emphasis on staff who commit to work with their hosting national regulatory authorities for at least five years.

The ultimate goal of the EDCTP scheme is to increase African regulatory personnel competences and expertise in regulatory pathway activities related.
Facilitating funding and technical support for RCOREs (cont.)

to clinical trials and registration of medicinal products and technologies for human use. This is planned to be undertaken through the RCOREs designated by NEPAD Agency under the African Medicines Regulatory Harmonisation (AMRH) Initiative.

A consultation meeting was convened by NEPAD Agency and EDCTP in February 2015 to bring together designated RCOREs, other potential funders and technical AMRH partners to develop a mechanism for supporting regulatory capacity development programmes within the NEPAD Agency RCOREs Framework. An operational plan was developed to facilitate the RCOREs readiness in accessing EDCTP funding. NEPAD Agency and EDCTP also undertook to create awareness amongst all African NMRAs, Ethics Committees and RCOREs on the upcoming EDCTP planned call on ethics and regulatory capacities.

More information on the EDCTP call can be found at http://www.edctp.org/funding-opportunities/calls


The NEPAD Agency in collaboration with the WHO AFRO and EMRO is pleased to announce the 2nd Biennial Scientific Conference on Medicines Regulation in Africa, to take place from 1-3 December 2016, in Tunis, Tunisia.

The initiative to organise this conference is borne of the necessity for African regulatory authorities, researchers, academic institutions and industry to work together to address some of the salient issues affecting their areas of delivery of medical products and technologies to the public. It is undisputable fact that most of the African pharmaceutical markets are poorly regulated which consequently puts public health at risk and erodes public confidence on health care delivery systems and specifically on the quality and safety of medicines they use. In recognition of this problem, various Governments and partners have embarked on regulatory capacity building programmes albeit in uncoordinated fashion. In addition, various Regional Economic Communities (RECs) in Africa have embarked on medicines regulation harmonisation initiatives with a view to increase patients’ access to quality, safe and efficacious essential medicines through capacity building programmes and streamlining regulatory processes and procedures.

The goal of the conference is to enable policy makers, regulators, industry, academia, research organisations and scientists to network and exchange information on innovative approaches for pharmaceutical sector development in Africa.

Register to attend the conference by emailing Nthabiseng@nepadst.org
Since 2011 the African Union Commission Department of Social Affairs (AUC-DSA) has developed a number of new initiatives to enhance the health programme. The NEPAD Planning and Coordinating Agency (NPCA) as the technical arm of the African Union plays an important role in providing support for the effective implementation of these programme activities.

The second meeting between AUC-DSA and NEPAD Science, Technology and Innovation Hub (NSTIH) was thus organised from 27 to 28 February 2015 in Nairobi, Kenya at the margins of AU’s meeting to review various health policies, strategies and frameworks due to expire at the end of 2015. The meeting reviewed the progress made on the previous joint activities such as implementation of Pharmaceutical Manufacturing Plan for Africa (PMPA); the AU Roadmap on Shared Responsibility and Global Solidarity in Response to HIV/AIDS, TB and Malaria; and the establishment of African Medicines Agency (AMA) as an offshoot of the African Medicines Regulatory harmonization (AMRH) Initiative.

The key outcome of the two days meeting was the development of a Roadmap for implementation of AUC-DSA and NEPAD joint activities on health. This road map includes an identification of the following areas of collaboration on: review of the African Health Strategy, implementation of the PMPA, support the establishment of AMA and development of its legal framework in terms of the provisions of the AU constitutive act; and the African Centre for Disease Control (CDC).

Other agreed areas of work include support in Health Research Data and Statistics and collaboration with African Peer Review Mechanism (APRM), clinical trial oversight, documentation of best practices progress in local production and AIDS Watch Africa (AWA).
UPCOMING EVENTS

July

- EAC Joint Review Mission by AMRH Partners, 6-7 July, Arusha, Tanzania
- Review of the EAC Regional Project Proposal on the strengthening and harmonization Pharmacovigilance and Post marketing surveillance systems, 13-15 July, Dar es Salaam, Tanzania
- Signing of a collaboration framework on implementation of AMRH in Central African Region, 15-17 July, Libreville, Gabon
- International Conference on fight against Ebola, 20-21 July, Malabo, Equatorial Guinea
- SADC Heads of NMRAs Medicines Regulatory Harmonisation meeting, 21-24 July, Victoria Falls, Zimbabwe
- EAC MRH Steering Committee Meeting, 29-31 July, Kampala, Uganda

AUGUST

- Regional Conference on Harmonisation & Standardisation of pharmaceutical quality assurance systems in IGAD States, 3-5 August, Addis Ababa, Ethiopia
- Africa Health Strategy Meeting, 6-7 August, Durban, South Africa
- NPCA-AUC-WHO Retreat, 10-11 August, Durban, South Africa
- RECs meeting on AMRH implementation toolkit, 17-18 August, Pretoria, South Africa
- Update to Pan African Parliament on AU Model Law, 17-21 August, Midrand, South Africa

SEPTEMBER

- 1st EAC Manufacturing Summit, 1-2 September, Dar es Salaam, Tanzania
- OCEAC meeting on Counterfeit Medicines in Central Africa, 8-10 September, Yaounde, Cameroon
- AMRH M&E electronic Pilot meeting, 14-16 September, Dar es Salaam, Tanzania
Calling for your valued Opinions and Feedback...

In order to further address your interests and preferences for an information-sharing tool, we are requesting that you kindly send us your feedback by emailing amrh@nepad.org. We look forward to your thoughts.

AMRH CONTACTS

**AMRH**
Tel: (office) +27 841 2833/4979/3294
Email: amrh@nepad.org

**NEPAD Agency**
Prof. Aggrey Ambali
Advisor NSTIH
Tel (office): +27-12-841-3653
Email: Aggrey@nepadst.org

Mrs. Margareth Ndomondo-Sigonda
AMRH Programme Coordinator
Tel (office): +27-12-841-2980
Email: Mnsigonda@nepadst.org

**BMGF**
Dr. Vincent Ahonkhai
Senior Advisor
Tel (office): +1-206-709-3715
Email: vincent.ahonkhai@gatesfoundation.org

**WHO - HQ**
Dr Samuel Azatyan
Manager, Medicines Regulatory Support Programme,
Quality Assurance and Safety: Essential Medicines and Pharmaceutical Policies
Tel: (office) +41-22-791-3528
Email: azatyan@who.int

**WHO - EMRO**
Dr. Marthe Everard
Coordinator
Health System Development
Email: everardm@who.int

**WHO - AFRO**
Dr Jean-Baptiste Nikiema
Regional Advisor, Essential Medicines, Health Systems Services.
Tel: +242 050403726
Email: nikiema@afro.who.int

Dr. Ossy MJ Kasilo
Coordinator, Essential Medicines and Health Technologies
Regional Advisor for Traditional Medicine Health Systems and Services Cluster,
Tel: +242 055 384 162
Email: kasiloo@who.int

**World Bank**
Dr. Andreas Seiter
Senior Health Specialist
Pharmaceuticals Health, Nutrition and Population
Tel: (office) +1-202-473-3629
Email: aseter@worldbank.org

Mr. Apollo Muhairwe
Operations Officer
Tel: +25641432409/414230094
Email: amuhairwe@worldbank.org

**CHAI**
Ms. Meredith C Moore
Country Support Manager, Drug Access Team
Tel: (Office) +1 617 784 5198
Email: mmoore@clintonhealthaccess.org

MORE INFORMATION ON THE AMRH PROGRAMME

For more information on the AMRH Programme activities; Frequently Asked Questions; Partners; AMRH useful links and older editions of the AMRH Newsletter, please visit the AMRH website: www.amrh.org.

© copyright. All rights reserved. This newsletter may be freely quoted and translated in part or in full provided authorization is received from the AMRH. Credit must be given to the AMRH if the newsletter is quoted in part or in full.