AMRH NEWSLETTER

Quarter 4: October - December 2016

African Medicines Regulatory Harmonization

New horizon for strengthening medicines regulatory harmonization in Africa a "dead cert"

Establishment of African Medicines Agency (AMA) beckons

ABOUT AMRH
African Medicines Regulatory Harmonization (AMRH) Programme

The African Medicines Regulatory Harmonization (AMRH) initiative is a programme of the African Union (AU) implemented as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA). Under the theme "Strengthening of Health Systems for Equity and Development in Africa", the AU Conference of Health Ministers (AUCHM) in April 2007 responded to the AU Assembly Decision 55 (Assembly/AU/Dec.55 (IV) taken during the Abuja Summit in January 2005 which mandated the African Union Commission (AUC) to develop the PMPA within the framework of the NEPAD. The programme started in 2009 as a response to addressing challenges faced by National Medicine Regulatory Authorities (NMRAs) in Africa. These challenges include; weak or non-coherent legislative frameworks, redundant/duplicative processes, sluggish medicine registration processes and subsequent delayed decision, inefficiency and limited technical capacity, among others. The work of AMRH is guided by three focus areas: policy alignment, regional integration and harmonization, and human and institutional capacity development.

The programme works in collaboration with the AUC, Pan-African Parliament (PAP), World Health Organization (WHO), Bill and Melinda Gates Foundation, World Bank (WB), UK Department for International Development (DFID) and US Government-PEPFAR and Global Alliance for Vaccines and Immunization (GAVI). The AMRH Strategic Plan defines the strategic direction for the medicines harmonization agenda in Africa and provides direction to advance the development of the pharmaceutical sector and provides guidance in monitoring and evaluation.

Our Vision in Africa
African people have access to essential medical products and technologies

Our Mission in Africa
Provide leadership in creating an enabling regulatory environment for pharmaceutical sector development in Africa

Content - Highlights

Draft EAC Protocol on Joint Post Marketing Surveillance (PMS) of antibiotics updated

The East African Community (EAC) Medicines Regulatory Harmonization (MRH) project successfully reviewed and updated the draft protocol on Joint Post Marketing Surveillance (PMS) of antibiotics in the region. This happened during a meeting of the Expert Working Group (EWG) on Pharmacovigilance and PMS that took place in Zanzibar, Tanzania on 21st and 22nd October 2016.

The aim of the meeting of the EWG was to harmonize the regional PMS protocol for antibiotics. The meeting also developed a PMS strategic plan and the policy, legal and regulatory framework for PMS in the EAC region. During the opening remarks, the Chairperson Ms. Alambo Mssusa welcomed the participants and encouraged them as experts to focus more on the key areas that shall guide the region and partners to arrive at the set goals of the project.

NEPAD Agency representative, Paul Tanui noted that the introduction of the PMS regulatory function and new development partners withinthe remit of the MRH project in the EAC region is an important development that will be used for learning and serve as a best practice. World Health Organization (WHO) representative, Dr Clive Ondari noted that PMS is getting very complex and there is a lot of concern over falsification of medicines and vaccines. United States Pharmacopoeia (USP) representative, Dr Mustapha Hajjou, also echoed these words.

"PMS IS A CHALLENGING REGULATORY FUNCTION THAT IS COSTLY AND INVOLVES MORE THAN ONE DEPARTMENT. HENCE, THERE IS NEED FOR THE INVOLVEMENT OF MANY EXPERTS", DR HAJJOU SAID.

The meeting also reviewed and updated the 2016-17 annual PMS work plan, which is ending on 30th June 2017 to include activities covering the 2017/18 period. The EWG encouraged the participants to use the work plan and implement activities on time.

Kenya leading the way in the use of Notepads to strengthen PMS

The meeting was attended by representatives from the NMRAs of Burundi, Uganda, Tanzania, Kenya, and Rwanda and officials from the Ministry, EAC Secretariat, and development partner officials from WHO, NEPAD Agency, World Bank (WB) and USP/PQM and German National Metrology Institute (PTB).

As the lead country on PMS, Kenya made a presentation during the meeting to highlight its PMS activities including the use of Minilabs to strengthen PMS. The presentation highlighted both successes and challenges. For example, the successful use of the electronic application using tablets in Kenya.

This electronic application using tablets is currently being used to manage the inspection activities and was recognized as a potential tool useful for PMS activities as it covered a range of initial information that is very crucial in the areas of PMS. Based on the Kenya PMS experience, the meeting made recommendations to address some of the common challenges as follows:

i. The Experts' Working Group and Partner States NMRAs to pilot a joint PMS exercise that will focus on antibiotics next year.

ii. That partner states should always share information from PMS activities especially information that resulted in regulatory action;

iii. That Partner States NMRAs and development partners commit adequate resources to support implementation of PMS activities in the region

iv. That Partner States NMRAs to explore the possibility of using the electronic tool and tablets for PMS activities

v. That EAC Secretariat and the German Metrological Institute proceed to procure tablets for Partner States NMRA;

Central Africa develop 2017 Work Plan to implement Common Pharmaceutical Plan & Medicines Regulatory Harmonization Project

CEMAC/OCEAC MRH Project Steering Committee meeting in Douala, Cameroon

NEPAD Agency has successfully supported the Economic and Monetary Community of Central Africa (CEMAC) Member States, through the Organization for the Fight Against Endemic Diseases (OCEAC) to develop a 2017 Action Plan that identifies priority areas and activities for the effective implementation of the Common Pharmaceutical Plan (CPP) and the Medicines Regulatory Harmonization (MRH) Project in Central Africa. The Terms of Reference (ToRs) of the Project Steering Committee were also reviewed and validated.

The Project Steering Committee is responsible for providing technical oversight of the CPP and MRH Project, as well as monitoring the implementation of the agreed Action Plan. This took place during the same meeting in Doula, Cameroon from 16 – 17 November, 2016 made possible through financial support from NEPAD Agency.

Officially opening the meeting on behalf of the Minister of Public Health in Cameroon, Dr Meguieze Loudang Marlise welcomed the participants and wished them a pleasant stay. She encouraged participants to work tirelessly to ensure effective implementation of the CPP as it will help to improve public health in our communities.

"All these efforts contribute to African people accessing safe, quality and efficacious medicines and the work of this meeting is laying a solid foundation to achieving this task", Dr Marlise lamented.

Chimwemwe Chamdimba from NEPAD Agency thanked the government of Cameroon for hosting this meeting and emphasized the importance of the African Medicines Regulatory Harmonization (AMRH) Took Kit in regulatory systems strengthening and harmonization processes in Africa.

The AMRH Tool Kit was adopted in December 2015 at the African Medicines Regulatory Conference in Addis Ababa, Ethiopia. It is aimed at guiding Regional Economic Communities (RECs) and Regional Organizations (ROs)

in setting up and reviewing MRH Projects at regional level and is a pinnacle to ensuring long term coherence of these projects.

"NEPAD Agency is aware of the good work that CEMAC is already doing in the harmonization of pharmaceutical policies in the region through the CPP. There is still room to scale up activities and ensure access to safe and quality medicines is achieved", Mrs. Chamdimba said.

She further stated that the CEMAC regional harmonization efforts are in line with African Union (AU) continental policies and frameworks. Hence, there is need to align these efforts to the AMRH initiative and draw lessons from similar MRH Projects being implemented in other regions i.e. East African Community (EAC), Southern African Development Community (SADC) and Economic Community of West African States (ECOWAS) through the West African Health Organization (WAHO).

Representing the Secretary General of OCEAC, Dr Aime Djitafo Fah reminded the participants that the CPP was adopted in June 2013 in the CEMAC region but there are some deficiencies in terms of implementation across different Member States.

This meeting is an opportunity to strategically structure the implementation of the CPP in each CEMAC Member State and ensure harmonization.

The meeting was attended by Heads of National Medicines Regulatory Authorities (NMRAs), Heads of Directorates of Pharmacy and Medicines of the CEMAC, representatives from the OCEAC Secretariat - Harmonization of National Pharmaceutical Policies (HPPN), NEPAD Agency and other stakeholders.

A total of 152 products considered since inception of ZAZIBONA

The seventh meeting of the ZAZIBONA Heads of Agencies (HoA), which met in Gaborone, Botswana on 23 and 24 November 2016 heard that a total of 152 products have been considered since the inception of ZAZIBONA. The 7th Heads of Agencies (HoA) meeting was convened to receive updates on the ZAZIBONA Assessment activities, Good Manufacturing Practice (GMP) inspection and feedback from the July 2016 Southern African Development Community (SADC) Regulators Forum, among other activities.

During the meeting, it was announced that a total of 50 products were reviewed in 2016 surpassing the target of 32. In addition, a total of 152 products have been considered since the start of ZAZIBONA, with 50 products recommended for registration, while 30 have been recommended for rejection. And 10 products have been withdrawn. The table below shows the products finalized by country since the inception of ZAZIBONA:

Country	Products submitted	Products assessed by country	Products registered by country	Products rejected by country	Total products finalized per country
Zambia	107	31	39	4	43
Zimbabwe	100	50	41	9	50
Botswana	101	31	42	0	42
Namibia	106	32	39	0	39

Building on these activities, the 13th meeting of Assessors agreed to hold a total of four (4) assessment sessions in 2017 in February, June, September and November while the Heads of Agencies will meet twice in June and November 2017.

ZAZIBONA Membership increasing – South Africa and Swaziland join

After observing the good work that ZAZIBONA has been doing since inception, South Africa decided to join the ZAZIBONA initiative and is currently an active member. The figures for South Africa will be recorded as finalization of products is being done. Since South Africa became an active member, the products considered have not yet to been finalized. In addition, Swaziland has also expressed interest and submitted their documents as non-active members of the ZAZIBONA initiative.

The ZAZIBONA Heads of Agencies (HoA) also agreed to develop an Advocacy Strategy by March 2017 and this will include how other SADC Member States can utilize information from ZAZIBONA. It was also agreed that information on ZAZIBONA would now be prominently featured on the Southern African Development Community Medicines Regulatory Harmonization (SADC-MRH) webpage. In addition, active members were encouraged to post ZAZIBONA information on their respective national websites.

ZAZIBONA GMP Inspectorate conducts 8 inspections in 2016

A total of 8 inspections were planned by ZAZIBONA in 2016 but by the time of this meeting a total of 5 facilities had been inspected and these included one facility in Zimbabwe and four in India. World Health Organization (WHO) also facilitated for one GCP inspection in December 2016.

During the meeting, it was reported that a comprehensive QMS system shall be put in place. As part of this inspectorate QMS, the Proposed Public Inspection Report (PIR), Inspectorate Quality Manual, Competency Matrix, and CAPA template, and 11 initial SOPs will be done. The ZAZIBONA also agreed to identify a pool of competence inspectors because competency assessments shall now be a function of inspection and report writing skills, and will be tied to various dosage forms.

In order to strengthen GMP inspection, capacity building activities will continue outside the routine inspections. ZAZIBONA inspectors have effectively utilized Skype to hold regular discussions and interact between themselves. The inspectors are now considering having WebEx facilities to improve communication.

SADC Ministers approve MRH-Project Phase II Work Plan and Budget

9 applications for registration of medicinal products assessed at 4th EAC-MRH Joint Dossier Assessment

Seven (7) applicants representing different pharmaceutical corporations submitted a total of nine (9) applications in different therapeutic categories that came up for assessment at the 4th East African Community Medicines Regulatory Harmonization (EAC-MRH) Project Joint Dossier Assessment. This meeting took place in Entebbe, Uganda from 5th to 8th December 2016 and the therapeutic categories considered for assessment included antibiotics, anti-cancer agents, anti-hypertensives, ARVs, NSAIDs, ant-TB products, and local antiseptics.

Out of the nine (9) applications submitted for registration of medicinal products, five (5) were new product applications and the remaining four (4) represented queries. After consideration at the EAC-MRH Joint Dossier Assessment, one (1) query response was successful and the product was recommended for registration, while six (6) applications were recommended for additional information. In addition, one (1) application is awaiting the Stringent Regulatory Authorities (SRAs) collaborative procedure final report and another application was partially reviewed awaiting feedback from the applicant.

The product applications all contained different active ingredients that included Cetuximab, Levofloxacin, Paracetamol, Chlorhexidine Digluconate, Amoxicillin dispersible, Sorafenib Tosylate, Valsartan, Abacavir sulfate and Bedaquiline. The Joint Assessment initiative of the EAC-MRH Project aims at increasing access to medicines, enhancing capacity, work sharing and confidence building among national medicines regulatory authorities. It also serves as a foundation for future mutual recognition of regulatory decisions among National Medicines Regulatory Authorities (NMRAs) of EAC Partner States.

Among other action points for 2017, it was agreed during the meeting that EAC should explore possibilities of engaging the Swiss Agency for Therapeutic Products (Swissmedic) in assisting the EAC to build capacity in clinical assessments of products and develop an abridged assessment procedure for products approved by SRAs. It was also recommended that there should be an abbreviated review of products that are domestically manufactured in EAC and already registered in some of the member states, using a risk based tool. This will contribute to improving the registration of locally manufactured products by fast-tracking the process.

Registration of locally manufactured products will improve

Experts from EAC NMRAs, World Health Organization (WHO), Swissmedic, and officials from the EAC Secretariat attended the meeting. Observers from the following organizations were also present: WHO, United States Pharmacopoeia (USO) Promoting the quality of medicines (PQM) Program and Ministry of Labour Social Protection and East African Affairs of the Republic of Kenya.

Interim Technical Working Group (TWG) after a succesful meeting in Johannesburg, South Africa.

Fund for African Pharmaceutical Development (FAP-D) a gateway to financial sustainability of Pharmaceutical sector in Africa

The inaugural meeting of the Interim Technical Working Group (TWG) to establish the Fund for African Pharmaceutical Development (FAP-D) held productive deliberations aimed at developing an international sustainable financing mechanism for supporting the growth and development of the African Pharmaceutical Sector within the framework of the Pharmaceutical Manufacturing Plan for Africa (PMPA). This First FAP-D TWG meeting was hosted at the NEPAD Agency Head Office in Johannesburg, South Africa on 6th and 7th December 2016.

The objective of FAP-D is to finance the development of the pharmaceutical manufacturing sector in Africa. The fund, as managed by a dedicated agency, is proposed to provide low interest loans and grants to private sector pharmaceutical companies toward improvement of their facilities to achieve international standards of good manufacturing practices (GMP), for building capacity to meet the needs of the continent and as working capital. The agency will also facilitate consultancy and technical services to recipients of FAP-D support and monitor use of funds to ensure effectiveness.

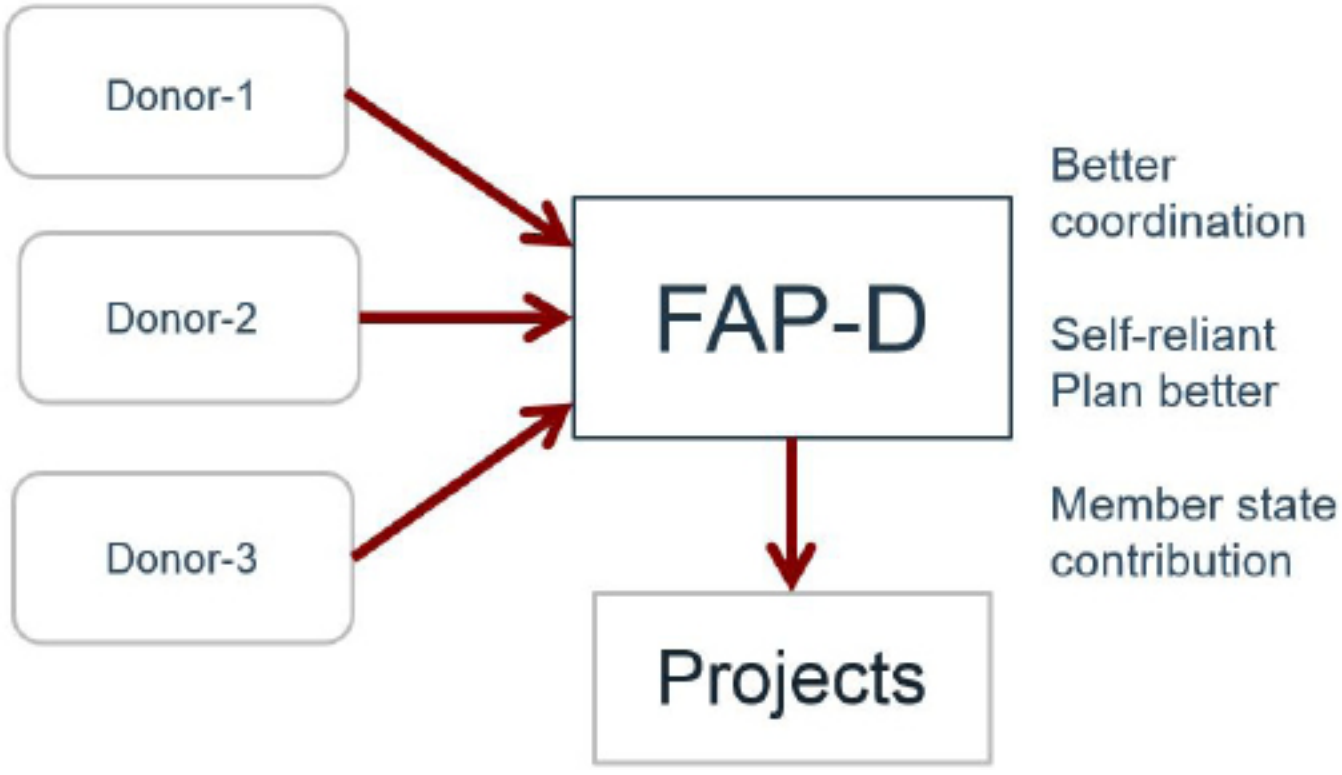
During the opening remarks, AUC Head of Social Affairs Dr. Margaret KY Agama-Anyetei reminded

members of the Interim Technical Working Group (TWG) that the proposal to establish a financing mechanism comes at a time when Leaders of the African Union have adopted the first 10 year implementation plan for Agenda 2063, thus setting the continent on a path towards 'the Africa we want'. She highlighted some challenges on sustainable financing that are currently facing Africa that FAP-D will address: (i) how African pharmaceutical firms can finance local production of medicines cost-effectively? (ii) how the cost of finance can be reduced? (iii) how financial institutions and firms can build finance capabilities to cost-effectively fund local production? (iv) the role played by medicines procurement in priming industrial development and innovation? (v) and how policy frameworks can support sustainable funding of local pharmaceutical production?

Other than financing, FAP-D shall also provide technical advisory services, conduct monitoring and evaluation and provide advise on national medicine policies in Africa. The AUC also presented the proposed roamap for the next steps of the FAP-D TWG and these include ffinalizing the draft AU Position Statement on FAP-D and drafting the Terms of Reference for the TWG on FAP-D and schedule a 2nd Meeting of the TWG on FAP-D on the margins of the Specialized Technical Committee on Health Population and Drug Control (STC-HPDC). The objective of holding a meeting at the 2nd meeting of the TWG on FAP-D at the STC-HPDC is twofold: to ddiscuss and adopt the TWG terms of reference and present the Position Paper to STC on HPDC for consideration and decision.

Members of the Interim TWG on financing mechanism of the PMPA attended the meeting and these are comprised of the African Union Commission (AUC), NEPAD Agency, African Development Bank (AFDB), Federation of African Pharmaceutical Manufacturers Associations (FAPMA), United Nations Industrial Development Organization (UNIDO), United States Pharmacopoeia (USP) and Innogen Institute of the University of Edinburgh.

FAP-D Proposed Financing Model



Legal and Institutional Frameworks for establishing African Medicines Agency (AMA) ready for stakeholder consultation

The Legal and Institutional Frameworks for the establishment of the African Medicines Agency (AMA) are now ready for intensive stakeholder consultation after being reviewed during the Third AMA Task Team meeting in Cape Town, South Africa. This meeting took place on 3rd December 2016 at the margins of the International Conference for Drug Regulatory Authorities (ICDRA).

The aim of the meeting was to discuss and consider the draft Institutional framework, Legal Framework and Business Plan for the establishment of AMA. This is in line with the Task Team's four (4) year Action Plan in the context of the commitment on the key milestones for the establishment AMA as agreed by the Ministers of Health at the first joint African Union (AU) and World Health Organization (WHO) Ministerial Conference held in Luanda in April 2014.

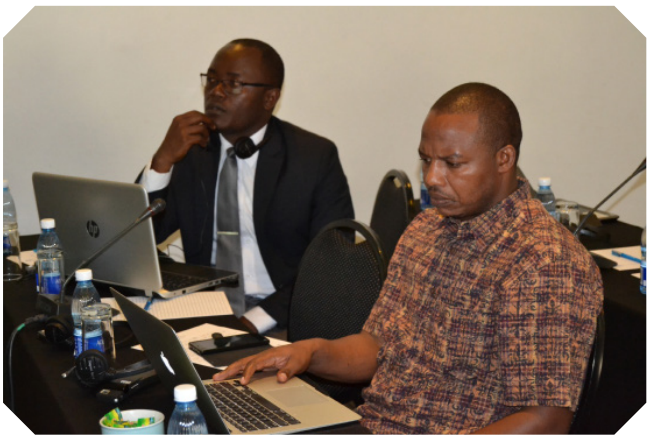
African Union Commission (AUC) Director of Social Affairs, Ambassador Dr Olawale Maiyegun and WHO Group Lead, Capacity Building and Harmonization Support Samvel Azatyan, AUC representatives including legal affairs, NEPAD representatives, members of the AMA Joint Secretariat, and representatives of Regional Economic Communities (RECs) from Africa attended the meeting.

It was agreed during the meeting that the documents should undergo in-depth deliberation across relevant stakeholders before the start of the review by the AU decision making organs such as the Specialized Technical Committee (STC) on Health Population and Drug Control (HPDC), STC on Legal and Justice Affairs and the Executive Council. It was agreed that a broad stakeholders' consultation meeting be convened in Johannesburg, South Africa from 13-17 February, 2017. Thereafter, submit the status report on AMA for generating a

(L-R) AUC Head of Social Affairs Dr. Margaret KY Agama-Anyetei, Chairperson of AMA TAsk Team, Ms. Gugu Mahlangu, and AUC Health Policy Officer, Dr Janet Byaruhanda during the AMA meeting

(L-R) AUC Director of Social Affairs, Ambassador Dr Olawale Maiyegun and WHO Group Lead, Capacity Development and Harmonization Support, Samvel Azatyan at the AMA meeting in Cape Town, South Africa

Consultatnts were also in attendance at the AMA meeting



RECs were also represented at the AMA meeting

decision of the STC on HPDC in March 2017 and request that the draft Legal and Institutional framework documents on the establishment of AMA be brought to them for deliberation at a special session of the STC on HPDC at the margins of the World Health Assembly (WHA) in Geneva. It was also agreed that the AMA Task Team shall also submit the draft AMA Legal and Institutional Frameworks to the special session of STC HPDC at the margins of the WHA in May 2017.

In addition, the AMA Task Team will submit the Draft Treaty for the establishment of AMA as part of the report to the Assembly of HOS via the Executive Council and generate a decision requesting the STC on Legal and Justice Affairs to review the Draft Treaty July 2017.

After this activity, the Draft Treaty for the establishment of AMA will be considered by the STC on Legal and Justice Affairs sometime in October or November 2017. The projected launch of the AMA is earmarked for 2018. Once established AMA will not replace national or regional existing structures but will have a mandate to oversee and provide guidance to ensure regulatory harmonization is achieved.

East African Community (EAC) to launch regional medicines regulation Information Management System (IMS) in January 2017

The East African Community (EAC) Secretariat has earmarked January 2017 for the launch of a comprehensive and functional regional medicines regulation Information Management System (IMS). This regional IMS is developed under the EAC Medicines Regulatory Harmonization (MRH) project and development of the IMS infrastructure is done in collaboration with TradeMark East Africa. IMS is important in supporting information sharing through integrated Information Management between National Medicines Regulatory Authorities (NMRAs) within the EAC region.

GMP applications in EAC are now processed online. An example here from the website of Uganda

IMS is a key component in the implementation of the EAC-MRH project and EAC Secretariat has already completed the development of key modules to make this process a success. Stakeholders can now use the IMS portals of the NMRAs to make product applications, GMP applications, import and export applications, premise applications, as well as access information concerning finance. All the EAC Partner States now have a national portal where this information is uploaded and applications are accepted electronically. The IMS infrastructure will not only make it possible for NMRAs to share information but also contribute to digitalizing medicines regulation Standard Operating Procedures that will cut on delays and speed up application processes to ensure that medical products reach the end users on time. The IMS infrastructure will also make the NMRAs more efficient in terms of the application processing time and it will be easy to track these applications online. EAC Partner States are at different levels in the implementation of IMS. However, all IMS activities are coordinated by EAC Secretariat to ensure that all the countries achieve this target. EAC Secretariat is supporting the Partner States by providing servers for the IMS portals to the NMRAs and these will be linked to the EAC Secretariat. The Pharmacy and Poisons Board of Kenya (PPB) and the Tanzania Food and Drugs Authority (TFDA) are the two most advanced countries in the implementation of IMS. The IMS in both countries has gone live internally and externally and the web portals for import and export of products (foods, medicines, medical devices and cosmetics) have also gone live and are functioning effectively.

The two countries are now looking at opportunities to link their IMS infrastructure with other private industry and state players Uganda, Rwanda and Burundi have also embraced IMS infrastructure and so far the user acceptance tests and the migration of old data in to the new system have been completed successfully.

17th Pre-ICDRA discuss NEPAD and AMRH partner accomplishments in medicines regulatory harmonization

The 17th Pre-International Conference of Drug Regulatory Authorities (Pre-ICDRA) opened on Sunday, November 27th, 2016 with a prominent discussion of NEPAD Agency and African Medicines Regulatory Harmonization (AMRH) partner accomplishments in the coordination of medicines regulatory harmonization in Africa. Participants from across the world hailed NEPAD and the AMRH partners accomplishments and discussed how to scale up these activities, as well as sharing best practices and lessons learnt to continue on this excellent route to developing mechanisms that promote African people's access to quality, efficacious and safe medical products and technologies.

This represents the first time ever that an ICDRA Conference is taking place in Africa and was officially opened by representatives of the organizers, World Health Organization (WHO) Head of Regulation of Medicines and other Health Technologies (RHT), Emer Cooke and Director General of Health in South Africa, Malebona Precious Matsotso. Emer Cooke and Malebona Precious Matsotso emphasized the need for enhanced convergence and the importance of collaboration between private and public sector, as well as other stakeholders in efforts to respond to and serve the needs of patients.

NEPAD Agency Head of Health Programmes, Margareth Ndomondo-Sigonda during a panel discussion at the Pre-ICDRA

Mrs. Emer Cooke said that this year's Pre-ICDRA is a unique opportunity for every stakeholder to contribute to the on-going work in line with the Conference theme of "patients are waiting: how regulators collectively make a difference: strengthening regulatory systems through convergence, reliance and networks". Mrs. Malebona Precious Matsotso reminded the drug regulators that it is their responsibility to serve public interest to ensure that medical products are safe, efficacious and meet acceptable international standards on quality.

"After this conference, we must leave here with a resolve that those who need quality medical products can have access, and access that is appropriate", Mrs. Matsotso said.

She further said that there is need for appropriate regulation and the agenda on how this will be achieved has to be set during this conference by exchanging ideas and brainstorming on innovative ways that will make a difference in people's lives. During the Pre-ICDRA, NEPAD Agency Head of Health Programme, Margareth Ndomondo-Sigonda made an erudite presentation of the accomplishments of the African Medicines Regulatory Harmonization (AMRH) initiative since inception in 2009 to date and also highlighted some challenges and mapped out the way forward.

Mrs. Sigonda also reminded participants of the importance of promoting local manufacturing of pharmaceuticals in Africa within the framework of the African Union (AU) Pharmaceutical Manufacturing Plan for Africa (PMPA).

"Local production of pharmaceuticals in Africa will only be achieved when African countries create an enabling regulatory environment that can attract investment", Mrs Sigonda said.

The discussions of the 17th Pre-ICDRA conference contributed to shaping discussions of the main ICDRA conference that took place from 29th November to 02nd December 2016 to regulators only.

Participants from different organizations, regional bodies and national representatives exchange ideas and knowledge during a discussion at the Pre-ICDRA

EAC regional Pharmacovigilance baseline survey to be finalized in early 2017

The East African Community (EAC) Partner States agreed at the 7th meeting of the Expert Working Group on Pharmacovigilance and Post Marketing Surveillance (PMS) to conduct a consolidated EAC Pharmacovigilance system baseline survey in early 2017. As a result, each EAC Partner State was requested to submit a work plan for this baseline survey in readiness for data collection. The baseline survey will be completed in January 2017, and the data cleaning process and report writing will follow immediately after the information is available.

After the report has been finalized with the participation of EAC Partner States, it will be validated at a Face-To-Face meeting planned for March 2017. Thereafter, the consolidated report will then be disseminated to the general public at the end of March 2017. In order to reflect this activity and others that have been planned, the schedule of activities for the EWG on Pharmacovigilance was revised and updated.

This meeting took place in Zanzibar, Tanzania from 17th to 19th October 2016. It was heard during the meeting that this activity was planned for implementation in 2016 but due to unforeseen circumstances it was not executed and new dates have now been set for implementation in the first quarter of 2017.

During the same meeting, the draft EAC harmonized Pharmacovigilance guidelines were also presented and discussed by the participants. This also fits well in to the African Medicines Regulatory Harmonization Initiative (AMRH) goal to increase access to quality, safe and effective medicines in Africa. Since inception, the scope of the AMRH has expanded to include the harmonization of regulatory functions including Pharmacovigilance and PMS. Discussions of these guidelines shall continue and once the document has been finalized, it will be presented to the Steering Committee meeting at a date to be announced by EAC Secretariat.

The meeting was attended by representatives from the National Medicines Regulatory Authorities (NMRAs) of Burundi, Uganda, Tanzania, Kenya, and Rwanda and officials from the Ministry, EAC Secretariat, and development partner officials from World Health Organization (WHO), NEPAD Agency, World Bank (WB), United States Pharmacopoeia (USP) and German National Metrology Institute (PTB).

Drug safety is important in the control of adverse effects of pharmaceutical products

Third Scientific Conference on Medical Products Regulation to sustain momentum for regulatory systems strengthening and harmonization in Africa

The Organizing Committee of the Biennial Scientific Conference on Medical Products Regulation in Africa have made tremendous progress in preparations for the hosting of the Third Biennial Scientific Conference which is slated for Abidjan, Ivory Coast between 27th to 29th November 2017. The Organizing Committee is comprised of the NEPAD Agency, African Union Commission (AUC), World Health Organization and International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and representatives from all the Regional Economic Communities (RECs) in Africa.

The theme for this year´s Scientific Conference is ***Sustaining the Momentum for Regulatory Harmonization in Africa*** and its overall goal is to review progress and deliberate on actions for sustaining the momentum for regulatory systems strengthening and harmonization in Africa for addressing diseases that affect the continent. The Scientific Conference on Medical Products Regulation in Africa is a biennial event that provides a platform for stakeholders to reflect on the progress in regulatory systems in Africa and map the trajectory moving forward.

The inaugural 1st Biennial Scientific Conference was held in Johannesburg, South Africa in 2013 with the theme "Building Partnerships for Sustainable Capacity Development in Medicines Regulation in Africa". This was followed by the 2nd Biennial Conference which took place in 2015 in Addis Ababa, Ethiopia under the theme: "Regulatory Systems Strengthening for Advancing Research, Innovation and Local Pharmaceutical Production in Africa".

The information gathered during this event will feed in to the subsequent meeting of the Drug Regulators Forum.

New Development: Submission of Abstracts and Registration will be online-based

The Organizing Committee members held a successful meeting on 08th December 2016 to kick-start the preparations for this event and this was followed by another meeting on the 12th of January 2017. During the meetings, the Organizing Committee reviewed the Draft Concept Note, Terms of Reference (ToRs) for the Organizing Committee, budget, Call for Abstracts, as well as content for the Call to announce the event to the general public and the registration form.

It was also agreed that the registration process for the Third Scientific Conference shall be done online in 2017, including the submission of abstracts. As a result, an online platform is currently being developed and will include many features regarding registration, submission of abstracts and information about the event and key documents such as the programme, concept note, pictures, logistics information, to mention a few.

The registration of participants for the Third Scientific Conference on Medical Products Regulation in Africa shall commence in January 2017 and a link to the registration portal will be shared with all the stakeholders across the world.

The deadline for Call for Abstracts will also be in May 2017 to give reviewers ample time to provide feedback and the authors to submit full papers. Therefore, authors are highly encouraged to submit their abstracts early.

Upcoming Events

- AMRH Strategy workshop with key partners and Regional Economic Communities (RECs): Johannesburg, South Africa, 8 – 9 February 2017
- AMA stakeholder consultation meeting: Johannesburg, South Africa, 12 – 18 February 2017
- 2nd meeting of the Technical Coordinating and Steering Committees of the African Vaccine Regulatory Forum (AVAREF): Zanzibar, Tanzania, 23 – 24 February 2017
- Documentation of EAC-MRH project achievements since inception: EAC member States, 05 – 18 March 2017
- EAC Pharmacovigilance Multi-Stakeholders and Donors Round-Table Resource Mobilization and Task Sharing Meeting: Nairobi, Kenya, 20 - 22 March, 2017
- Regional training of EAC communication focal persons: Arusha, Tanzania, 27 – 31 March 2017
- Third Scientific Conference on Medical Products Regulation in Africa: Abidjan, Ivory Coast, 27 – 29 November 2017

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