AMRH Newsletter

Quarter 1: January - March 2018

AFRICAN MEDICINES REGULATORY HARMONIZATION

2nd STEERING COMMITTEE MEETING

African Union

NEPAD
TRANSFORMING AFRICA

World Health Organization

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AMRH Partnership Platform - a game changer in the medicines regulatory space in Africa

PEI set to improve supply of vaccines, blood & blood products in Africa

ZAZIBONA recommends 4 new products for registration

A total of four (4) new products have been recommended for registration through the ZAZIBONA Initiative in four therapeutic classes namely; analgesic, antibiotics, antineoplastic and blood thinning agent. This took place at the 18th ZAZIBONA Assessment Session in Gaborone, Botswana from 26th February to 03rd March 2018.

During the session a total of 9 new products were discussed, 4 recommended for registration and 0 were recommended for rejection. A total of 21 additional data was also considered during this meeting. This positive outcome of the 18th joint assessment session builds upon the work of the ZAZIBONA collaborative procedures from 2017.

ZAZIBONA helps to improve access to medicines for SADC Member States by reducing the timelines for registration through joint collaborative processes. One of the biggest challenges to public health in the SADC region is access to medicines with the medicines registration processes taking up to three years in some countries. ZAZIBONA was established to address this challenge and also conduct joint Good Manufacturing Practise (GMP) inspections to reduce the workload and improve technical improved capacity to conduct inspections.

Since its establishment, the ZAZIBONA Initiative has grown with more countries from the Southern Africa Development Community (SADC) joining and expressing interest to participate in the process. South Africa, Angola, Democratic Republic of Congo (DRC) and Seychelles have now joined.

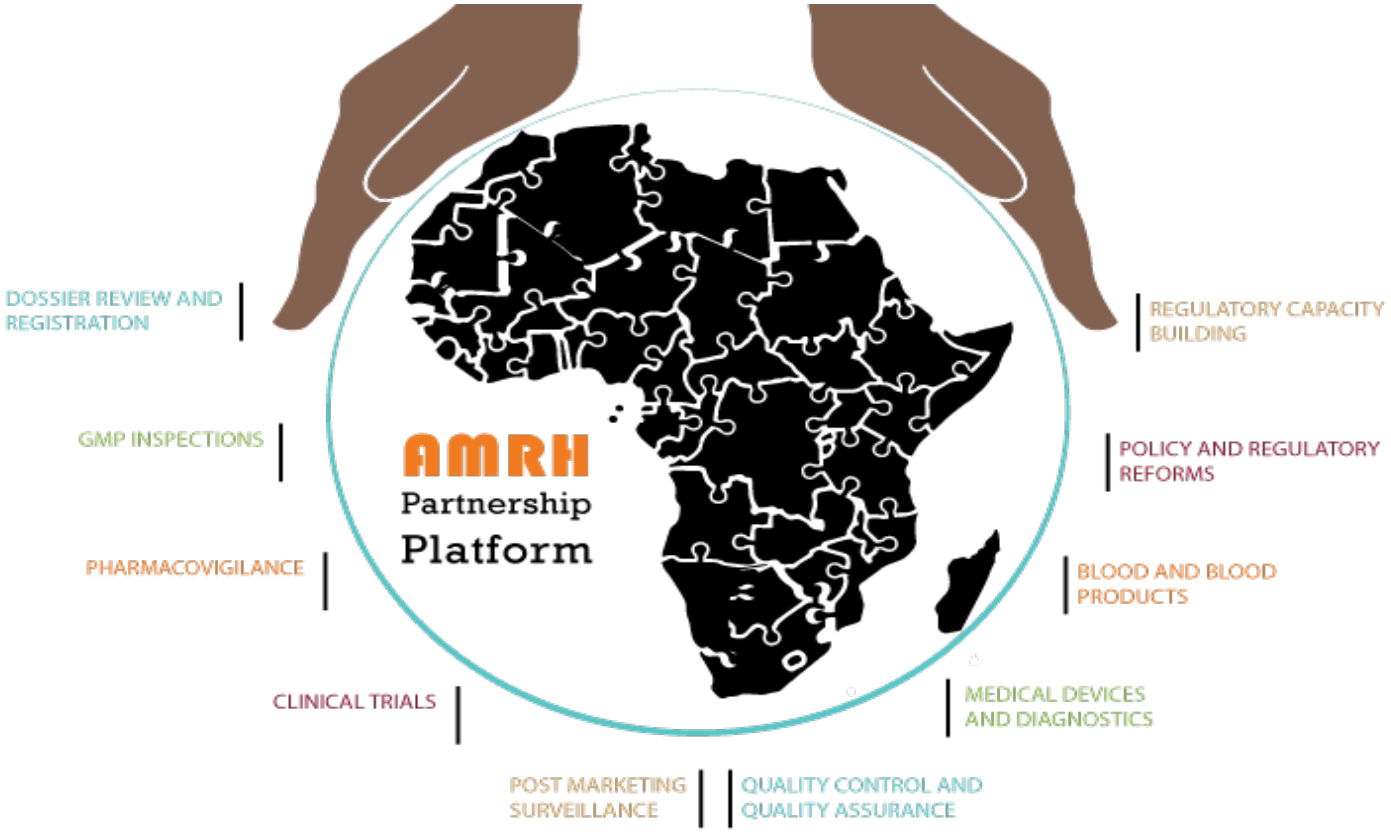
A total of 3 manufacturing sites located in India have been inspected between 06 – 18 March 2018 by inspectors from Namibia, South Africa and Zimbabwe. The scope for two of the sites was sterile product manufacturing while the third site was oral solid dosage forms. Interim Inspection Reports have been availed to the manufacturing sites and upon receipt of the Final Inspection Reports, the manufacturers will be given 60 days to respond to the observations made through presentation of Corrective Actions and Preventive Actions (CAPA).

In addition, desk reviews to consider the approval of two sites, one in India and another in Cyprus are also nearing conclusion. The inspections and desk reviews will be concluded in a virtual meeting of inspectors from all active countries. The meeting will discuss the findings and the CAPAs, and finalise recommendations for approval or rejection of the manufacturing sites.

AMRH Partnership Platform - a game changer in the medicines regulatory space

Many international and local partners and stakeholders working in the medicines regulatory systems strengthening and harmonization space in Africa have for a long time worked in silos and lacked coordination especially at the continental level. Technical capacity and human resources end up being spread thinly, impact is limited with no proper mechanism to promote exchange of information and learning. As a result, sustainability of these parallel interventions is now a challenge and it has become difficult to take stock on who is doing what, where are they focusing their work, who are they targeting and what their interests are in Africa.

These pertinent questions are now a subject of critical reflection if we are to attain the common agenda of improving access to safe, efficacious and good quality essential medicines in Africa. This obviously common shared vision is threatened by the lack of coordination in this stream of work in Africa. Hence, NEPAD Agency in collaboration with the World Health Organization (WHO) and other partners have agreed on establishing a coordination mechanism that will not only oversee medicines regulatory systems strengthening and harmonization work in Africa but also coordinate various partners by establishing a single platform. This platform is vital in efforts aimed towards avoiding duplication of work, ensure optimal utilization of resources and establish consensus on priority areas of intervention (continued on next page)...



Africa ups fight against fake drugs

The prevalence of Sub-standard and Falsified (SF) medical products in Africa remains a major challenge. To help address this public health issue, the NEPAD Agency, the United States Pharmacopeia (USP), Tanzania Food and Drugs Authority (TFDA), and the World health Organization (WHO) organized a meeting of public health and regulatory experts from across the African continent to establish the African Medicines Quality Forum (AMQF) to

The African Medicines Regulatory Harmonization (AMRH) Partnership Platform is the answer to ensuring that there is effective coordination and management of different partners and stakeholders in the medicines regulatory systems strengthening and harmonization space in Africa. The AMRH PP will be established as an African chapter of the global WHO Coalition of Interested Parties (WHO-CIP). The AMRH-PP shall serve African interests and priorities in the medicines regulatory space in alignment with global WHO priorities. The AMRH-PP shall provide coordination and direction to partners and stakeholders working in Africa in addressing the many challenges in the continent's public health sector.

The AMRH-PP comes at the right time when AMRH and African Vaccines Regulatory Forum (AVAREF) have agreed in principle to harmonize and align the initiatives. The AMRH-PP will leverage harmonization and alignment of AMRH and AVAREF in Africa to build on the proven operating model of working through the National Medicines Regulatory Authorities (NMRAs) and Ethics Committees (ECs), Regional Economic Communities (RECs) and Regional Health Organisations (RHOs), and the African Union Commission (AUC) to address gaps in regulatory capacity at national, regional and continental levels.

A call for Expression of Interest (EOI) to join the AMRH-PP was circulated to all partners and stakeholders in early February 2018 with a deadline to submit by 15th March 2018. Over 50 applications have been received and the First AMRH-PP meeting of existing partners will be held in Johannesburg, South Africa on 11th April 2018.

oversee the quality, safety and efficacy of medicines. The meeting took place in Dar es Salaam, Tanzania from February 12 – 15, 2018.

The AMQF's mandate is to advance the agenda of strengthening and harmonizing national quality control laboratories and post marketing surveillance activities to help protect African patients from substandard and falsified medicines. During the event, which was opened by Tanzania's Deputy Minister of Health, Community Development, Gender, Elderly and Children, Dr. Faustine Ndugulile, participants helped shape the proposed mandate and work plan for the AMQF and associated Technical Working Group (TWG). The AMQF will be formed under the African Medicines Regulatory Harmonization initiative (AMRH) that is coordinated by NEPAD Agency.

Emanating from the Network of Official Medicines Control laboratories (NOMCoL), whose inception was funded by the United States Agency for International Development (USAID) and supported by USP, the AMQF represents a significant advancement towards elevating and expanding the critical role national quality control laboratories play in ensuring access to high quality medicines.

"Transforming NOMCOL-SSA into the African Medicines Quality Forum is a critical step for alignment with the African Medicines Regulatory Harmonisation Initiative and a foundation for establishing the African Medicines Agency," said Margareth Ndomondo-Sigonda – Head of Health Programmes at NEPAD Agency.

Participants at the workshop also discussed approaches to strengthen post marketing surveillance. Building on WHO guidance and best practices presented by leaders from Europe's EDQM and Brazil's ANVISA, participants reviewed and discussed applications for a risk-based post marketing surveillance approach developed by the Promoting the

Quality of Medicines (PQM) program, a USAID-funded and USP-implemented initiative dedicated to strengthening quality assurance systems in over 20 countries worldwide.

The proposal for the official formation of the AMQF and associated TWG will be brought forward for formal endorsement by the Steering Committee (SC) on Regulatory Systems Strengthening and Harmonization Initiatives in Africa this April. Additionally, the work plan developed at the Tanzania meeting will be shared with the steering committee; key components will include advancing post marketing surveillance activities in Africa through improved coordination, information sharing and application of risk-based approaches as well as a plan to advance the capabilities of African national quality control laboratories towards achieving globally-recognized quality standards.

EAC REVIEWS 12 NEW PRODUCTS, 3 QUERY RESPONSES

The 8th session of the East African Community (EAC) Medicines Regulatory Harmonization (MRH) joint dossier assessment has reviewed assessment reports of twelve (12) new applications, three (3) query responses and 1 variation. The review looked at product ranges from anti-cancers, Anti-Retroviral (ARVs), antifungals, products to treat urinary incontinence, urinary tract infections, pneumonia, and conjunctivitis among others and the meeting took place in Entebbe, Uganda from 19 – 24 March 2018.

Two of the query responses were recommended for approval. 1 variation for extension of shelf life was approved, 2 products were recommended for registration subject to submission of controlled specifications for the drug substance, drug product and container closure systems and 11 products required additional information. The EAC region is the pioneer in joint dossier assessments in Africa and has paved the way for other regions to also implement similar initiatives. The EAC joint dossier assessments are aimed at improving access to safe, efficacious and good quality essential medicines for the treatment of conditions of public health importance through putting up harmonized and functioning medicines registration and regulation systems within the region in accordance with the national and internationally recognized standards and best practices.

The session also reviewed joint assessment procedures to identify current challenges. During the meeting, the integrated regional Information Management System (IMS) was discussed as a shared point to enable secure information sharing of dossier applications for both medicines dossiers and GMP Inspections and other related regulatory information among the regulatory authorities participating in the process. This process is expected to enhance information exchange across countries and encourage peer-to-peer learning. The regional IMS platform is seamless and also allows for online application for registration of medicines in the NMRAs in the region. A demonstration of the regional IMS system was done.

The EAC joint dossier assessments are conducted based on the regional harmonized guidelines, requirements and standards for Medicines Evaluation and Registration (MER), Good Manufacturing Practices (GMP) and Quality Management Systems (QMS) that were approved by the 29th Ordinary meeting of the EAC Council of Ministers in 2014 through its Decision EAC/CM29/Decision 036. The Decision directed the EAC Partner States' National Medicines Regulatory Authorities (NMRAs) to begin domesticating and implementing the approved EAC harmonized guidelines, requirements and standards for MER, GMP and QMS from January 2015. Since this decision and subsequent joint dossier assessments being conducted, the EAC region has managed to reduce the average timelines for review of medicine registration applications from 1-2 years to a median of 7 months, representing a 40-60% reduction. This has improved patient access to essential medicines in the region.

PEI set to improve supply of vaccines, blood & blood products in Africa

Most African countries have inadequate regulatory systems for regulating vaccines and blood and blood products, and this is a huge challenge especially during times of crisis or emergency. The Paul-Ehrlich-Institut (PEI) through its Global Health Program (GHP) is committed to strengthening national health systems in Africa and is partnering with NEPAD Agency, World Health Organization (WHO) and other partners to advance this stream of work.

In collaboration with NEPAD Agency and WHO, PEI hosted a workshop from 6 to 8 December 2017 to enhance collaboration, exchange ideas, share best practices and identify strategies for strengthening existing regulatory systems in Africa.

This approach will help to make a sustainable contribution to the African population's health care systems and during crises. Experts from 17 African countries, Europe, Health Canada, and the Center for Biologics Evaluation and Research of the Food and Drug Administration in the United States (FDA CBER) attended the workshop.

A well-established and efficient health system with well-functioning regulatory structures is important especially during health threats. This was also shown by the outbreak of Ebola fever in 2017 that led to more than 11,000 deaths and more than 28,000 infected persons.

One of the prerequisites for mitigating such emergency situations include putting in place efficient and experienced medicine regulatory authorities that assess and authorise clinical trials of new medicines and perform marketing authorisation for medicinal products in a timely manner. During the Ebola, too, the PEI became involved and made its contributions, so that a clinical trial with a vaccine candidate could take place.

During the workshop, common strategies for the harmonisation of regulatory structures and standards were discussed; especially how collaborations within Africa could be strengthened to be better prepared and to react quickly in cases of health crises.

The PEI is the Federal Agency for Vaccines and Biomedicines and lends expertise to the GHP in order to contribute to better provision of blood and blood products and vaccines in African countries by ensuring intensive professional exchange, which is also taking place on site, and a strong network of specialized experts.

Building public health delivery systems that support Africa's industrialization

"It is a fact that Africa is the second most populous continent in the world, with the population projected to grow by 25% by 2050 and 40% by end of the century. Yet the continent has health challenges that need to be addressed in order to support the growing population," Dr Ibrahim Mayaki, CEO of the NEPAD Agency made the remarks at the organisation's event during Africa Week on 17th October 2017 in New York, USA.

Africa continues to grapple with high disease burden, weak health care delivery systems and fragmented markets for medical products and health technologies. NEPAD Agency has taken critcial steps to address the continent's disease burden by building systems that provide an enabling environment for pharmaceutical sector development through the African Medicines Regulatory Harmonisation (AMRH) Initiative. AMRH provides a foundation for strengthening regulatory systems and establishment of strong institutions to ensure long term sustainability.

In her opening remarks, NEPAD Agency's Head of Health Programmes, Mrs Margareth Ndomondo-Sigonda maintained that "you cannot talk of sustainable socio-economic growth without addressing the health of the people who are the drivers of industrialisation."

During the event, participants explored available options for health financing; promotion of research and development and innovation on medical products and technologies including traditional medicines; local production of medical products and health technologies for stronger health care delivery systems.

Dr Janet Byaruhanga, from NEPAD's Health programme focused on strenghtening regulatory systems, local production of medical products and access to finance. She stressed the need to provide conducive environment for the private sector to secure capital for increased investment in this sector. In addition, the pharmaceutical sector has huge potential to create jobs for youth through the use of modern technologies.

Speaking on the promotion of investments and creating knowledge based jobs, in improving competitiveness as well as public health, Dr Paul

Lartey, founding Chair of Federation of African Pharmaceutical Manufacturers Associations (FAPMA), made the case for reliable and sustainable capital for investment in manufacturing and assurance of compliance to good manufacturing practices and standards in order to produce quality medicines.

The World Bank representative, Dr Andreas Seiter remarked that Africa should be proud of the achievements made in medicines regulatory harmonisation. He indicated that progress made this far working through the reginal economic communities is commendable. He highlited on achievements made in the East African Community (EAC), Economic Community of West Africa States (ECOWAS) and the Southern African Development Community (SADC) and the impact of the African Union Model Law on Medical Products Regulation in assisting countries to review their national laws, adding that the momentum should be maintained.

Ninth EDCTP Forum: Call for Abstracts, Scholarships and Scientific Symposia

The Ninth EDCTP Forum will be held in Lisbon, Portugal, from 17 to 21 September 2018. The EDCTP Forum programme committee invites submission of abstracts, applications for scholarship, and proposals for scientific symposia.

Visit the EDCTP Forum website: www.edctpforum.org

The Ninth EDCTP Forum 2018 is held in partnership with the Portuguese Foundation for Science and Technology and the Calouste Gulbenkian Foundation. The theme of the Forum is Clinical research and sustainable development in Sub-Saharan Africa: the impact of North-South partnership.

Over the last 13 years the Forum has evolved to become one of the most prominent cross-disease and inter-disciplinary conferences. The Forum brings together scientists, policy makers, funders and global health partners in the field of clinical research and development (R&D) for poverty-related diseases, with emphasis on African and European participation, providing a valuable opportunity to share new results and form new collaborative links with international colleagues. The main Forum programme includes plenary sessions, parallel sessions, exhibition of posters, symposia, workshops, and various opportunities for discussion and collaboration. The EDCTP Forum is held alternately in Africa and Europe.

EDCTP 2018 Prizes: Call for Nominations

The European & Developing Countries Clinical Trials Partnership (EDCTP) invites nominations for the following prizes: Scientific Leadership, Outstanding Female Scientist, Outstanding Research Team, and the Dr Pascoal Mocumbi Prize. Nominations of candidates are invited by **20 April 2018, 17:00 CET**. The prize ceremonies will be held at the Ninth EDCTP Forum in Lisbon, Portugal, from 17 to 21 September 2018.

- **Scientific Leadership**: Awarded to excellent world-class scientists in Africa up to 50 years of age working on HIV/AIDS, tuberculosis, malaria and neglected infectious diseases in the scope of the second EDCTP programme. It consists of a recognition trophy and a cash prize of €10,000.
- **Outstanding Female Scientist**: Awarded to excellent world-class female scientists in sub-Saharan Africa and working in the scope of the second EDCTP programme. It consists of a recognition trophy and a cash prize of €20,000.
- **Outstanding Research Team**: Awarded to outstanding research teams in Africa and Europe working on HIV/AIDS, tuberculosis, malaria and neglected infectious diseases in the scope of the second EDCTP programme. It consists of a recognition trophy and a cash prize of €50,000.
- **Dr Pascoal Mocumbi Prize**: This prize is in special recognition of the significant contribution made by Dr Pascoal Mocumbi, the first High Representative of the EDCTP. It is to be awarded to senior scientists, policy-makers or advocates for health and research (aged 51 years and above). It consists of a recognition trophy and a cash prize of €50,000.

The EDCTP prizes recognise outstanding individuals and research teams from Africa and Europe who have made significant contributions to health research. In addition to their scientific excellence, the awardees will have made major contributions to the EDCTP objectives of strengthening clinical research capacity in Africa and supporting South-South and North-South networking.

For more information please visit: http://www.edctp.org/call-nominations-edctp-prizes/

Blood and Blood products Benchmarking Exercise

18-20 April 2018, Pretoria, South Africa
23-27, Harara, Zimbabwe
07-11 May 2018, Addis Ababa, Ethiopia

Africa Pharma Hub Meeting

06-10 May 2018, Algiers, Algeria

World Health Assembly and AU Health Ministers Meeting on African Medicines Agency (AMA)

17-21 May, Geneva, Switzerland

13th Steering Committtee Meeting to review progress on PV program and EAC-MRH

29 May - 02 June 2018, Zanzibar, Tanzania

UPCOMING EVENTS

African Medicines Regulatory Harmonization Partnership Platform (AMRH-PP) Meeting

11 April 2018, Johannesburg, South Africa

Meeting of the Steering Committee (SC) on Regulatory Systems Strengthening and Harmonization Initiatives in Africa

12-13 April 2018 - Johannesburg, South Africa

EAC Vaccines Production Symposium

16-19 April 2018, Arusha, Tanzania

WHO regional workshopfor national focal pointson Substandard and Falsified (SF) medical products

16-20 April, Abuja, Nigeria

EAC Joint GMP Inspections

16-20 April 2018, India, Europe

EWG Sessions on PV to develop harmonized manuals, guidelines, requirements and tools

13-19 April, Kigali, Rwanda