AMRH NEWSLETTER

Quarter 3: July - September 2017

African Medicines Regulatory Harmonization

Regulation of blood and blood products gets a boost in Africa

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

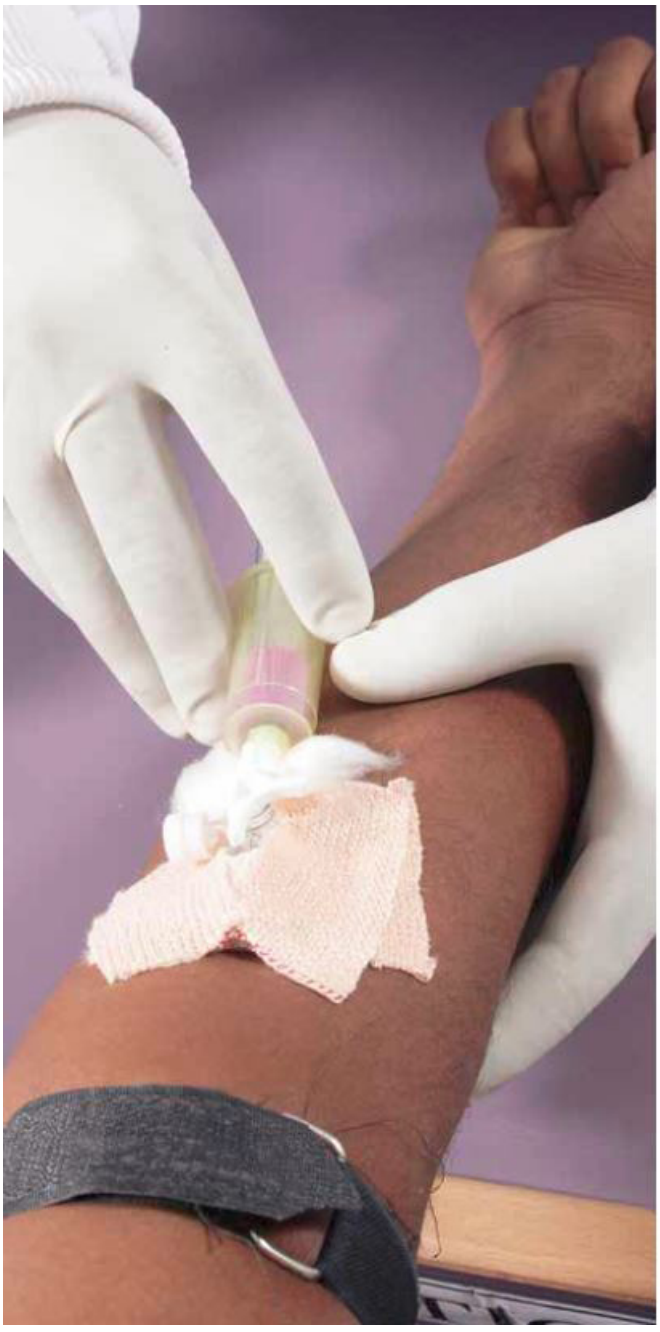
PEI and NEPAD collaborate to strengthen regulation of blood and blood products in Africa

Paul Erhlich Institut (PEI) and NEPAD Agency engaged in bilateral consultations to explore opportunities for collaboration on the regulation of blood and blood products stream of work in Africa. During a meeting in Johannesburg, South Africa from 18 – 19 June 2017, a team of senior experts from PEI met with the African Medicines Regulatory Harmonization (AMRH) initiative team to identify gaps and priorities in blood regulatory systems in order to develop capacity building programmes and activities to support the introduction of regulation of blood, blood components and blood products in Africa.

The bilateral consultations have led to the development of a concept note for collaboration which will serve as a basis for the development of a Memorandum of Understanding (MoU) between PEI and NEPAD Agency in future.

As part of its start-up activities, the Global Health Project (GHP) at PEI in collaboration with NEPAD Agency and World Health Organization (WHO) have opened a call for submission of applications for funding of pilot projects to strengthen regulatory oversight of clinical trials, strengthening the regulation of blood and blood products, reinforce stablished regional networks and facilitate collaboration between National Medicines Regulatory Authorities (NMRAs) in Africa, and international partners.

The regulation of blood and blood products stream of work in Africa will be guided by the WHO Global Benchmarking Tool/BRN Criteria in accordance with the recommendation of the World Health Assembly (WHA) 63.12, 2010 resolution on the availability, quality and safety of blood products. The GHP at PEI focuses on two modules that align with the WHO Criteria and WHA recommendations on the regulation of blood and blood products and these include;



PEI-AMRH collaboration will strengthen regulation of blood and blood products in Africa

- **BloodTrain – Module 1: Availability, safety, and quality of blood and blood products – supporting the development of regulatory structures and its adaptation to crises in partner countries**

❖ VaccTrain – Module 2: Regulatory Training and advice in the area of vaccines and biomedical therapeutic products

PEI is well positioned to undertake this work as it is a recognized WHO collaborating centre for blood and Invitro diagnostic devices and vaccines. PEI will work towards strengthening the regulatory capacity of NMRAs in Africa and will begin by jointly convening a workshop in Langden, Germany with NEPAD Agency and WHO to focus on strengthening international cooperation, both within the regional and pan-African networks as well as with other international partners. The topics to be covered at the workshop include current and/or new models of reliance for regulation of vaccines, and the establishment of regulatory systems for blood, blood components and blood products as well as clinical trials related to specific blood components such as convalescent plasma.

NEPAD and PEI team exchange knowledge materials during the meeting in Johannesburg, South Africa

In addition, PEI will leverage the AMRH Regional Centres of Regulatory Excellence (RCOREs) to establish a forum for regulators of blood in Africa to encourage networking. This forum is expected to contribute to the role of the AMRH programme as a continental technical expert group and will facilitate the implementation of e-Health-structures for data-driven regulation of blood and blood products. NMRAs in Africa can submit applications for consideration of pilot projects on blood regulatory systems by responding to the following link; **http://www.nepad.org/sites/default/files/GHP%20call%20for%20proposals.pdf**

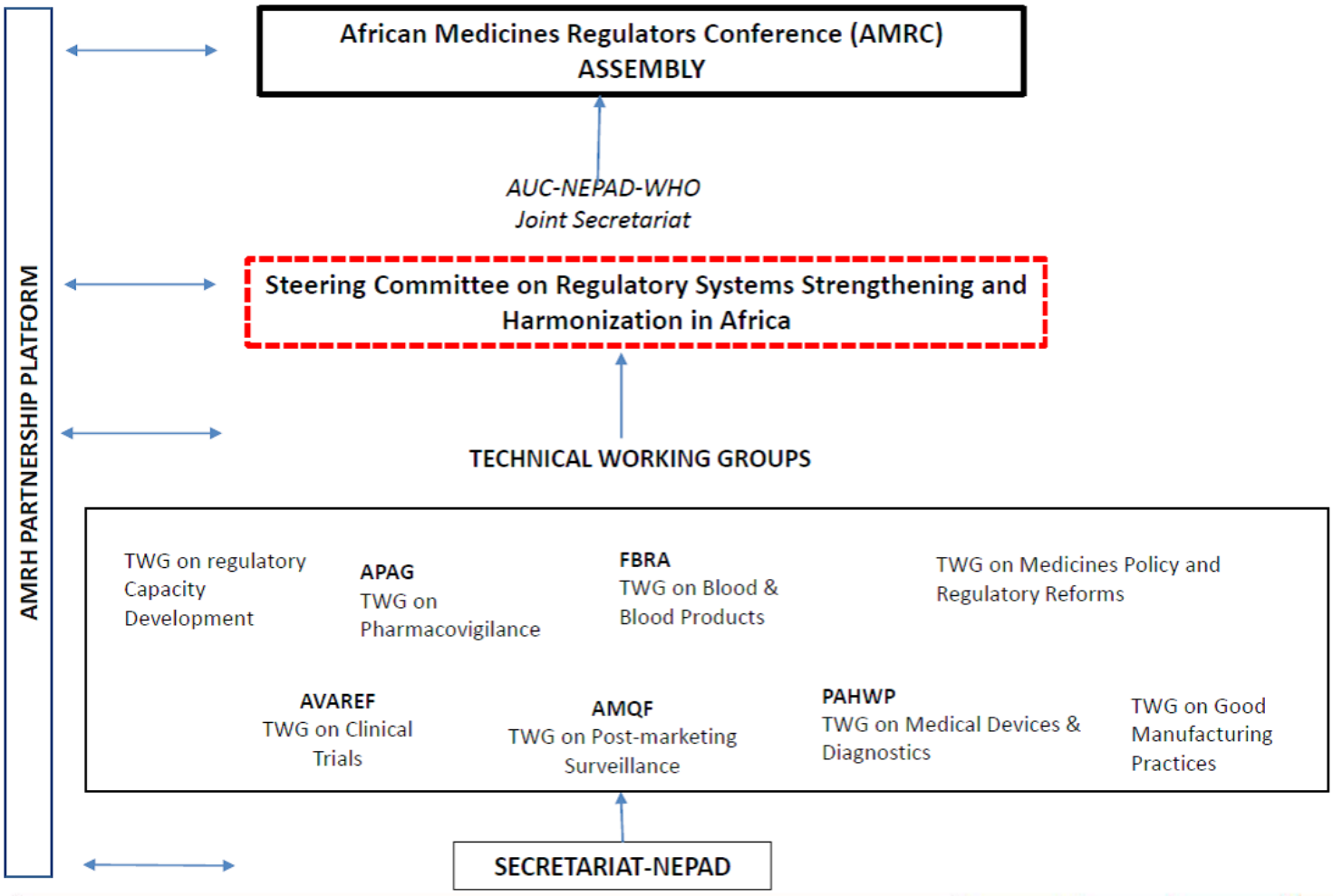
Strides taken to establish single continental Steering Committee on regulatory affairs in Africa

Partners and stakeholders of the African Medicines Regulatory Harmonization (AMRH) and African Vaccines Regulatory Forum (AVAREF) Initiatives have validated the principles behind the idea of setting up one Steering Committee on medical products regulatory systems strengthening and harmonization. The establishment of this single Steering Committee is aimed at providing harmonized strategic direction of the two Initiatives and other partners in the regulatory space, as well as ensure coherence in efforts to accelerate alignment of the AVAREF and other similar Initiatives with the AMRH Initiative.

The inaugural Interim Steering Committee meeting took place at the NEPAD Agency Head Office in Johannesburg, South Africa from 4 – 5 September 2017. During the meeting, AMRH and AVAREF partners and stakeholders discussed and revised the draft Terms of Reference for the Steering Committee and the continental Partnership Platform that will be established to address challenges of duplication of efforts by ensuring alignment and increasing stakeholder collaboration among partners supporting the agenda of regulatory systems strengthening and harmonization in Africa. The Partnership Platform will serve as the Africa chapter of the World Health Organization (WHO) Coalition of Interested Parties (CIP) and shall work towards fostering mutual and collective accountability.

NEPAD Agency Head of Health Programmes, Margareth Ndomondo-Sigonda presented the integrated continental Monitoring and Evaluation Framework and its associated Indicator Reference Manual. The M&E Framework is meant to be inclusive to track implementation of MRH projects and the performance of National Medicines Regulatory Authorities (NMRAs) by taking on-board priority measurement areas for different partners and stakeholders in the regulatory space to avoid overwhelming NMRAs with demand for similar information.

The Interim Chair of AVAREF presented the new governance structure and proposed alignment with AMRH, while prog-



Representatives from different organizations that attended the Steering Committee meeting in September 2017

ress on Medicines Regulatory Harmonization (MRH) projects at regional level was presented by representatives from the Regional Economic Communities (RECs). More presentations from WHO added value by outlining their technical support in the implementation of MRH projects, while the World Bank (WB) reflected on action points as agreed by partners and stakeholders at the AMRH strategy workshop in February 2017.

At the end of the meeting, RECs priorities were presented and discussed followed by a summary of the 5-year plan by AMRH partners in support of the identified RECs priorities. The 5-year plan was made by the Bill and Melinda Gates Foundation (BMGF) on behalf of the donors.

The members of the Steering Committee shall be nominated by their organizations and institutions. The inaugural Steering Committee was attended by representatives from the African Union Commission (AUC), AVAREF Chair, NMRAs, RECs, RHOs, WHO Head Office, WHO-AFRO, World Bank, BMGF, Swiss Development Agency (SDC), Federation of African Pharmaceutical Manufacturers Association (FAPMA) and representatives from NEPAD Agency as the Secretariat of SC.

Apologies were received from International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and the UK Department for International Development (DFID).

"The AMRH Partnership Platform will be the Africa chapter of the WHO global Coalition of Interested Parties (CIP)"

AMA Treaty presented to African Ministers of Health

Building on the three continental consultations with legal and regulatory experts to review the draft Treaty for establishing the African Medicines Agency (AMA), African Ministers of Health gathered on the margins of the 67th session of the Regional Africa Committee (RAC) of the World Health Organization (WHO) in Victoria Falls, Zimbabwe on 29th August 2017 where they were presented with the AMA Treaty to facilitate further High-Level consultations. The Ministers of Health met as a working group of the Specialized Technical Committee on Health, Population and Drug Control (STC-HPDC) of the African Union (AU).

During the side meeting, African Minsters of Health acknowledged receipt of the AMA Treaty and requested that they be given more time to conduct internal consultations and follow up with legal and regulatory experts who represented their countries at the three continental consultations. As a result, the Ministers recommended that the AMA Task Team should revise current timelines to accommodate the request for another Ministers of Health consultation.

Dr Amira Elfadil Mohamed, Commissioner for Social Affairs at the African Union Commission (AUC), acknowledged that the side meeting was a demonstration of the strong collaboration between AUC, WHO and NEPAD Agency. Dr Amira emphasized the need to have strong support from the AU Member States in order to establish an AMA that will be a strong and legitimate institution with the buy-in from all the countries.

"Once established, AMA will be a strong institution to ensure the health of African people is protected from threats posed by Sub-standard and Falsified (SF) medical products and technologies, as well as promote local pharmaceutical industries

though the Pharmaceutical Manufacturing Plan for Africa (PMPA)," Dr Amira said.

Speaking on behalf of the WHO-AFRO Regional Director, Dr. Delanyo commended the work of the AMA Task Team and collaboration between the AMA Joint Secretariat, and reiterated that the ultimate goal of establishing AMA is to have very strong national regulatory systems, with very good technical backup at regional and continental levels in Africa.

"AMA will be a strategic institution for strengthening Medicines Regulatory Harmonization (MRH) initiatives and pulling together expertise, human and financial resources to effectively manage the burden of access to medicines in Africa," Dr Delanyo said.

NEPAD Agency Head of Industrialization Science Technology and Innovation (ISTI), speaking on behalf of the Chief Executive Officer (CEO) emphasized the importance of a stepwise approach to address regulatory challenges facing Africa by scaling up activities of the African Medicines Regulatory Harmonization (AMRH) and the African Vaccines Regulatory Forum (AVAREF), and ensure harmonization and alignment between these initiatives.

"AMRH and AVAREF serve as building blocks for AMA in efforts towards providing an enabling regulatory environment for research and development, innovation and local production of pharmaceuticals, optimizing competitiveness and expanding markets," Prof. Ambali said.

The AMA Joint Secretariat comprised of WHO, AUC and NEPAD Agency is planning to hold another Ministers of Health consultation in Kampala, Uganda in October at the upcoming 4th Global Health Security Agenda High Level Meeting.

African Ministers of Health during the AMA side meeting in Victoria Falls, Zimbabwe

EDCTP partnering with NEPAD to enhance medicines regulatory systems in Africa

EDCTP and NEPAD Agency will compliment each other to accelerate access to quality, safe medicines in Africa

European & Developing Countries Clinical Trials Partnership (EDCTP) and NEPAD Agency are working to identify priority areas of common interest to enhance South-South medicines regulatory systems and fast-track efforts to improve access to safe, quality and efficacious medical products by the African people. Senior level experts from the two organizations held internal discussions on 01 August 2017 at the NEPAD Agency Head Office in Johannesburg, South Africa together with the Bill and Melinda Gates Foundation (BMGF) and agreed to work towards developing a Cooperation Agreement to formalize this partnership.

Director of South-South cooperation at EDCTP, Prof. Moses Bockarie indicated that his organization is in the process of moving from project based funding to portfolio funding i.e. coalitions of partners, networks, etc. to accelerate impact and advance the health of the African people in a sustainable manner.

"EDCTP have identified NEPAD Agency as a key strategic partner in advancing the work of the organization especially in Africa," prof. Bockarie said.

Current data on health research funding in Africa is fragmented. Therefore, EDCTP will work closely with NEPAD Agency to come up with data on how much African countries are spending on health research. There is need to quantify research activities in African countries using a formulae that accounts for all costs. In addition, the organizations agreed to work together to build the capacity of African countries in regulatory issues through training and twinning by conducting joint workshops and pairing countries with weak regulatory systems with those that have strong regulatory systems for learning purposes respectively.

EDCTP indicated that they have Networks of Excellence (NoE) in Africa and these get three year funding. Once the Cooperation Agreement is signed with NEPAD Agency, EDCTP is willing to increase funding to the NoEs and explore opportunities to link them up with the Regional Centres of Regulatory Excellence (RCOREs) designated by the NEPAD Agency. EDCTP believes the work of the NoE will benefit from the portfolio NEPAD Agency brings by leveraging its political influence, advocacy and coordination role in the medicines regulatory strengthening and harmonization space in Africa.

Although currently doing a lot of work in this space, EDCTP is not visible and NEPAD Agency

will be a strategic partner is accelerating this front.

Furthermore, the earmarked Cooperation Agreement will be useful not only in enhancing partnership but also in harmonizing similar work of the two organizations to ensure alignment with the African Medicines Regulatory Harmonization (AMRH) initiative.

EDCTP, NEPAD and BMGF team that attended the meeting in Johannesburg

IGAD finalize project proposal on medicines regulation

The Intergovernmental Authority on Development (IGAD) this morning opened the 1st Regional Experts Meeting on Medicines Regulatory Harmonization Initiative (MRHI) during an inauguration session chaired by Mr. Abdoulkader Walyei Fato from the Ethiopian Food, Medicine, and Healthcare Administration & Control Authority, and in the presence of the Reproductive Maternal Child Health Coordinator,Dr. Fatuma Adan, and Mr. Abraham Gebregiorgis of the World Health Organization (WHO) Geneva Office.

This two-day meeting is bringing together Experts and officials from IGAD Member States in charge of their respective National Medicine Regulatory Authority (NMRA) whose mandate is to guarantee populations' access to essential quality, safe, and efficacious medicines.

This 1st Experts Meeting is essentially aimed at reviewing and finalizing a draft project proposal for IGAD Medicines Regulatory Harmonization (IGAD-MRH) and establishing and IGAD Expert Committees for the Project.

Speaking on behalf of the Acting Director of the Health & Social Development Director for IGAD Executive Secretary, Dr. Fatuma noted that "the presence of unregulated Sub-standard, Falsified, and Counterfeit medicines circulating within IGAD member states" was "a serious public health threat which if not prevented and controlled, will undermine confidence in the public healthcare systems and programmes". She highlighted that IGAD established the MRH Project with support from WHO and the World Bank despite the lack of proper funding within its Directorate.

Dr Fatuma reminded the audience that their inputs to the proposed draft project proposal were essential in view of submitting it the IGAD Heads of National Medicines Regulations Authorities (NMRAs) for ratification and approval in August 2017.

Mr. Gebregiorgis reassured the participants that "at global and regional level, WHO as the technical agency is supporting the regional economic communities medicine regulatory harmonization initiatives and in a broader level the NEPAD African Medicine Regulatory Harmonization".

After the official opening remarks, the Chair declaring the meeting officially open.

"DON'T BE LEFT OUT, BE THERE!!"

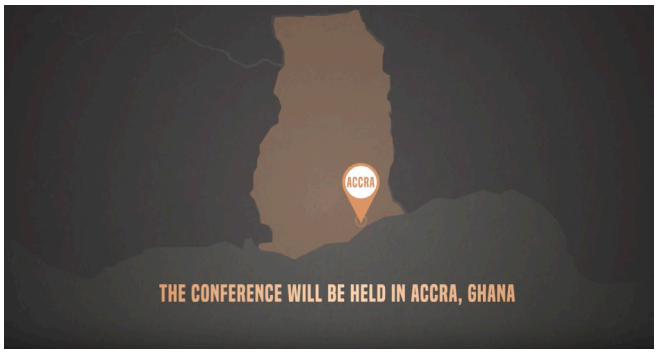
AMRH Champion, **Madame Precious Malebona Matsoso** shares her thoughts on the upcoming 3rd Biennial Scientific Conference on medical products regulation in Africa

African Medicines Regulatory Harmonization (AMRH) Champion, the venerable Madame Precious Malebona Matsoso has urged drug regulators, private sector, public sector, industry players, representatives of Civil Society Organizations, and members of the public to participate in this year's 3rd Biennial Scientific Conference on medical products regulation that will take place in Accra, Ghana from 27 - 28 November 2017 and contribute to shaping the future of medicines regulatory strengthening and harmonization in Africa. You can watch a video of Madame Matsotso via the YouTube link provided below;

Watch #SCoMRA video teaser here: https://www.youtube.com/watch?v=8-ubUr0qUlo

Madame Matsoso will also be attending the Conference and will give the keynote presentation as AMRH Champion reflecting on *regulatory harmonization in Africa: the journey and the future outlook.*

THEME: SUSTAINING THE MOMENTUM FOR REGULATORY HARMONIZATION IN AFRICA



Upcoming Events

- NEPAD/AMRH side event at the Africa Week on Transforming Regulatory Landscape for Africa's Blossoming Pharmaceutical Industry - New York: 17 October 2017
- Experts meeting to develop Medicines Policy and Regulation for ECOWAS region - Accra, Ghana: 19 - 23 October 2017
- First Experts Group meeting on dossier evaluation of medicines for the MRH Project (SWEDD) - Accra, Ghana: 24 - 28 October 2017
- Meeting with Management of Sciences for Health on USAID-MTaPS Project - Washington DC, USA: 25 - 27 October 2017
- Meeting with African Ministers of Health on Treaty to establish African Medicines Agency (AMA) - Kampala, Uganda: 25 - 27 October 2017
- ECOWAS Medicines Quality Control Laboratories (MQCL) meeting - Niamey, Niger: 13 - 18 November 2017
- 3rd Biennial Scientific Conference on Medical Products Regulation in Africa - Accra, Ghana: 27 - 28 November 2017
- NEPAD Agency and PEI-GHP joint meeting on regulatory capacity strengthening, international cooperation and emergency preparedness on blood and blood products - Langen, Germany: 04 - 08 December 2017

NEPAD Agency Contact Information
230, 15th Road, Randjespark, Midrand, Gauteng, South Africa
Telephone: +27 (0) 11 256 3600
Email: amrh@nepad.org

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