AMRH



January – June 2016

African Medicines Regulatory Harmonization



Key documents to facilitate establishment of the African Medicines Agency (AMA) successfully

examined and revised at 2nd Task Team meeting





Editor's Note

Dear all,

As we reach mid-year, it is our hope and prayer that you have made steady strides towards achieving some of your objectives of 2016 and will continue to work hard in the coming six months to realize your targets by year end. African Medicines Regulatory Harmonization (AMRH) programme has already recorded some milestones in 2016, but also recognize that more work is required to encourage Regional Economic Communities (RECs), Member States and cooperating partners and agencies to realize the medicines regulatory harmonization agenda in Africa.

Most notably, during the reporting period the African Union (AU) Model Law was endorsed by the African Heads of State

and Government at the AU Summit in Addis Ababa, Ethiopia in January. In addition, RECs have now developed Regional Roadmaps for implementation of the AU Model Law. AMRH has also completed the pilot of the Monitoring and Evaluation Framework in the East African Region (EAC) and it is expected that this will be rolled out to other RECs in due course. ECOWAS and SADC Member States have reached the implementation phase of the MRH project and IGAD has signed a Call for Action to establish structures for the implementation of the MRH regional project.

Lastly, we hope you enjoy reading the highlights in this newsletter, feedback is welcome. We wish you a fruitful 2nd half of 2016 and look forward to continued collaboration.

Content Africa charts way forward for Regional and National Approaches for GMP Compliance	3
RECs using AMRH Implementation Tool Kit to align regulatory harmonization programmes	4
2 nd Task Team meeting to facilitate the establishment of African Medicines Agency (AMA) successful	5
RECs develop Regional Plans for implementing African Union (AU) Model Law	7

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, sluggish medicine registration processes and subsequent delayed approval 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

Africa Charts way forward for Regional and National Approaches for GMP Compliance

The inaugural Expert Working Group (EWG) meeting on Regional Good Manufacturing Practices (GMP) Roadmaps for implementation of the African Union (AU) Pharmaceutical Manufacturing Plan for Africa (PMPA) was successfully held in Dakar, Senegal on 16th and 17th of May 2016. The main objective of the meeting was to develop regional GMP approaches aimed at aligning national GMP Roadmaps with the PMPA and AMRH Frameworks.

The specific objectives of the meeting included reviewing and approving the terms of reference (TORs) for the EWG Regional GMP Roadmaps; discussing and providing advice on the Regional Approach for GMP Roadmaps for implementation of the AU PMPA; discussing and reviewing innovative regional certification schemes for GMP and compliance by manufacturers; and discussing efforts by Regional Economic alignment of Communities (RECs) and development partners towards a common approach in attaining acceptable GMP status of pharmaceutical manufacturing in countries.

During the meeting RECs, countries represented and technical partners shared their approaches and experiences in developing and advancing GMP compliance in RECs and countries. Speaking during the meeting, African Union Commission (AUC) representative Dr. Janet Byaruhanga emphasized that the Pharmaceutical sector is one of the areas the AU has identified to contribute to diversifying the industrialization agenda through the PMPA Framework. NEPAD Agency Senior Programme Officer, Paul Tanui added that the EWG on GMP has been embraced as a mechanism within the PMPA Framework for realizing the AU industrialization agenda and pharmaceutical development in particular.

The meeting identified key principles for a Regional Approach for GMP Roadmaps through regional and national certification schemes for implementation of the AU PMPA. These principles include policy and legislation and guidelines that encompass medicines regulation and manufacturing; a



Dr Janet Byaruhanga from AUC (top) and Paul Tanui from NEPAD Agency (below) at the meeting in Dakar, Senegal

common vision for all stakeholders including regulators, pharmaceutical manufacturers, industry associations and relevant governmental departments such as Ministries of Health; Ministries of Finance; Customs Departments and development partners. Other important considerations include government mechanism for protection and incentives for local manufacturers support; sustainability effective mechanism and compliance; for the harmonization of standards; enabling conducive environment for pharmaceutical manufacturing; capacity development and multi sectoral capacity building. At the end of the meeting, the EWG on GMP developed a Work Plan identifying key objectives, activities, timelines, indicators, as well as roles and responsibilities in line with its overall goal of implementing recommendations of the AU Specialized Technical Committee (STC) on Health Population and Drug Control (HPDC) on developing Regional GMP Roadmaps.

The EWG GMP Roadmaps Work Plan key objectives include to: identify existing regional GMP Certification schemes, review and pilot for scale up through RECs; support RECS in developing strategies and approaches for attainment of universal GMP Standards by local pharmaceutical manufacturers in Africa and monitoring & evaluation of innovative GMP implementation schemes for piloting and scale up at national and regional level.

RECs using AMRH Implementation Tool Kit to align regulatory harmonization programmes



AMRH 4th Advisory Committee Meeting Participants from RECs and cooperating partners in Dakar, Senegal

Regional Economic Communities (RECs) have confirmed that they will continue utilizing the African Medicines Regulatory Harmonization (AMRH) Implementation Tool Kit in the process of setting up and reviewing Medicines Regulatory Harmonization (MRH) projects at regional level. This was heard during the AMRH Advisory Committee Meeting held in Dakar, Senegal from 19th– 20th May 2016.

The use of the AMRH Implementation Tool Kit is a pinnacle to ensuring long term coherence of MRH initiatives by different RECs. Meeting participants representing different RECs agreed that they will review and align their regulatory harmonization programmes with the AMRH Implementation Tool Kit. For example, Inter-Governmental Authority on



Paul Tanui and Nancy Ngum from NEPAD Agency

Development (IGAD) representative, Fatuma Adan mentioned that they have been relentless in making sure their MRH project is aligned with the AMRH Implementation Tool Kit and will continue to use it as a guiding tool.

"IGAD has the AMRH Implementation Tool Kit and will keep referring to it especially on issues of governance of the regional MRH project," said Mrs Adan. AMRH Programme Coordinator Margareth Ndomondo-Sigonda encouraged the RECs that have joined and are embarking on new MRH projects to use this as a guide, and those reviewing their MRH projects to continue relying on this document for consistency and sustainability of the projects. She also said that the AMRH Implementation Tool Kit has been made available in all the African Union languages i.e. English, French, Portuguese and Arabic, so that RECs can utilize it effectively.



2nd Task Team meeting to facilitate the establishment of African Medicines Agency (AMA) successful

AMA Implementation Roadmap developed, key working documents revised



AUC Head of Division – Social Welfare, Dr Johanne Strijdom at the official opening of the 2nd AMA Task Team Meeting

The NEPAD Agency, as a member of the Joint Secretariat comprised of the African Union Commission (AUC) and World Health Organization (WHO) organized a successful 2nd Task Team meeting to facilitate the establishment of the African Medicines Agency (AMA) and subsequent launch by end of 2018.

This is in line with the January 2015 decision of the 26th Ordinary Session of the African Union (AU) Executive Council recognizing the need to strengthen the regulatory capacity of medical products in Africa, as well as harmonization of medicines regulatory systems as a foundation for the establishment of a single





WHO, a member of the Joint Secretariat was also represented

Participants from Regional Economic Communities (RECs)

regulatory agency on the continent within the context of the African Medicines Regulatory Harmonization (AMRH) Programme which is part of the Pharmaceutical Manufacturing Plan for Africa (PMPA) Framework.

"The establishment of the AMA shall build upon already existing structures of the Regional Economic Communities (RECs) and Member States that have already started implementing the AMRH programmes within the framework of the PMPA," NEPAD Agency Pharmaceutical Coordinator, Margareth Ndomondo-Sigonda explained.

This meeting was convened in Addis Ababa, Ethiopia from 07th – June, 08th 2016 and was attended by representatives from AU Member States and RECs, supported by AMA Joint Secretariat and key cooperating partners that included the United Nations Development Programme (UNDP), World Bank (WB), United Nations Economic Commission for Africa (UNECA), and United Nations Programme on HIV/AIDS (UNAIDS). The meeting reviewed progress on

the implementation of the Task Team's four year Action Plan in the context of the commitment on the key milestones towards the establishment of the AMA agreed by the Ministers of Health at the first joint AU-WHO Ministerial Conference held in Luanda, Angola in 2014.

During the meeting, the draft AMA Legal and Institutional Framework and draft Business Plans were presented, examined and revised accordingly.

The AMA implementation roadmap was also developed and participants elected the Chairperson and Vice Chairperson of the Task Team represented by Ms Gugu Mahlangu from Zimbabwe and Dr. Nadia Fenina from Tunisia respectively.

The meeting was officially opened by the Head of Division – Social Welfare, Dr Johanne Strijdom on behalf of the AUC Director of Social Affairs. Dr Strijdom thanked the organizers of the meeting and reminded participants that this critical meeting has come at the right time when African Union (AU) leaders have adopted the first 10year implementation plan for the AU Agenda 2063 and the 2030 "Our role is to facilitate the establishment and operationalization of institutions and systems to enhance access to good quality medicines and technologies for the people of our continent"

UN Sustainable Development Goals (SDG's), both of which emphasize the significant role health is expected to play.

"Our role is to facilitate the establishment and operationalization of institutions and systems to enhance access to good quality medicines and technologies for the people of our continent," Dr Strijdom said.

The main role of the Task Team is to build consensus on the key milestones towards the establishment of the AMA and work out detailed modalities, institutional framework, legal and financial implications.

RECs develop Regional Plans for Implementing AU Model Law



Official opening of the Technical Working Group (TWG) on Medicines Policy and Regulatory Reforms (MPRR) in Senegal

Regional Economic Communities (RECs) in Africa have developed Regional Plans of Action to guide their Member States in the implementation of the African Union (AU) Model Law on medical products registration and harmonization. This milestone that took place in Dakar, Senegal on 17th May 2016 during the 4th meeting of the Technical Working Group (TWG) on Medicines Policy and Regulatory Reforms (MPRR) was facilitated by the African Medicines Regulatory Harmonization (AMRH) programme of the NEPAD Agency.

The meeting brought together legal experts, regulators, Chairpersons of regional Technical Working Groups (TWGs) on Medicines Policy and Legal Frameworks from seven (7) RECs to brainstorm and develop key activities to facilitate the domestication of the AU Model Law and discuss modalities for targeted national level intervention. The AU Model Law provides a guide for RECs and AU Member States in harmonizing medical products regulatory systems and providing an enabling environment for the development and scaleup of health technologies. AMRH Programme Coordinator, Margareth Ndomondo-Sigonda retaliated the importance of working through the RECs.

"The engagement of RECs in advancing the medicines regulatory harmonization agenda in their respective regions is critical in enhancing policy standards and achieving policy harmonization in a manner that shall ensure effective use of the already scarce resources on our continent", said Mrs Ndomondo-Sigonda.

Regional Plans of Action best option for implementing AU Model Law

The developed Regional Plans of Action map out the best option for implementing the AU Model Law in different RECs and their Member States. This process is based on preliminary assessments of Member States medicines regulatory environments conducted and presented by the RECs and forms part of the implementation strategy of the AU Model Law at both regional and national levels. This milestone builds upon the endorsement of the AU Model Law by the AU Heads of State and Government in January 2016 in Addis Ababa, Ethiopia.

"Since this endorsement, a lot of AU Member States have shown interest in utilizing the Model Law to review and develop their laws", explained AMRH Programme Officer, Chimwemwe Chamdimba.



She further disclosed a positive development that four (4) countries have already used the Model Law to review and develop their national laws including Lesotho, Seychelles, Swaziland and Zimbabwe. Despite this growing interest, Mrs Chamdimba bemoaned the lack of a comprehensive and systematic approach that shall respond to the specific immediate needs of Member States in identified regions to ensure successful adoption and adaptation of the AU Model Law.



Participants from Regional Economic Communities (RECs) engaged in group work



Meeting procession during presentations from participating RECs

It is expected that the newly developed Regional Plans of Action will guide Member States for the successful implementation of the AU Model Law at national level. AMRH is committed to working through the RECs to help Member States improve their medicines regulatory environment for faster, quality, predictable and transparent approval of medical products.

A total of seven (7) RECs and Regional Organisations (ROs) participated in the meeting and these include the Southern African Development Community (SADC), Economic Community of West African States (ECOWAS) represented by the West African Health Organization (WAHO), Central African Economic and Monetary Community (CEMAC) represented by Organization for Coordination of the Fight Against Endemic Diseases in Central Africa (OCEAC), West African Economic and Monetary Union (UEMOA), East African Community (EAC), Intergovernmental Authority on Development (IGAD) and the Common Market for Eastern and Southern Africa (COMESA), as well as other cooperating partners in health and legislative affairs.



Medicines Policy and Regulatory Reforms (MPRR) and Good Manufacturing Practices (GMP) meeting participants continuing discussions during the lunch break in Dakar, Senegal

East African Community 8th Steering Committee on Medicines Regulatory Harmonization notes progress on key milestones

The East African Community (EAC) Medicines Regulatory Harmonization (MRH) Project Steering Committee convened its 8th meeting from 2nd to 3rd June 2016, in Entebbe, Uganda. The goal of the EAC-MRH Project is to have a harmonized and functioning medicines registration system in the region.

This objective shall be achieved through attainment of key milestones that include; ensuring that agreed harmonized technical requirements for registration of medicines and procedures are in use in all the EAC Partner States; and that products are registered using harmonized guidelines.

During the meeting, the MRH Project Steering Committee noted significant progress made to date, being the first region where the MRH Project implementation started. The progress recorded so far notably includes harmonized regional guidelines for registration of medicines which are currently in use in all the EAC Partner States since 2015.

Since October 2015 interested applicants are able to submit product registration dossiers through a regional application procedure

The procedures for marketing authorization in the region are also in place and since October 2015 interested applicants are able to submit product registration dossiers through a regional application procedure. The registration of dossiers through an EAC regional application procedure is evidence of the results of the MRH Project in the region which other regions can emulate.



NEPAD Agency staff Margareth Ndomondo-Sigonda (4th from left) with Nancy Ngum (far left) with representatives during a recent visit to the National Drug Authority (NDA) of Uganda

For example, out of the twenty four (24) applications received as of June 2016 and the two joint assessments conducted so far, four (4) products have been registered in Kenya, Tanzania (Mainland) and Uganda.

Full registration is expected in Rwanda, Burundi and Zanzibar within 90 days from 1st June 2016. The registration of these products is a testimony of the hard work and consistency of the EAC region in working towards the harmonization agenda in Africa.

The EAC region is comprised of a five (5) Partner States that include Burundi, Kenya, Rwanda, Tanzania and Uganda. The Head Quarters of EAC are located in Arusha, Tanzania.



Left: AMRH team led by Margaret Ndomondo-Sigonda pose for a photo with ABNE staff outside NEPAD offices in Dakar, Senegal. Right: Paul Tanui exchanging ideas with Head of Regional Office, Dr Jeremy Ouedraogo

"NEPAD regional presence key to successful implementation of programmes" – Dr. Ouedraogo



Dr Jeremy Ouedraogo outside ABNE offices in Dakar Senegal

NEPAD Agency Head of Regional Office on African Biosafety Network of Expertise (ABNE), Dr. Jeremy Tinga Ouedraogo has stressed the importance of the NEPAD Agency physical regional offices in the implementation of regional programmes of the organization. He was speaking during a courtesy call on his office by NEPAD Agency African Medicines Regulatory Harmonization (AMRH) staff in Dakar, Senegal on 18th May 2016.

According to Dr. Ouedraogo, the presence of the NEPAD Agency office in Dakar, Senegal has accelerated the implementation of programmes in the region and positioned the organization strategically to engage with relevant authorities and institutions to ensure the African Union (AU) agenda on social-economic development and eradication of poverty is realized.

"These kinds of regional hubs make it easier for NEPAD to implement regional programmes", emphasized Dr. Ouedraogo.

NEPAD Agency Pharmaceutical Coordinator, Margareth Ndomondo-Sigonda, who was leading the courtesy call delegation added that NEPAD programmes need to engage more with regional offices by sharing information and materials regularly to make full use of such platforms.

"We will rely on this NEPAD regional office to be an advocate for the AMRH programme in this region and to continue dialogue and engagement with our partners in order to foster fruitful partnerships", Mrs Ndomondo-Sigonda explained.

Dr. Ouedraogo welcomed this initiative and encouraged other NEPAD programmes operating in the region to do the same and took the opportunity to also add that they have the capacity to even expand in to central Africa. Currently, the NEPAD Agency regional office has a total of seven (7) employees working in Senegal and have plans to expand the office premises. IGAD Member States sign Call of Action to implement regional medicines regulatory collaboration and harmonization programme



NEPAD Agency is committed to supporting implementation of MRH projects at regional level

On 27th April, 2016, InterGovernmental Authority on Development (IGAD) Member States signed the Khartoum Declaration to Call for Action towards the implementation of a regional medicines regulatory collaboration and harmonization programme. This took place during the second IGAD regional medicine regulatory authorities conference on regulatory collaboration and harmonization held in Khartoum.

The representatives of the IGAD Member States included Djibouti, Ethiopia, Kenya, Somalia, South Sudan, Sudan and Uganda. In attendance was representatives from IGAD Secretariat, NEPAD Agency, African Union Commission (AUC), World Bank (WB), World Health Organization (WHO) and other partner agencies.

One of the recommendations of the Khartoum Declaration is to strengthen national medicines regulatory authorities' capacity and support the authorities with inadequate regulatory systems, as well as strengthen partnerships between IGAD Member States to ensure regulatory harmonization. The ten point recommendation plan also includes conducting assessments of National Medicines Regulatory Authorities (NMRAs) using WHO adopted guidelines and assist them to develop summary project proposals for funding, as well as establish a sustainable funding mechanism for the regional IGAD Medicines Regulatory Harmonization (MRH) programme, among others.

The second IGAD conference is a follow up from the first IGAD scientific conference on health and it has resulted in the establishment of an IGAD MRH Steering Committee, Technical Working Groups (TWGs) and a Coordination Unit. The government of Sudan has agreed to host the IGAD regional medicines regulatory collaboration and harmonization programme.

ZAZIBONA initiative recommends 46 products for registration in SADC Member States

Zambia, Zimbabwe, Botswana and Namibia (ZAZIBONA) Heads Agency's (HoA's) of have discussed 116 products over 10 meetings and finalized a further 83 products from October 2013 to February 2016. Out of these 116 products, 46 have been recommended for registration, while 26 are recommended for rejection, this represents 40% and 22% respectively. The Mean time to recommendation is estimated at 8.84 months (= 9 months) for both the regulator and applicant's time.

These are cumulative figures based on assessments conducted during the time period and is part of the Medicines Regulatory Harmonization (MRH) project implementation phase that was agreed following the signing of a tripartite Memorandum of Understanding (MoU) between the NEPAD Agency, World Bank (WB) and Southern African Development Community (SADC) Secretariat.

The ZAZIBONA HoA's meetings are held after the Assessor's meetings where the SADC participating Member States discuss the products and initiate the registration process in their respective countries.

For example, Botswana has already registered a total of 25 products, Zimbabwe has registered 20, while Namibia has registered a total of 13 products and Zambia has registered 11 products. All these countries remain committed to the agenda of harmonization of medical products registration. Following the achievements of the ZAZIBONA initiative, South Africa has come on-board and is the most recent addition. The ZAZIBONA initiative is part of the SADC Framework for Regulatory Harmonization and was endorsed by the SADC Regulators Forum to ensure that there is harmonization of product registration among the SADC Member States. The ZAZIBONA initiative represents a solid foundation for the implementation of the recently endorsed African Union (AU) Model Law on medical products registration in the SADC region and also implement the AU Model Law.

The momentum gained through the ZAZIBONA initiative will be strengthened so that African countries and Regional Economic Communities (RECs) can move towards harmonization of medical products registration. In order to achieve this, more ZAZIBONA Assessors meetings will be held in 2016 and the work of the SADC MRH project and ZAZIBONA will be harmonized.

AMRH Monitoring and Evaluation Framework

piloted in the East African Community (EAC)

The African Medicines Regulatory Harmonization (AMRH) programme successfully completed the pilot exercise of the Monitoring and Evaluation (M & E) Framework in the East African Community (EAC) region. The M & E Framework includes the indicators tracking table and data collection tool.

Using this Framework, information has been collected from all the National Medicines Regulatory Authorities (NMRAs) in the EAC partner states. These included: Tanzania Food and Drug Authority (TFDA), 29th March; Zanzibar Food and Drug Board (ZFDB), 30th March; Ministry of Health in Rwanda, 31st March; and the National Drug Authority (NDA) of Uganda, on 01 April 2016.

The information collected has been validated and is currently being cleaned before analysis commences and the completed report is expected by end of July 2016.

The results of this pilot will facilitate the development of the AMRH Indicator's Manual and the M & E Framework will be rolled out in other Regional Economic Communities (RECs) and Member States.



NEPAD Agency Monitoring and Evaluation team conducting the pilot exercise and interacting with NMRA participants in Rwanda



NEPAD Agency Monitoring and Evaluation team pose for a photo with participants in the pilot exercise outside the Zanzibar Food, Drugs and Cosmetics Board in Zanzibar, Tanzania

Apology

In the previous AMRH newsletter, inadequate or incorrect information was published concerning F. Hoffmann-La Roche Ltd (Basel, Switzerland) product indications for Avastin and Herceptin respectively. The following is the clarification on the indications for Avastin and Herceptin: the claims made in the publication related to indications for Avastin was incorrect. Avastin (Bevacizumab) is not indicated for the intraocular use in diabetes but was assessed and approved for; (a) Metastatic colorectal cancer (b) Metastatic breast cancer (c) Advanced, Metastatic or Recurrent Non-small Cell Lung Cancer (d) Advanced and/or Metastatic renal cancer (e) Glioblastoma (WHO grade IV) and(f) Ovarian cancer. (Reference: Product Information, dated December 2014, Genisys - No. 10164240 submitted with the application. The claims made in the publication related to indications for Herceptin that was insufficient. Herceptin was assessed and approved for not only early breast cancer but also metastatic breast cancer and metastatic gastric cancer or cancer of the gastrooesophageal (Reference: Product junction. Information EFA, dated December 2013, Ro-45-2317 submitted with the application).

FOR MORE INFORMATION ON THE AMRH PROGRAMME

For more information on the AMRH Programme Activities: Frequently Asked Questions: Partners: AMRH Useful Links; please visit the AMRH webpage on <u>http://www.nepad.org/content/african-medicines-</u> <u>regulatory-harmonisation-armh-programs</u>

You can also follow us on twitter: @NEPAD_AMRH

Upcoming Events

*	EAC Pharmacovigilance and Post-Marketing Surveillance Proposal Development Workshop: 4 – 8 July, Entebbe, Uganda
*	SADC Regulators Forum: 26 – 29 July, Victoria, Seychelles
*	AMA Working Session: 1 – 5 August, Durban, South Africa
*	Health Research Working Session: 8 – 12 August, NEPAD Office, Midrand
*	Development of Harmonized Pharmacovigilance Guidelines and Tools to strengthen monitoring of pharmacovigilance system performance indicators in the EAC - Partner States: 9 – 11 August, Zanzibar, Tanzania
*	AMRH M & E Framework and EAC MRH Evaluation Report Validation Meeting: 20 – 24 August, Nairobi, Kenya
*	5th Heads of NMRAs Forum and 9th Steering committee meeting for EAC-MRH Project: 1 – 4 September, Nairobi, Kenya
*	Meeting with ECOWAS, WAEMU and WAHO: 5 – 9 September, Abuja, Nigeria and Ouagadougou, Burkina Faso
*	Technical Working Group on Health Research Strategy: 12-16 September, Midrand, South Africa

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