First Scientific Conference on Medicines Regulation in Africa

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Johannesburg
South Africa

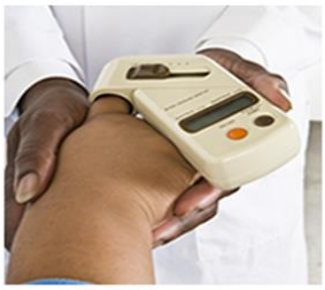
"Building Partnerships for Sustainable Capacity Development on Medicines Regulation in Africa"

Conference Report







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List of Acronyms

ADRs	Adverse Drug Reaction
AfDB	African Development Bank
AIDA	Accelerated Industrial Development of Africa
AIDS	Acquired Immunodeficiency Syndrome
AMA	African Medicines Agency
AMRC	African Medicines Regulators Conference
AMRH	African Medicines Regulatory Harmonisation
ANDI	African Network for Drugs and Diagnostics Innovation
ARV	Antiretroviral
AU	African Union
AUC	African Union Commission
AVAREF	African Vaccines Regulatory Forum
BMGF	Bill and Melinda Gates Foundation
CAMI	Conference of African Ministers of Industry
CDDDP	Centre for Drug Discovery, Development and Production
CEMAC	Economic and Monetary Community of Central Africa
CePAT	Centre for Pharmaceutical Advancement and Training
CHVI	Canadian HIV Vaccine Initiative
COHRED	Council for Health Research and Development
DFID	United Kingdom's Department of International Development
DNDi	Drugs for Neglected Diseases Initiative
EAC	East African Community
ECOWAS	Economic Community Of West African States
EDCTP	European and Developing Countries Clinical Trial Partnership
EMA	European Medicines Agency
FAPMA	Federation of African Pharmaceutical Manufactures Associations
FEAPM	Federation of East African Pharmaceutical Manufacturers
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GMP	Good Manufacturing Practices
HIV	Human Immunodeficiency Virus
HSOG	Head of States and Government
ICH	International Conference on Harmonisation
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IMS	Information Management Systems
IPM	International Partnership for Microbicides
IPR	Intellectual Property Rights
IRB	Institutional Review Boards
LICs	Low Income Countries
MCAZ	Medicines Control Authority of Zimbabwe
MDGs	Millennium Development Goals
NAFDAC	National Agency for Food and Drug Administration and Control

NCE	New Chemical Entity
NEPAD	New Partnership for Africa's Development
NGOs	Non-Governmental Organizations
NMRAs	National Medicines Regulatory Agencies
NRAs	National Regulatory Agencies
OCEAC	Organization for the Coordination of Endemic Disease Control in Central Africa
PAP	Pan African Parliament
PEPFAR	President Emergency Plan for AIDS Relief
PMPA	Pharmaceutical Manufacturing Plan for Africa
PV	Pharmacovigilance
QMS	Quality Management Systems
RCOREs	Regional Centres of Regulatory Excellence
RECs	Regional Economic Communities
SADC	Southern Africa Development Community
SAGMA	Southern African Generic Medicines Association
SARPAM	Southern Africa Regional Programme on Access to Medicines and Diagnostics
SEAMRAC	South and East African Medicines Regulatory Conference
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SRAs	Stringent Regulatory Authorities
SSFFC	Substandard, Spurious, Falsely-Labelled, Falsified, or Counterfeit
TB	Tuberculosis
TFDA	Tanzania Food and Drug Authority
UEMOA	West African Economic and Monetary Union
UNAIDS	United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development
USFDA	United States Food and Drug Agency
USP	United States Pharmacopeia
WAHO	West African Health Organisation
WAPMA	West African Pharmaceutical Manufacturers Association
WHO	World Health Organisation
WHO-AFRO	World Health Organisation – Regional Office for Africa ()
WHO-EMRO	World Health Organisation – Regional Office for the Eastern Mediterranean
WHO-PQ	World Health Organisation – Prequalification Programme

Message from Co-Chairpersons, Conference Organizing Committee

It is with great pleasure that we bring to you the report of the 1st Biennial Scientific Conference on Medicines Regulation in Africa which was held in Birchwood Hotel Johannesburg South Africa. The conference was a clear milestone as the first platform to interaction and discussion of regulatory work and research efforts in different regulatory science fields in Africa. The conference was the first of several biennial scientific conferences that will be organised by the NEPAD Agency African Medicines Regulatory Harmonization (AMRH) Programme and collaborating organizations and agencies.

The overall goal of the conference was to enable policy makers, regulators, industry, academia, research organizations and scientists to network and exchange information on innovative approaches for pharmaceutical sector development in Africa. The papers that were presented during the conference facilitated sharing of scientific advances and current best practices in regulatory science disciplines amongst policy makers, regulators, industry and scientists. The conference also reviewed the current global developments in the regulatory environment and their impact on the commercialization of health research products as part of implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA). The key recommendations of the scientific conference provided inputs to the third African Medicines Regulators Conference (AMRC) that was held from 4 to 6 December 2013.

We would like to thank the entire Organizing Committee of the conference for its intensive work in making the conference a reality. We also extend our gratitude to all the individuals and organizations that contributed their financial, time and intellectual resources in ensuring that it succeeds. We also thank all the presenters and abstract reviewers as well as session chairpersons and rapporteurs for contributing effectively to the difference conference themes.

Thank you

Prof Jean-Baptise Nikiema - Regional Advisor on Essential Medicines, WHO

Margareth Ndomondo-Sigonda – Pharmaceutical Coordinator, NEPAD Agency

Co-Chairpersons of the Conference Organizing Committee

Acknowledgements

The conference organisers including NEPAD Agency, World Health Organisation (WHO), Drugs for Neglected Diseases initiative (DNDi) and the United States Food and Drug Administration (ASFDA) would like to extend sincere gratitude to partners that contributed financial support to the success of the 1st Biennial Scientific Conference on Medicines Regulation in Africa. These partners include:

- The Government of South Africa
- Bill and Melinda Gates Foundation
- World Bank
- AERAS

Heartfelt gratitude also goes to the various individuals who agreed to lead structured plenary and parallel sessions as chairpersons and rapporteurs. Furthermore, the organisers would like to thank to various presenters who took time to prepare papers in the required format and met deadlines of their abstracts revisions. Finally, many thanks to all abstract reviewers who spent considerable periods of time to review abstracts and provided constructive feedback.

Special appreciation goes to the Government of the Republic of South Africa for hosting the conference and ensuring high level hospitality to all participants.

Executive Summary

The first Biennial Scientific Conference on Medicines Regulation in Africa was co-organised by the AU/NEPAD Agency's African Medicines Regulatory Harmonisation (AMRH) Initiative and the World Health Organisation (WHO). The conference, with the theme ***"Building Partnerships for Sustainable Capacity in Medicines Regulation in Africa",*** was held prior to the 3rd African Medicines Regulatory Authorities Conference. The scientific conference brought together more than 300 participants from African National Medicines Regulatory Authorities (NMRAs), foreign NMRAs, ethics committees/ Institutional Review Boards (IRB), industry representatives, regulatory affairs professionals, scientists, academia, health financing specialists, and development partners in health and pharmaceutical Sectors in Africa.

Medicines regulation remains an important but **neglected component of promotion and protection of public health** in many countries in Africa. As a result, the NEPAD Planning and Coordinating Agency undertook in collaboration with its partners, to spearhead the African Medicines Regulatory Harmonisation (AMRH) initiative through the regional economic communities and countries. The AMRH initiative is being implemented under the framework of the Pharmaceutical Manufacturing Plan for Africa (PMPA) which was endorsed by the AU Conference of Ministers of Health in 2007 in response to a call by the African Heads of State in 2005. The AMRH envisages filling in the medical products regulatory capacity challenges for protecting public health and promoting local production. The AMRH promotes the values of strengthening national regulatory capacities while at the same time promoting shared practices and joining expertise which paves the way to the establishment of a future continental regulatory body, the African Medicines Agency (AMA).

National Medicines Regulatory Authorities (NMRAs) are mandated to ensure quality, safety and efficacy of all medicines in circulation in their countries, including regulating and monitoring their development, manufacture, approval for marketing, distribution, import, export, supply, sale and promotion with a view to promote and protect public health. Regulatory needs and approaches differ from country to country in Africa for a variety of reasons including the resource base, size of the industry and level of development, research capacity and political commitment among others. However, no matter the approach; delivery of regulatory functions requires a broad range of knowledge and skills from general inspection of medicines distribution channels to manufacturing sites, product evaluation, pharmaceutical and clinical science just to mention a few. In addition, it requires the availability of comprehensive policy and legislative provisions and the ability to effectively manage and translate them in a manner that will assure public health protection and promotion.

Most of the African pharmaceutical markets are poorly regulated which consequently puts public health at risk and erodes public confidence on health care delivery systems especially on the quality and safety of medicines they use. Many factors have contributed to a situation of weak medicines regulatory systems in Africa including inadequate regional legal frameworks and national medicines legislation, limited financial and human resources (both in number and skills)

and poor regulatory infrastructure. Further to this, some African countries do not yet all have NMRA which affects the effectiveness and efficiency to which key regulatory functions are executed at the national level.

The first Biennial Scientific Conference on Medicines Regulation in Africa brought together under one roof regulatory authorities, pharmaceutical industry, researchers, academia, and policy makers to share scientific advances and current best practices in regulatory science disciplines. This report provides an overview of the such discussions and key recommendations contributed at the conference.

Conference Overall Goal

The overall goal of the first Biennial Scientific Conference on Medicines Regulation was ***"to enable regulators, policy makers, private sector, civil society and scientist network and exchange information and knowledge on innovative approaches for enhancement of medicines regulation and protection of public health in Africa"*.**

Specific Objectives

The specific objectives of the conference were to:

i. Provide a forum to share scientific advances and current best practices in regulatory science disciplines
ii. Provide a platform to foster collaboration and networking between African NMRAs
iii. Establish unified approaches for advancing regional and continental collaboration in medicines regulation
iv. Review current global developments in the regulatory environment and assess their impact on the commercialisation of health research products.
v. Contribute to global knowledge on regulatory science
vi. Create a platform for exchange and information sharing among regulators, policy makers, private sector, civil society and scientific community.

The first Biennial Scientific Conference on Medicines Regulation in Africa was structured to promote discussion and exchange of ideas so that all participants actively take part in generating the main conference outcomes. The format of the conference included oral presentations, poster presentations and panel discussions to maximise contributions around the key topics.

The presentations made during the conference fell under the following categories:

1. Global regulatory environment: Where is Africa?
2. Situation analysis and legal background for medicines policies and regulatory reforms in Africa
3. Regulatory oversight of clinical trials in Africa: Where are we?
4. Regulatory Capacity Development & Partnerships
5. Substandard & falsified medicines: what is Africa doing to combat the menace?

6. Strengthening pharmacovigilance Systems in Africa
7. Providing an enabling environment for pharmaceutical production in Africa

1. Conference Proceedings

1.1 Opening session

1.1.1 Welcome address by the Chair Persons of the Organizing Committee: NEPAD Agency and WHO AFRO.

Ms Margareth Ndomondo-Sigonda, NEPAD Agency

Ms Sigonda welcomed all the participants to the first biennial Scientific Conference. She indicated that the conference forms an important milestone in medicines regulation in Africa as the first platform that brings together all key stakeholders with interest in medicines regulatory agenda for Africa. The conference organisation was inspired by the need for sharing information, promoting discussions and exchange of ideas among the research community, academia, policy makers, regulators and the pharmaceutical industry in order to shape the future of medicines regulation in Africa. Ms. Sigonda informed participants that the objectives of the conference contributed to two AU policy frameworks: (1) the Pharmaceutical Manufacturing Plan for Africa and (2) the AU Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa.

Prof Nikiema, WHO AFRO

Professor Jean-Baptiste Nikiema started his address by welcoming participants and thanked the South Africa Department of Health and all other organizers. He said that the conference provided a platform to discuss recent advances in medicines regulation. He also noted that weaknesses in regulation continue to delay access to quality medicines. He highlighted that the quality medicines is key to providing treatment and care and that counterfeit products are a big challenge on the African Continent. He decried the low priority given to development of regulatory systems. He said that other challenges include lack of coherence; inappropriate legal frameworks; financial and human resource challenges. He noted that the AMRH Programme, WHO-PQ, Programme and African Vaccines Regulatory Forum (AVAREF) have significantly improved the regulatory situation in Africa. He said that there is need to capitalize on these approaches and strengthen the 2012 AU decision to **establish African Medicines Agency (AMA**); He also said that access to high quality essential medicines will enhance universal health coverage.

1.1.2 Welcome remarks, by Prof H Leng, Medical Control Council, Department of Health, South Africa

Prof Leng welcomed all participants to the conference which is an important step in facilitating collaboration and cooperation in ensuring quality of medicines in African countries. He indicated that there is a clear correlation between the quality of medicines circulating in a country and the strength of its medicines regulatory agency. Strength of local manufacturing industry however builds upon compliance and adherence to good manufacturing practices. It is however important

to note that quality is expensive and since the primary goal of any industry is maximising profit, adherence becomes a problem. Therefore, investing in quality-assured production is key rather than to focus on maximizing profits. Counterfeit products come from countries with promising drug production capacity but with weak NRAs. It is therefore a prerequisite that before a county decides to build its pharmaceutical industry, there is a need to strengthen its regulations.

Prof Leng further indicated that NMRAs are normally weak due to lack of funding and dependence on limited government support. The markets in most African countries are small to warrant fees charged by big markets. Therefore, Africa with such **fragmented markets**, need to strengthen its legal systems and consolidate its weak management structures and processes, and a severe lack of staff and resources in the regulation of the continents medicines. Efforts should be made to build upon the decision made by the continent's leadership to establish the African Medicines Agency (AMA). This will facilitate pulling of resources together in ensuring quality of the medicines circulating on the continent. The model of the European Medicine Agency (EMA) can be studied for lessons learned and adapted where possible.

1.1.3 Key note address, by Ms Gugu Mahlangu, DG Medicine Control Agency of Zimbabwe (MCAZ)

Ms Gugu Mahlangu started the keynote address by highlighting some of the key public health challenges Africa is facing including (i) high HIV/AIDS infections, (ii) the continent has 42% of the 106 countries where Malaria is endemic, (iii) 26 % of 8.7 million global incidences in 2011 were in Sub-Saharan Africa, and (iv) increasing incidences of non-communicable diseases and neglected diseased. She indicated that in the advent of such challenges, medicine and health products quality and safety is important in safeguarding public health in Africa. She pointed out that, the challenge in ensuring quality and safety of medicines is worldwide. However, the challenge in Africa is compromised by poorly resourced regulatory systems that exist in some countries. This therefore highlights the need for developing partnerships that will ensure efficient regulatory processes.

She reiterated the history of regulatory harmonization and partnership in medicines regulation in Africa which dates back to over 20 years ago. Notable initiatives include the dialogue that started in SADC in 1993 between regulators from South Africa and Zimbabwe and their industry counterparts. This resulted in the formation of South and East African Medicines Regulatory Conference (SEAMRAC). The initiative resulted in draft guidelines being published though implementation remained a challenge and the partnership with the industry was lost.

Ms. Mahlangu indicated that, harmonization discussions then moved to a global platform with the involvement of WHO. This facilitated dialogue and exchange of lessons amongst regulators from different regions, with varying capacities and opening up of regulators from well-resourced countries to engage with developing country regulators under the guidance of WHO. Apart from the participation in WHO PQ which has provided a trust and capacity building platform for regulators, Ms. Mahlangu also cited other global quality assurance systems supporting

developing countries including the USFDA tentative approval 2004, European Medicines Agency (EMA) Article 58 (2004), and Canada's Access to Medicines Regime.

Ms Mahlangu reiterated some of the existing and emerging issues in medicines regulation in Africa including:

- Emerging challenges with regulating biosimilars and vaccines
- Regulation of clinical trials and the establishment of clinical trial registries
- Ensuring integrity of the supply chain, how to formalize the informal markets in particular
- Regulating Blood and blood products
- Medical devices, particularly diagnostic agents

In conclusion, she emphasised on the need for African regulatory systems to put emphasis on the following five key areas:

1. Be innovative, adaptive and outcome oriented instead of process oriented
2. Focus on product safety outcomes not the process, therefore there is need to rely on decisions made by other quality assurance systems
3. Adopt risk based approaches – allocate resources and attention based on the level of risk
4. Be able to respond to crises in a pragmatic manner, minimize health impact
5. Respond to changing environments, technology and scientific advances

1.1.4 Remarks by Dr Janet Byaruhanga African Union Commission (AUC)

Dr Janet Byaruhanga expressed gratitude to the sponsors and organisers of the conference and the government of the Republic of South Africa for organising the conference. She indicated that Africa's socio economic development has continued to be affected by a heavy disease burden that immensely reduces the human capital required to drive the desired level of sustainable growth on the continent. The period that immediately followed the declaration of HIV and AIDS pandemic as an emergency on the continent saw tremendous international interventions and the advent of a significant number of initiatives geared towards addressing the pandemic and related infectious diseases such as Tuberculosis and Malaria. It was during this period that the global fund, the President Emergency Plan for AIDS Relief (PEPFAR) and others were established to support the implementation of the 'Abuja commitments and plan of action'. By 2005, although significant progress had been made towards addressing the three pandemics including the advent of the use of antiretroviral drugs it became increasingly evident that Africa needed to source solutions from within the continent and to implement sustainable programs that would respond to the primarily infectious disease burden that disproportionately affected the continent and hampered its progress towards the achievement of the MDGs. Moreover Africa cannot continue to depend on only imported medicines to sustain the increasing numbers of its people on the lifelong ARV treatment.

Consequently in 2005, among other initiatives, the AU Heads of State endorsed a decision to promote local production of pharmaceuticals and bolster research & development which would

facilitate an enhancement in health status by improving access to essential medicines amongst others while strengthening economic autonomy and sustainable development. The Pharmaceutical Manufacturing Plan for Africa (PMPA) was duly developed and adopted in 2007 and last year a business plan comprising a package of solutions to intervene positively in the pharmaceutical sector from both the public health and industrial development perspectives was endorsed by African Heads of State and government.

Furthermore, at the19th ordinary session of the Conference of African Ministers of Industry (CAMI), consensus was built on the need to focus on pharmaceutical industry as a priority sector to spearhead the economic diversification process in Africa as envisaged in the African Union Action Plan for the Accelerated Industrial Development of Africa (AIDA). The AUC intends to successfully navigate the interface of public health and industrial development for the benefit of the African citizens. In promoting our PMPA agenda, quality will not be compromised and through the NEPAD Agency and its consortium of partners, Member States will continue to be motivated to apply the solutions proffered in the business plan to ensure strict adherence to requisite quality standards. The continent will work to boost inter-state and intra-state markets while strengthening systems that will serve to render them inaccessible to counterfeits and poor quality medicines. Africa will no longer be a dumping ground! In this regard, The Commission noted with considerable appreciation the efforts of the NEPAD Agency of the AU and its consortium of partners in providing technical support to African member states and regional economic blocs especially through the AMRH programme.

Dr Byaruhanga indicated that the Commission within the framework of the consortium of partners (UNIDO, WHO, NEPAD, FAPMA, UNAIDS, ANDI, UNDP, USP and AfDB) supporting the implementation of the PMPA business plan, pursuant to a suggestion by the WHO AFRO Regional Director, agreed to embark on consultations at both the technical and political levels for the establishment of an African Medicines Agency (AMA). The Agency is expected to build on the NEPAD's ongoing efforts in harmonizing medicines regulations at regional level. Africa knows that the journey towards AMA will not be easy but that the concerned continental institutions through building strategic partnerships will surely confront the hurdles encountered.

She reiterated that the continent needs to seize the prevailing opportunity that Africa is revitalizing the 1991 Abuja treaty for the establishment of the African Economic Community through strengthening and fast tracking its integration processes. These efforts are expected to culminate in the establishment of **grand continental free trade area**, expanded and integrated markets that will boost intra African trade. These efforts are triggering countries within trading blocs to harmonize and reform their regulatory systems. She therefore indicated the conference will prepare the continent to successfully achieve its full economic integration by building partnerships for capacity building of national regulatory authorities. She emphasized the importance of ensuring that the recommendations of the conference will lead to the creation of an enabling regulatory environment for production of quality medicines on our continent.

1.1.5 Remarks, by AMRH Programme Partners

World Health Organisation

Dr Samvel Azatyan said that Africa is known as a continent with diverse regulatory capacity. However, in the last decade Africa has shown an increase in the continents regulatory capacity capability. The AMRH initiative has supported NMRAs in the endeavour to help build their capacities and systems to ensure safety, quality and efficacy of medicines. WHO has an advantage as the oldest partner in Africa and in collaboration with the current partner, African Medicine Regulatory Harmonization (AMRH) initiative and would like to continue and maintain its support in the regulatory harmonisation initiative. WHO provides technical support (international norms and standards, policy development) to the AMRH initiative through its regional and country offices. The AMRH initiative has demonstrated success in a very short period of time by working together with WHO.

Bill and Melinda Gates Foundation (BMGF)

Dr Vincent Ahonkai referred to the theme of the conference, "Building Partnerships for Sustainable Capacity Development on Medicines Regulation in Africa" and said that it was well thought of with two key words "*Partnership* and *Sustainability"*. He indicated that the focus should be on ensuring access to essential medicines as a core component for the achievement of the MDGs 4, 5 and 6. He reiterated that BMGF believes that "Every person deserves a chance to live a healthy and productive life". It is in this regard that the Foundation is forging partnerships in Africa with the aim to accelerate access to medicines and hence in 2009 financially supported the establishment of the AMRH. He said that since establishment, the AMRH has received a lot of interest from all African Regional Economic Communities (RECs). The RECs are now working towards the implementation of:

1. Collaborative approach in medicines regulation;
2. Common requirements for regulation; and
3. Sharing work and resources.

Dr Ahonkai further indicated that since the establishment of the AMRH, the medicines regulatory harmonisation programme of the East African Community (EAC) has been launched and is progressing well towards achieving its set targets. The EAC programme is a catalyst for expanding the AMRH programme to other RECs. He noted that the right capacity building is necessary to strengthen NRAs, while fostering mutual alliances for accepting each other's information and decision-making.

World Bank

Dr Eric Mallard reaffirmed the World Bank's commitment to strengthening medicines regulations which is a key area of health systems strengthening. He indicated that a Global Multi-Donor Trust Fund for medicines regulation has been set up by the World Bank with initial funding from the BMGF and the United Kingdom's Department of International Development (DFID) . The fund is expected to expand as more partners are coming on board., A large portion of the financial resources are committed to Africa. He elaborated that the World Bank manages the funds of the AMRH initiative by providing financial management and project management

guidance, overseeing implementation, and mobilizing additional funding in collaboration with partners. Financial support provided to countries in regulatory strengthening is approved based on identified needs. The World Bank reaffirmed their commitment to support strengthening of medicines regulation in Africa through the AMRH initiative.

Federation of African Pharmaceutical Manufacturers Association (FAPMA)

Dr Paul A. Lartey gave a brief overview of the Federation of African Pharmaceutical Manufactures Associations (FAPMA). He explained that 3 regional associations agreed to officially form FAPMA and these are:

1. Federation of East African Pharmaceutical Manufacturers (FEAPM),
2. Southern African Generic Medicines Association (SAGMA); and
3. West African Pharmaceutical Manufacturers Association (WAPMA).

The launch of the Federation of African Pharmaceutical Manufacturers Associations (FAPMA) took place in Addis Ababa on January 25, 2013.

Dr Lartey said that the three regional associations are in unison in the development of a self-sustaining pharmaceutical manufacturing industry in Africa that not only contributes to the reduction of disease, but will also drive the economic development on the continent. There are currently 231 manufacturers that are members of FAPMA. Quality, safety and efficacy are key principles in FAPMA pharmaceutical production. According to Dr. Lartey, “FAPMA will be a central mouthpiece for advocacy and will promote collaboration between the regions in order to address the common challenges facing the sector”.

He indicated that the Pharmaceutical Manufacturing Plan for Africa (PMPA) has been endorsed by African Union for strengthening pharmaceutical production in the continent. Within the PMPA, medicines regulation has been identified as one of the enablers for stimulating the growth of the pharmaceutical industry in Africa. In this regard, FAPMA envisages support to its members to set up competent regulatory departments in pharmaceutical companies and develop roadmaps of GMP development and regulation. He concluded by indicating that FAPMA supports the Medicines Regulatory Harmonisation in Africa and looks forward to the establishment of a single African medicines regulatory agency.

New Partnership for Africa’s Development (NEPAD) Agency

Prof Aggrey Ambali from the NEPAD Agency pointed out that the first Biennial Scientific Conference on Medicines Regulation in Africa was held at an appropriate time when Africa is witnessing progressive economic growth. African countries with leadership from the AU, are demonstrating strong political commitment by embracing transformative reforms to address health, especially the epidemics of AIDS, tuberculosis (TB) and malaria, and by building efficient health systems. The AU has framed a compelling vision for the future of the continent and has developed powerful policy frameworks including the 2006 Abuja Call for Accelerated Action towards Universal Access to HIV/AIDS, Tuberculosis and Malaria Services in Africa; the

Pharmaceutical Manufacturing Plan for Africa (2005); and the Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa (2012), just to mention a few.

He emphasised that critical to all these is the realization of the need for; i) Diversified, balanced and sustainable financing models; ii) Access to medicines through local production and regulatory harmonization; and iii) Leadership, governance and oversight for sustainability. It is also important to note that African governments are cognisant of the fact that delivery of quality health care in the majority of African countries is hampered by lack of health care workforce, weak infrastructure and unsustainable health care financing mechanisms among others. In the endeavour to meet these challenges, global partnerships of stakeholders play a crucial role.

Prof Ambali reiterated the key mandates of the NEPAD Agency as a technical body of the AU to conduct and coordinate research and knowledge management, and to mobilise the resources and partnerships needed to address continental, regional and national priority programmes. He indicated that the organization of this conference fulfils this mandate. The first Biennial Scientific Conference in Africa has begun to contribute to global knowledge on regulatory science and helps shape regulatory policy options and approaches that would be beneficial to public health. He reminded the participants that the success of the conference would not only be judged by the quality of scientific papers presented, but more by its ability to stimulate broad support for medicines regulation specifically and public health in general. He called upon the conference to assess the various regulatory initiatives and models with a view to identify best practices at country and regional levels in order to best utilize the limited resources available and promote sharing of best practice with a view to promote regulatory standards and practice in Africa.

He assured the conference participants that NEPAD, as a widely accepted continental framework for sustainable development, provides a strategic platform for spearheading the African socio-economic development agenda. While African countries are striving to achieve the MDGs, new ambitions have emerged to go beyond mitigating poverty and its effects towards building a prosperous future with a common rallying call of '**Transforming Africa'**. The conference therefore needed to reflect on some of the challenges facing African governments with a view to provide pragmatic solutions to address them. Prof Ambali concluded his remarks by thanking all the conference organizing institutions and applauded the presence and support of the Government of South Africa through the Department of Health. The gratitude was also extended to all African government representatives, NMRA representatives as well as representatives of RECs and AMRH Partner organizations including authors, speakers, presenters and to those who worked behind the scenes to make the conference a reality.

1.1.6 Opening speech by Ms Precious Matsoso, Director General, Department of Health of South Africa

The Director General of the South African National Department of Health Ms. Precious Matsoso told delegates that she was happy and honoured to see that her dream and vision to see Africa harmonising medicines regulatory systems becoming a reality. She said that there are key

regulators who championed the harmonisation processes and thanked them for laying out the foundation for the harmonisation process. This process was initiated by these regulators through the drafting of guidelines with minimal changes happening in the regulatory situation on the ground. She thanked the BMGF as a vital partner that believed in the efforts and supported the initial proposal on medicines regulatory harmonisation.

Ms. Matsoso further thanked the NEPAD Agency for taking up the challenge and steering the AMRH initiative while allowing the regulators to drive the agenda. She mentioned that the Government of South Africa was pleased to host the conference and welcomed all participants to South Africa. She elaborated that the theme of the conference has three very important words; (i) building, (ii) partnership and (iii) sustainability. Building of partnerships is important for the success of medicines regulation in Africa. However, it has to be noted that partnerships are based on multi-stakeholders who accept different views and ideas, work together, and support capacity building. Sustainability of these partnerships is anchored in the capacity to endure and be resilient. She mentioned that access to medicines has three key dimensions namely therapeutic access, financial access, and physical access. All these elements of accesses need to be addressed in order to see meaningful change.

She urged all the participants to ensure responsiveness to the needs of people, foster relationships in areas of mutual interest, speed up technology transfer, Intellectual Property Rights (IPR), research and innovation; and fight against counterfeits. She noted that these are important areas that may influence access to medicines. She reiterated the need for regulators to take lead in coming up with conceptual definitions for the key terms used in medicines regulation including counterfeits. She further indicated that since 1976 there are many WHO resolutions endorsed to fight counterfeits but the focus has still been on debate on terminologies with minimal actions on the ground. This is time to move beyond debates and to act.

Ms Matsoso pointed out that ensuring access to medicines requires a critical mass of skilled people. Sharing of human resources and partnerships will facilitate availability where it is lacking. There is also a need to seek ways to ensure that patient groups, civil society organisations - that should serve as eyes and ears of regulators-, and pharmaceutical industry should be involved as partners in the medicines regulation harmonisation process. Harmonisation must be seen as the pooling expertise and improving efficiency in regulatory activities.

She applauded the Eastern African Community (EAC) for the progress it has made in regulatory harmonisation activities. She emphasised the need to use EAC experiences in expanding the AMRH initiative in other RECs. Since medical products are a global commodity, Ms. Matsoso encouraged the exchange of experiences beyond the continent. She expressed the need to ensure that medicines regulation is not a stumbling block but rather facilitates access to the people that need the medical products. NRAs are responsible for the entire medicine cycle: from pre-clinical drug development to use by patients and have oversight over medical products circulating in the local market. She therefore advised NRAs to work efficiently and share

knowledge to overcome prevailing challenges. The conference provides a great platform for stimulating discussion and knowledge exchange.

1.2 Global Regulatory Environment: Where is Africa?

1.2.1 African Medicines Regulatory Harmonisation Programme; Continental Progress Update: Margareth Ndomondo-Sigonda, NEPAD Agency

AMRH Programme is being implemented as a continental initiative aimed at strengthening the continent's regulatory capacity through medicines regulation harmonisation in the regional economic communities. AMRH was established under the framework of the Pharmaceutical Manufacturing Plan for Africa (PMPA). PMPA identified the creation of an enabling regulatory environment as a priority to be addressed. So far roughly 85% of sub-Saharan Africa has been covered by MRH Proposal frameworks or implementation is in progress.

In terms of the pharmaceutical sector development there is need for optimizing the African Market for new medical products and technologies. This will lead to increased access to medical products and technologies. The AU Summit in July 2012 endorsed the Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa. Pillar II of the Roadmap provides for accelerated access to affordable and quality-assured medicines and health related commodities as enshrined in the Pharmaceutical Manufacturing Plan for Africa (PMPA). AMRH is also a critical foundation for regional and continental medicines agencies. The AMRH Programme is focused on three key interventions areas namely: (1) Policy and regulatory reforms; (2) Regulatory Capacity Development and (3) Knowledge Management. Through the AMRH platform, a draft Model Law on Medicines Regulation & Harmonization in Africa was developed and endorsed by Pan African Parliament (PAP) Committee on Health, Labour & Social Affairs and is ready for consultations in 2014. Through the Continental Technical Working Group on Regulatory Capacity Development, the AMRH is developing criteria for establishment of Regional Centres of Regulatory Excellence (RCOREs). A Call for expression of interest for RCOREs & Pool of regulatory experts was launched since Oct 2013. The AMRH is also geared towards the development of a harmonised curricula and regulatory capacity development strategy for Africa.

Harmonization of medicines Regulation Requirements within the East African Community (EAC): John Patrick Mwesigye, EAC

Chapter 21 (Article 118) of the EAC Treaty of 7th July 2000 provides the legal framework on EAC Regional Cooperation on Health. This Treaty provides for the harmonization of drug registration and regulation; harmonization of drug registration procedures; development of common drug policy, the establishment of quality control capacities, good procurement practices; and harmonization of national health policies and regulation to promote the exchange of information on health issues in order to achieve quality health within the EAC. The situation in the six NMRAs in EAC namely Burundi, Rwanda, Kenya, Tanzania, Uganda and Zanzibar is that, human resources are limited both in numbers and skills, physical facilities are inadequate, and there are only three drug quality control laboratories. At present all six NMRAs have different requirements for the format and content of application for registration of pharmaceutical products and with inadequate guidelines to comprehensively cover all the key regulatory

functions and requirements. Through the MRH project which was launched in in March 2012, the EAC has developed guidelines in medicines registration, GMP Inspection and Quality Management Systems (QMS). The region has also established a common Information Management Systems (IMS) for the participating NMRAs. The draft guidelines are undergoing consultations before adoption at the regional level. EAC Member States have also embarked on exchange programmes with the view to foster peer learning and sharing of available human resources in the region. As a means of building capacity, the EAC MRH project with support from partners hosts training programmes for NMRA staff and has started the process of establishing Regional Centres of Excellence.

1.2.2 Impact Of Regional Regulatory Interventions in ECOWAS Region: Sybil Nana Ama Ossei-Agyeman-Yeboah, WAHO

The West Africa region has also registered substantial progress in the development of harmonized directives, regulations and guidelines. Additionally in the ECOWAS/WAHO Region there has been increased progress towards harmonization where technical working groups among participating member countries have been established. Progress has also been made in combating SSFFC products through the drafting of a law. WAHO conducted an assessment of impact of interventions in strengthening regulatory systems in ECOWAS Region. The study questionnaire focused on Quality Control Laboratories, GMP, Pharmacovigilance (PV), documentation and pharmaceutical production support. Summary of responses was received on the regulatory elements surveyed and the results indicated that challenges in the pharmaceutical industry continue to pose a problem. These challenges include high cost of business finance, shortage of relevant human resources and relatively small markets due to slow pace of medicines regulatory harmonization, thus the need for a holistic approach to strengthen regulatory functions.

1.2.3 Regulatory harmonization on the Economic and Monetary Union for West Africa: Traore Corneille, UEMOA

The West African Economic and Monetary Union (Union Economique et Monétaire Ouest Africaine, UEMOA) has like other regions in the continent developed harmonized directives, regulations and guidelines. The UEMOA region has been actively involved in capacity development e.g. training of pharmacists in quality control, training of pharmaceutical inspectors, and approval of directives for changing the status of NMRAs for more autonomy. The evaluation study of pharmaceutical system regulation among UEMOA member states has also been conducted.

1.2.4 Position on the process of harmonising pharmaceutical policies and regulations in Central Africa: progress, issues and challenges: Emiliene Pola Yissibi, OCEAC

Progress has been made in the harmonization of Pharmaceutical policies in Economic and Monetary Community of Central Africa (CEMAC)/ Organization for the Coordination of Endemic Disease Control in Central Africa (OCEAC) Region. However challenges remain including

insufficient capacity and inefficiency of the institutional framework and legal deficiencies in legislative and regulatory framework. There is also weak infrastructure, lack of adequate and qualified human resources, as well as material and financial resources. There is also poor performance of national drug supply systems and inefficient pharmaceutical inspection and the absence of effective pharmacovigilance systems and lack of acceptable quality level control. Despite these challenges the CEMAC/OCEAC region is ready for consultation with experts that will help them to launch the harmonization project under the coordination of AMRH Programme.

Session observations and recommendations

1. The AMRH Programme is a critical foundation for regional & continental medicines agencies. Thus there is a need to utilize the AMRH Platform for the establishment of continental and regional medicines agencies.
2. Involvement of key stakeholders and Parliamentarians is crucial for ownership and the ability to sustain the harmonization programme at national and regional level.
3. There is need to widen the scope of regulatory functions that are being harmonized to include other medical products and technologies.
4. Harmonizing of legal and regulatory framework is essential for the success of the on-going regional initiatives on access to medicines. Countries are therefore urged to adopt the Model law on medicines regulations and harmonization where there are gaps in legislative provisions.
5. Training modules that are being developed through the AMRH initiative should be relevant and tailor made to meet the needs of regulators in the African countries.
6. There is need to fast track the establishment of semi-autonomous NMRAs where none exist and further financial sustainability of the established NMRAs should be considered.
7. Robust monitoring and evaluation framework for harmonization programme should be developed to enable assessment of the progress and impacts of harmonisation of medicines regulation harmonisation at the national, regional and continental levels.

1.3 Regional initiatives for strengthening regulatory systems

1.3.1 Perspectives on harmonized clinical research governance regulatory framework for Africa: Solomon K. Sackitey

Development and implementation of a harmonized clinical governance regulatory framework for Africa is an important step towards improving clinical trial oversight in Africa. Harmonization facilitates pooling of resources and expertise to concerted clinical trials oversight and brings about transparency in tackling key issues affecting clinical trial oversight in Africa. There is high dependence of African countries on ICH GCP guidelines which are not tailored to the laws and regulations of African countries. This is despite the emphasis of The Declaration of Helsinki that clinical research protocol must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standard. African Regulatory Agencies therefore need to work in partnerships to form a PAN-AFRICAN REGULATORY TASK-FORCE. There is also a need for collaboration with non-African regulatory bodies, academic and commercial clinical research entities, local African community leaders in the establishment of a Pan-African Regulatory Governance Database among other key initiatives.

1.3.2 The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Network view on the African harmonization process burden on the industry and its impact on patient access to medicines (aspirations and challenges): Sharmila Parsatom and Merce Catula

The main challenge faced by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is the long turnaround time in medicines registration which affects earlier access to good quality medicines in Africa. On average, it can take up to 5 years to make a product available to patients from the application review time of the medical product. The AMRH initiative provides a window for addressing these challenges. However, the industry involvement is fundamental in bringing experience that will help authorities drive for efficiency in the harmonised approach, improve speed of review/handovers within the review process and shorten the time for medicines access to patients. The IFPMA-ARN noted that quicker patient access to medicines on the African continent is achievable if the entire end to end marketing approval process is streamlined (Figure 2). The industry therefore needs to be engaged in providing early feedback on new/draft processes/guidelines.

1.3.3 Medicines Regulation in Africa- the controversies and way forward: Ben Botwe

Some of the key challenges affecting African regulators today include weak regulatory systems, lack of regulatory capacity, inadequate regulatory framework, poor funding, weak or absent legislation as well as the menace of counterfeit medicines. Coupled to these challenges is the increased proliferation of counterfeiting of regulated products for medicines that are used in high

volume for managing diseases of public health interest such as, Anti-malarials, Antibiotics, Anti-hypertensive and Anti-diabetic agents. According to the World Health Organization (WHO), over 270 million people in Africa do not have access to the most essential medicines. In response to these challenges, the NMRAs have implemented a number of initiatives that are thus far bearing positive benefits. For instance, NAFDAC has implemented strategies such as public enlightenment, national and international collaboration, capacity building, law review and the use of Cutting-Edge Technologies to secure the supply chain. Such success stories are important for facilitating peer learning and replication in other NMRAs.

1.3.4 Harmonization of pharmaceutical regulation in West Africa: Realities and prospects: Amari Anthoine Serge

The West African countries have embarked on a process of harmonizing medicines regulation with the view to improve access to medicines to their populations. The initial step that the region has taken is to harmonize pharmaceutical regulations, based on two main sub-regional economic bodies: the West African Economic and Monetary Union (UEMOA) and the Economic Community of West African States (ECOWAS). Some of the major milestones thus far include the successful establishment of legally binding norms on member States (Regulations, directives) - such as Regulation No 06/2010/CM/UEMOA on registration procedures for medicines in UEMOA member states. The key focus has also been given on harmonizing the training curricula for pharmacists and harmonizing codes of ethics for the practice of pharmacy in ECOWAS. Though there have been there successes, it is also important to note that there has been a delay by member States in implementing decisions taken by the region.

Session observations and recommendations

1. As medicines regulation harmonisation is being promoted, there is need to clearly note that Harmonization is not uniform.
2. With the increased focus on ensuring self-sustainability and generation of income, NMRAs are becoming revenue generating agencies rather than medicines regulatory agencies. There is need to shift focus from revenue generation to project based and targeted regulation.
3. Efforts should be made to achieve greater collaboration between UEMOA and ECOWAS which are the main two sub regional organizations in the West African Region. This will facilitate progress in the regional harmonisation efforts.
4. Governments should avoid "PURE" political appointments to the leadership of NMRAs.

1.4 Leveraging Global Regulatory Interventions

1.4.1 Registering medicines for low income countries: how suitable are the stringent review procedures of the World Health Organisation, the US Food and Drug Administration, and the European Medicines Agency?; Joachim Yorokpa Doua

Stringent review procedures were established by the European Medicines Agency (EMA) Article-58, the Food and Drug Administration (FDA) PEPFAR-linked Review and WHO - Prequalification as a means for facilitating registration of new medicines in Low Income Countries (LICs). This was in response to the challenge faced by the LICs on the registration of new medicines where the demand outweighs the resources due to the resource intensity demand for the process. Though the WHO-Prequalification and PEPFAR-linked Review are free of charge and have accelerated access to antiretrovirals and built capacity in Sub-Saharan Africa. However, the stringent review procedures may be challenged by the scant pharmacovigilance infrastructure in Africa. In order to meet the high demand for quality medicines in LICs there is still need for these stringent review procedures to enlarge their disease coverage, increase collaboration, and build regulatory capacity in Sub-Saharan Africa. There is also need to build local capacity to avoid overdependence on external regulatory expertise. There should also be involvement of users in LICs to facilitate implementation of approval recommendations stringent review procedures.

1.4.2 Intersection of Public Policy and Regulatory Science: US and EU Efforts to Address Unmet Medical Needs from Serious Bacterial and Neglected Tropical Diseases: Dr Ekopimo Ibia, US Food and Drug Authority Alumni Association

Despite great scientific advancements and improved investments in global public health, a large segment of the world continues to experience significant unmet medical needs from serious bacterial infections and neglected tropical diseases. This undesirable situation is not simply due to the increasing bacterial resistance to available antibacterial drugs, but mostly results from the dwindling antibacterial drug pipeline from lack of commercial viability of new drugs that could stay ahead of the resistance challenge. In addition, given that the bulk of neglected tropical diseases occur in resource-scarce countries, the limited health expenditure in those countries may be neither attractive to multinational drug companies nor able to sustain a viable local research and development enterprise. Fortunately, policy makers, regulators, and funders have recognized these challenges and have redoubled their efforts to address them through legislative and other public policy initiatives. These partners are also promoting advances in regulatory science.

1.4.3 Harmonisation and Beyond: The Case of Medicines Regulatory Systems in Africa; Julius Mugwagwa

Harmonisation of approaches in various aspects of health systems has been envisaged as one of the methods for improving public health in Africa and globally. Academicians, policy makers as well as practitioners have therefore invested effort in advancing harmonized processes and

systems. Within medicines regulation, low levels of regulatory expertise coupled with high regulatory costs and increased prevalence of counterfeit and unregistered medicines, has made harmonization of medicines regulatory systems a desirable policy option. Interconnectedness of supply of health remedies and the increasing challenges for institutions and governments to solve problems unilaterally has facilitated increased interest in medicines regulatory harmonisation. Harmonisation is a change process and can be analysed using the 8 step change model of John Kotter including (i) establishment of a sense of urgency; (ii) creation of actor coalitions; (iii) developing a clear plan; (iv) sharing the vision; (v) removing obstacles; (vi) securing short-term wins; (vii) building on the changes; and (viii) anchoring the change.

Looking forward in medicines regulation harmonisation, it is important to note that short-term targets and successes are as important as long-term goals in policy change. It is important to embed assessment of targets and anchoring positive policy change and redressing potential harmful change agents. Key to the harmonisation of medicines regulation is balancing between commercial, regulatory and health care interest.

1.5 Case studies and country experiences in strengthening regulatory systems

1.5.1 NAFDAC e-Registration process: Babatunde Olajide Jayeola

The **National Agency for Food and Drug Administration and Control in Nigeria** (NAFDAC**)** Automated Product Administration and Monitoring System specially designed to serve as the platform for the NAFDAC Electronic registration process. This is a web-based application that allows for electronic submission and commencement of the registration process by applicants. In September 2012, a pilot deployment of the e-Registration platform for drugs, cosmetics and herbal products manufactured in Nigeria commenced. Hitherto, applications for marketing authorization of food, drugs and other regulated products had only been paper based. The adoption of the automated systems has facilitated:

1. The capture of important data of products previously registered via submission of physical products
2. A more convenient means of submission of relevant documents to support a company's application
3. Easier automated processing of applications by staff of NAFDAC
4. Higher levels of transparency
5. Saving of valuable time
6. Creation of a robust database of registered products

It is important to note that the number of applications submitted through the platform has progressively increased due to the benefits gained by both the regulators and the applicants.

1.5.2 Medicines registration in Zimbabwe: Luther Gwaza

Trend analysis of medicines regulation in Medicines Control Authority of Zimbabwe (MCAZ) was conducted for the period 2003 to 2013. MCAZ works through a Board and committees and the registration committee approves products. In summary the registration process involves receipt and screening; evaluation: peer review system is used; registration committee initial decision; 2nd, 3r…nth review cycles; final regulatory decision. The study found that Anti-HIV medicines accounted for the highest number of approvals within the period under analysis. The median time to registration is higher compared to well-resourced regulatory authorities. Strategies such as partial reviews based on approvals in other countries can improve access to quality assured medicines by reducing the regulatory burden.

1.5.3 A unique regulatory perspective developing an NCE solely for the prevention of HIV-1 in African Women: Elias Nyberg

Silicone ring containing Dapivirine is being developed by the International Partnership for Microbicides (IPM) for the prevention of the vaginal transmission of HIV-1 in HIV-uninfected women. Dapivirine is a non-nucleoside reverse transcriptase inhibitor that has potent anti-viral activity against HIV-1 in vitro and in vivo. The Dapivirine vaginal ring is a NCE, not approved anywhere in the world. Region-specific requirements for a NCE regulatory submission are often not published or widely known. There is therefore need to develop access programmes with

international organizations to make this medicine of critical need available to people who have no medical treatment.

1.5.4 Assessment of the Policy and Legal Frameworks of the Ethiopian Pharmaceutical Supply Chain; Edmealem Ejigu

A study was conducted to assess the policy and legal frameworks of the Ethiopian Pharmaceutical Supply Chain. The study objective was to identify shortcomings of the national drug policy and its legal frameworks contributing to the existing pharmaceutical supply chain problems. Based on the review, the national drug policy of Ethiopia has included the major building blocks of such a policy for developing countries. The basic regulatory frameworks for manufacturing, importation, distribution and use of medicines are also addressed in the country's legislations. However, only the minority of stakeholders (45%) said that the national drug policy enables the establishment of competitive pharmaceutical supply chains in Ethiopia. Overall, 81% of them said that implementation of the national drug policy is not properly managed to achieve the policy objectives.

1.5.5 Providing a Conducive Regulatory Environment; The NAFDAC Perspective: Paul Botwev Orhii

The essence of control and regulation is to protect public health by ensuring that only quality regulated products that are safe, efficacious and wholesome reach the market, and ultimately the consuming public. This is an immense task that requires undying commitment and comes with its own numerous challenges. NAFDAC has adopted a holistic, multifaceted, diverse and well-coordinated anti-counterfeiting strategy that transcends local, national and international boundaries. Effective regulation is key to ensuring quality and safety of regulated products. NAFDAC is relentlessly working with all relevant stakeholders to ensure that all NAFDAC regulated products, irrespective of their origin are of good quality, wholesome, safe and efficacious.

Session observations and recommendations

1. National Medicines Regulatory Authorities should adopt modern technologies such as e-registration and other electronic platforms to ensure faster processing of regulatory applications and enable bulk renewal submissions
2. Countries should conduct analysis of their medicines registration systems to get more insight on medicines regulatory trends and recommend appropriate strategies to address identified challenges. This would include making comparison with other regulatory agencies in the region, continentally and make a comparison with Stringent Regulatory Authorities (SRAs). Such studies may reveal issues such as variations in approvals by therapeutic area.
3. NMRAs should consider risk based approaches to regulatory decision making. There is need to apply such strategies as expedited reviews and abridged/partial reviews.
4. NMRAs should consider regional collaboration and work-sharing as a means to sharing limited resources.

5. Pre-submission meetings are valuable to gain regulatory input on the development programme and regulatory submission requirements especially for New Chemical Entities (NCE) where the product has not been approved elsewhere.
6. There is need to improve the elaboration of policy to action pathway for medicines policies in Africa. Legal and institutional frameworks need to be worked out to effectively implement the national drug policy.
7. Applicants for registration especially for NCE need to obtain input and guidance from African Regulatory Agencies on the path forward to a successful regulatory submission.

1.6 Panel discussion on situation analysis and legal background for medicines policies and regulatory reforms in Africa

1.6.1 Legal Experience from EU in implementation of decisions: guidelines versus directives: Marie-Hélène Pinheiro, EMA

The European Medicines Agency (EMA) experience is an existing regulatory model that can be used to learn experiences and challenges encountered in harmonization. The EMA model is still evolving and a specific treaty was developed to help set up harmonization in Europe. Engaging the right partners and stakeholders is key for the success of any harmonization initiative. It is also critical to consider electronic platforms for communication, sharing information quickly in relation to medicine development and registration. It is also important that guidelines are validated by regulators and applicants who use them. Impact assessment is also a critical element to ensure that objective progress is measured.

1.6.2 Country perspective on national legislation and regional harmonisation: Hiiti Sillo, TFDA

Regulations and regulatory guidelines are difficult to implement without a proper legal framework. Every country should consider establishing a legal framework and updating legislations. As medicines regulation is about standards and skills there is need that it operates under a legal framework. It is important for the legislation to include purpose, scope of products to be regulated, the key elements of pharmaceutical regulation, roles and responsibilities of all actors, and prohibitions and penalties. WHO has guidelines and guidance on the area of establishing a regulatory system for NMRAs. The experiences of TFDA are also important lessons to be learnt. TFDA has successfully developed comprehensive legislative provisions and guidelines to cover all the key regulatory functions including diagnostics.

1.6.3 Need for Regulatory Reforms in Africa: Chimwemwe Chamdimba, AMRH/NEPAD Agency

The NEPAD agency, commissioned a situation analysis on medicines regulation in Africa. The study identified that most member states have national medicines policies & legislation that gives mandate to the government to regulate medicines within their territories. However, most of the laws were outdated and their comprehensiveness varied from one country to the other. The existing policies and legislations are territorial and they do not enable NMRAs to legally recognize decisions made by other NRAs, mutually recognize or accept and recognize joint regulatory decisions. This situation poses a challenge to achieving medicines regulation harmonisation. In response to this challenge, the NEPAD Agency in partnership with the AUC, PAP and AMRH partners, embarked on a processes to develop and Model Law on Medicines Regulation and Harmonisation in Africa which will be endorsed by the AU structure for adoption by the AU Summit. Once endorsed by the AU structures the model law will be available for Member States to use in the development and/or review of their national laws. This will enable amongst other benefits, countries to recognise decisions of collaborating NMRAs and other

regulatory systems. The model law is also a useful reference guide to help countries reviewing outdated pieces of legislation.

1.6.4 Strengthening regional capacity for regulatory reforms: Lessons learnt and experiences from the regional 'Flagship' course on Pharmaceutical Policy Reform in the Southern Africa Region: Celestine Kumire, SARPAM

Countries are at varying levels of development in human resources and infrastructure to drive effective medicines regulation. In this regard, there is need for political will and support as well as ownership to facilitate that gains made in medicines regulation harmonisation make a real lasting change in individual countries. There is need to focus on low-hanging fruits such as information and work sharing to kick-start regulatory harmonisation. It is important that in any medicines regulatory regime, Technical Working Groups with clearly defined terms of reference and membership of member states should be established. This will facilitate ownership by member states that will drive the agenda for policy and process change through the Technical Working Groups.

1.6.5 Pharmaceutical legislation and regulatory harmonisation: Samvel Azatyan, WHO-HQ

Implementation of medicines regulation and guidance is difficult where the legal framework is lacking. Legal systems and provisions are critical for the regulation of medical products. There are also issues that each country needs to consider when establishing pharmaceutical regulation. Medicines regulation is about standards and skills that operate within a legal framework. In developing comprehensive legislation on medicines regulation the following needs to be taken into account: (i) statement of purpose; (ii) defining scope of products; (iii) key elements of pharmaceutical legislation; (iv) creation of the NMRA; (v) defining roles, responsibilities, prohibitions and penalties. Pharmaceutical legislation should contain provisions for transparency and accountability. The first step in developing the legislation is to create an inventory and what is critical is whatever is done should involve key stakeholders that will be using the standards developed. Common legal framework in RECs is essential for harmonization to take effect.

Session observations and recommendations

i. Countries should consider Model law on medicines regulation and harmonization as a benchmark for strengthening regulations and to aid regulatory reforms. However, caution has to be taken not ensure that harmonisation is not taken as uniformity.
ii. There is need for strong advocacy on the model law to facilitate its adoption and implementation at the national, regional and continental level.
iii. RECs and countries should carry out impact assessment of the developed guidelines within the harmonization initiatives
iv. Results assessment / M&E model to track achievement of the harmonization to implemented with RECs and member states

1.7 Panel Discussion on Regulatory oversight of clinical trials in Africa: Where are we?

The panel comprising Dr. Nathalie Strub Wourgaft (DNDi), Christine Wasunna (KEMRI, IRB Representative), Mohamed Benslimane MANSOURI (NMRA Algeria) and Helen Ndagije (AVAREF) discussed the key milestones that have been made in clinical trial oversight in Africa through both regional and national initiatives. Focus was also made on some of the key challenges still outstanding and recommended steps that the continent should take to improve clinical trial oversight. The country experience of Algeria was also shared to facilitate peer learning. The structure of Algeria NMRA was explained with the various institutes involved in medicines evaluation, including the testing by the drug quality control laboratory. A centre of bioequivalence studies is required for conducting clinical trials and the use of healthy volunteers.

Overall the panel noted that there are some steps being taken to improve oversight of clinical trials through capacity building programme and joint activities implemented by initiatives like AVAREF. Joint reviews done through DNDi are one of the capacity building programme that is promoted as on-the-job capacity building exercises beside training courses for individuals. Furthermore, a lot of awareness has been created in countries and institutions on the importance of ethics in clinical trials. However, it was noted that some challenges are still prevailing including;

(1) Lack of clarity between the roles and responsibilities of ethics committees and regulatory authorities is a challenge in most countries. There is also minimal collaboration between the ethics committees and NMRAs leading to bureaucracy that influences the kind of study that can be done and inconsistency in decision making processes.
(2) Increased complexity of clinical trials entails new and unique ethics issues which require unique interventions by the ethics committees. There is therefore need to increase the capacity of ethics committees to match the complexity of science in clinical trials.
(3) There is administrative gap in most countries with limited infrastructural capacity to collect and share information within and between countries.
(4) There is still a challenge in monitoring and evaluation in the regulatory systems.

Key Recommendations

1. The AMRH Programme should mobilize other partners and resources to facilitate the creation of a platform for clinical trial oversight and consider the integration of AVAREF in the AMRH Framework
2. The capacity of ethics committees and regulatory agencies should be strengthened to match the complexity of emerging science
3. Collaboration and information sharing between the regulators and ethic committees critical for success

1.8 Improving efficiency of clinical trial applications review

1.8.1 Clinical Trials in Africa: Impediments and Opportunities: Joseph Fadare

With the increased need for treatment of non-communicable diseases like hypertension and diabetes mellitus in Africa there is need for clinical trials of medicines for treating these diseases to be conducted in African countries among the potential users. However, data from the clinical trial registration website (Clinicaltrial.gov) shows that out of about 147,867 trials that had been registered worldwide, only 3342 are carried out in Africa. It is a known fact that populations have variable genetic composition hence may respond differently to the same medication. There are however a number of challenges in conducting clinical trials in Africa including poor infrastructure in many African countries, lack of qualified clinical research personnel, cultural issues, lack of or inefficient regulatory authorities and lack of trust to deliver credible results are some reasons for this lopsidedness. Despite these drawbacks, there are opportunities for the African people and pharmaceutical companies in Africa. Promoting clinical trials would go a long way in improving access to health care for the teeming population of Africa through extended post-trial benefits, improved healthcare infrastructure and equipment and capacity building for healthcare personnel among other opportunities. However, African governments need to put in robust mechanisms for ensuring ethical, regulatory and business standards.

1.8.2 Timelines for ethical and regulatory review of clinical trial applications in low- and middle-income countries: challenges and opportunities: Loren Becker

Ethics committees and national regulatory authorities (NRAs) play an important role in ensuring that clinical trials are conducted safely and ethically. However, in most countries, they are not adequately resourced and have insufficient expertise to evaluate clinical investigations. Another challenge prevailing is lengthy and uncertain timelines for approval of clinical trial applications and amendments which at times substantially delay the initiation and conduct of clinical trials. Lack of coordination of reviews by ethical committees and NRAs within and across countries also prolongs process. These challenges ultimately lead to lengthened time for new interventions to reach patients and communities and may increase the cost of developing products significantly. The Global Health Regulatory Team comprising regulatory professionals working for non-profit product developers collected and analysed data on ethical committees and NRA review timelines for clinical trials in various therapeutic fields. The resulting data set represents nearly 60 Phase I through III trials of drugs, vaccines, and diagnostics conducted in 25 endemic countries over a 10-year period.

1.8.3 Research for Health and Innovation organiser (RHInnO): Striving for Quality and Efficient Review of Clinical Trial Protocols: Mary Kasule

The conduct of biomedical research and in particular clinical trials must be controlled by medicines regulatory authorities and research ethics committees to protect the rights, safety and welfare of human participant populations. Most African countries are however challenged with lack of capacity to enable quality and efficient review of clinical trial protocols. This is further complicated in the advent of demand for new technologies and health care techniques requiring increased volume and complexity of clinical trial protocols. Some of the issues that need to be addressed include reliance on manual systems for the review due to lack of electronic information management systems, various 'unlinked' databases and unreliable local servers. In response to these challenges, the Council for Health Research and Development (COHRED)-Web for Development (Web4Dev), created software called "Research for Health and Innovation Organiser for Ethics (RHInnO Ethics 1.0)". RHInnO is a customized web-based platform designed to manage the entire life cycle of a clinical trial protocol review process. RHInnO provides a quick and reliable near real-time data to monitor and evaluate the review process and enable communication among researchers and regulatory bodies.

Session observations and recommendations

- There is need to increase efficiency and effectiveness of the reviews of the NRAs and ethics committees.
- There is need to increase the pool of regulatory reviewers to enhance quality reviews.
- There is need to develop normal reference values that are relevant to the local settings where research is done.
- Networking and sharing of information (intra-national and International Collaboration) will play an important role in improving efficiency. Special attention should be paid on Risk Benefit Analysis and risk management (committees should have contingency plans of action).
- The use of online submission of applications with a document management system that provides easy access to information irrespective of location should be promoted.

1.9 Regulatory Capacity Development & Partnerships

1.9.1 Regional Centres of Regulatory Excellence (RCORE): Paul Tanui, AMRH/NEPAD Agency

Regional Centres of Regulatory Excellence (RCOREs) are being established as part of the implementation of the African Medicines Regulatory Harmonisation (AMRH) initiative. RCORE are expected to be institution or partnership of institutions with specific regulatory science expertise as well as training capabilities such as National Medicines Regulatory Authorities (NMRAs); university faculties; national or regional training centre or scientific and/or research institutions; industry, Quality Control Laboratory; Pharmacovigilance Centre; and/or Drug Information Centre. The RCOREs will produce regulatory workforce in Africa through: provision of academic training in regulatory science applicable to different regulatory functions and managerial aspects; skills enhancement through hands-on training, twinning and exchange programmes among NMRAs and practical training through placement in pharmaceutical industry. The eligibility criteria for consideration of RCOREs include regulatory capability; training capacity; existing governance & management systems; and supporting infrastructure.

1.9.2 Regulatory Capacity Development: Role of Centers for Pharmaceutical Advancement and Training (CePAT): Kwasi Pokun Boateng, USP/PQM

Regulatory capacity is the ability of a medicines regulatory authority to sustainably perform core regulatory functions effectively and efficiently. Medicines regulation is one of the fundamental success factors of any successful health system hence capacity building in regulatory science should be considered a health care and economic development priority. As part of addressing regulatory capacity gaps in underserved regions, the USP through its Global Health Impact Programmes has established the Centres for Pharmaceutical Advancement (CePAT) and Training. The centres are aimed at addressing the following challenges:

1. Limited regulatory capacity which contributes to the proliferation of substandard and counterfeit medicines
2. Heavy dependence on imported medicines from sources with minimal regulatory oversight prior to export
3. Poor GMP compliance by local manufacturers
4. Disease specific donor-funded programmes have little to no systemic impact on strengthening regulatory systems

CePAT provides an integrated platform for training, education, consulting and laboratory training. The centre provides its services to medicines regulators, official medicines control laboratories, manufacturers, donor agencies, procurement organisations and others in need of support in pharmaceutical training. The first CePAT centre in Africa was inaugurated in May 2013 in Accra, Ghana. The centre has so far provided concept and hands-on training to 65 participants from 8 African countries (Ethiopia, Ghana, Kenya, Liberia, Sierra Leone, Nigeria, Senegal and Zambia). Three custom programmes have also been organised since May 2013. The CePAT laboratory has tested products from Ghana and Sierra Leone.

Looking forward, CePAT plans to launch five programmes in:

1. Project management for pharmaceutical industry
2. Bridge programme – College Graduates Industry Induction Training
3. Purchasing equipment and capital acquisition
4. GMP for executive management

1.9.3 Role of Academia in medicines Regulation: Centre for Drug Discovery, Development and Production (CDDDP): Prof. Chinedum Peace Babalola

Africa's ability to discover, develop and regulate medicines that meet local needs is mainly hampered by lack of pharmaceutical innovation and critical mass of trained pharmaceutical scientists and professionals with the technical know-how. This has made the continent dependent on imports in meeting local needs for essential medicines with about 90% of available drugs in Sub-Saharan Africa imported mainly from Asia. As part of addressing this challenge and contributing to drug development and medicine regulation, the Faculty of Pharmacy, University of Ibadan, Nigeria through a MacArthur Foundation grant set up a Centre for Drug Discovery, Development and Production (CDDDP). The Centre aims at addressing the following objectives:

- Developing and running postgraduate Diploma and Masters programmes in drug development and medicine regulation as well as short courses.
- Strengthening existing facilities for research and development (R&D) in drug discovery, development and production
- Establishing a facility pre-qualifiable by WHO for pilot manufacturing and quality assurance of medicines circulating in the sub-region.
- Providing services for regulators and pharma industry in areas of bioequivalence, clinical trials, drug analysis and pharmacovigilance.

Some of the notable achievements of the Centre include the launch of two part-time post-graduate courses targeting regulators, pharmaceutical industry, academia and others i.e.:

1. Postgraduate diploma in Drug Development
2. Master of Science Degree in Drug Development and Regulatory Pharmacy

The center also offers short courses and training sessions, Training of Trainers and convenes regulatory conferences to facilitate knowledge exchange and sharing of lessons and best practices.

1.9.4 EDCTP Networks of Excellence (NoEs): Dr Thomas Nyirenda, EDCTP

The European & Developing Countries Clinical Trials Partnership 1 (EDCTP) was set up with the objective of accelerating research and development of new or improved clinical interventions against these diseases through the coordination of the European member state national programmes working in **partnership** with sub-Saharan African countries and other global product development partners. Through EDCTP, networks of excellence have been established

as a consortium of institutions working together to strengthen team and individual capacities for clinical research. These institutions have varying capacities but utilise their complementary strengths to support each other paying attention to the less endowed members. The networks are therefore envisaged to strengthen clinical trial capacity, collaboration and quality of clinical research in Africa.

So far, the EDCTP Networks of Excellence have achieved the following:

- 63 students are being trained at Bachelors, Master's and Doctoral level, 4 postdoctoral researchers and 11 Senior Fellows
- There have been 988 enrolments for short-term courses
- 24 laboratories are undergoing revitalization for accreditation using WHO SLIPTA system
- 24 studies (baseline, epidemiologic and social) are being supported
- Networking (inter network training, exchange visits, reciprocal trial monitoring and joint grant applications)
- Refurbishment of sites and purchase of equipment
- The networks provided input to NEPAD's consultation process on how to improve regulatory functions in Africa
- Publications in journals including 22 publications in CANTAM, 13 in EACCR and 8 in TESA

Future activities of the NoEs will include (i) support to multi-centre research (regional or pan-African); (ii) contribution to strengthening of ethics reviews in regions; (iii) contribution to strengthening of regulatory activities; and (iv) contribution to efficient disease surveillance and control.

1.9.5 Creating a Regulatory Profession in LMICs via a Global Regulatory Curriculum Framework: Beverly Corey, US-FDA

Lack of high quality and consistent training for food and drug regulatory staff is a major challenge in ensuring food and drug safety across the globe, especially in low and middle income countries (LMICs). This was noted by the report, on "Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad," in 2012. Recently, efforts have been initiated by a multi-stakeholder group comprising non-profits, government, industry and standard setting organizations to create a competency based, modular curriculum to educate regulatory staff in LMICs which will include defining the minimal competencies needed by regulatory professionals in LMICs. The resulting competency/curricula could be effectively integrated into strategies for education and training with various centres of excellence. The global curriculum is expected to create a global regulatory professional identity and a core-competency based training which will help to protect and promote global public health by ensuring drug and food safety.

1.9.6 Capacity Building and Partnership in Regulation of Vaccines for Tuberculosis in Africa: Michael Brennan; USA

Nine African countries are among the 22 High Burden Countries (HBC) which account for 82% of the 8.7 million global tuberculosis incident cases in 2011. Global Epidemiological Goals for TB control are unlikely to be met *without an effective vaccine.* Currently 90-year-old BCG vaccine is the most widely used vaccine for TB in the world. However, though it reduces the risk of severe pediatric TB disease, the vaccine is unreliable protection against adult pulmonary TB, which accounts for most TB worldwide and hence has no significant impact on the global TB epidemic. The vaccine is also not known to protect against latent TB and is not recommended for use in infants infected with HIV.

The last decade has seen 15 novel TB vaccine candidates going to clinical trials and robust pipeline of 2nd generation candidates, novel vaccine constructs and new delivery platforms are being explored. In order for these vaccine candidates to benefit high burden countries, there is need for capacity and infrastructure development for large-scale trials. Specific capacities need to be developed along the regulatory pathways as well as market and economic impact research to accelerate adoption and uptake of new TB vaccines.

Session observations and recommendations

- Regulatory Science should be considered as a profession and efforts should be made to:
  - develop expertise in all the regulatory fields,
  - AMRH to facilitate the establishment of regional centres of regulatory excellence to increase the regulatory workforce in Africa
  - Engage the academia in the development of a common regulatory science curriculum that is dynamic and meets the needs of the continent
- Training quality assurance measures should be instituted to ensure quality, relevance and response to needs of countries in Africa and impact
- Medicines regulation in Africa should embrace the important role that the African Diaspora can play and provide a platform and opportunity for their engagement. The pool of regulatory experts should be utilised as a means for engaging the Diaspora.
- Sustainability and success in medicines regulation harmonisation will only be achieved if it is anchored on competent professional in all areas of regulatory science.
- Training should be tailor-made to reduce the gap that exists between the academia, regulatory agencies and the industry.
- The AMRH partnership platform should be presents an opportunity for alignment of initiatives and collective impact in regulatory capacity building in Africa.

1.10 Partnerships in regulatory capacity development

1.10.1 Health Canada's Regulatory Capacity Building Activities in Support of Developing National Regulatory Authorities; Greg Monsour

Infectious Diseases constitute a huge health and economic burden across Africa. One in three worldwide is at risk of a Neglected Tropical Disease. These infectious diseases strike the world's most vulnerable populations – those without access to clean water, basic sanitation or healthcare – making it almost impossible for these communities to lift themselves out of poverty. Capacity gaps have been identified as a key challenge. In efforts to build regulatory capacity leveraging private industry capabilities in drug discovery, regulatory processes, clinical trials and product life-cycle management is an effective approach. Mentorship programmes are effective strategies for capacity building principally because it provides tangible and lasting outcomes. Regulatory capacity also has to be strengthened on an organizational level and not just training of individuals. Participant NRAs in mentorship programmes also been shown to have enhanced their knowledge and the way they regulate vaccines. NRAs are therefore motivated to continue driving capacity building from within, based on momentum gained from mentorship. Drug regulation incorporates several complementary activities that are mutually reinforcing and that all aim to promote and protect public health. Their implementation differs from one country to another, but they are common in sharing the relevant standards to ensure public health: quality, safety, efficiency and performance.

1.10.2 Role of a regional economic community in the harmonisation of pharmaceutical regulations at national level: the experience of the Economic and Monetary Community of Central Africa (CEMAC): Helene Degui, Cameroon

In keeping with its mission of implementing the coordination of development programmes, the Commission of the Economic and Monetary Community of Central Africa (CEMAC) in 2007 created a sub-regional programme for the Harmonisation of National Pharmaceutical Policies. The harmonisation programme emphasises on supporting efforts towards regulatory capacity development programmes towards the establishment of autonomous NMRAS and implementation of good regulatory practices such as the WHO prequalification. However, key success factors to harmonisation efforts in the region include (i) the existence of regional structures to support proper coordination of harmonization initiatives; (ii) global political commitment and support by all partners; (iii) proper planning and availability of adequate resources. Advocacy for ensuring stakeholders buy-in and participation including national health departments, international partners, and local and international organizations and civil society in the process is important for accomplishment of the harmonisation goal.

1.10.3 Strengthening regulatory and partnership regulation; Mohamed Benslimane Mansouri

A systematic product evaluation process was established at the national laboratories in Algeria 15 years ago. The National Laboratory for the Control of Pharmaceuticals (LNCPP) is a member

of the Franco-African network of quality control laboratories, observer member of the European Pharmacopoeia, and a WHO Collaborating Centre for Drug Compliance. The centre has been qualified as reference centre for drug control at an international level and is accredited in ISO 1725 standard.

Product evaluation process in the national laboratories is supported by international standards. Algeria is also finalizing the Algerian Pharmacopoiea. Technical evaluation is important and involves the quality control of raw materials and bioequivalence of drugs amongst other activities. There is also an autonomous Pharmaceutical Commission. However, there is still need for benchmarking to learn from what already exists. Algeria is therefore working closely with WHO, NEPAD and USAID to improve the regulatory system and exchange of good practices.

1.10.4 Building capacity in African research institutions through facilitated partnerships and scientist exchange; Jennifer Dent, Bio Ventures for Global Health

Infectious diseases devastate the lives of over 2 billion people living in poverty. These diseases not only cause significant morbidity and mortality, but the number of productive life-years lost has a crippling effect on endemic countries' economies. To reduce disease and death, and positively affect health and wellbeing of individuals in the developing world, BIO Ventures for Global Health is taking a unique approach to capacity building. Developing world countries often have significant gaps in biomedical research and development, including managing regulatory processes and filings, project management, understanding of clinical trial management, drug discovery and development, and broad industry dynamics. Facilities within these countries lack the necessary experience to successfully take a program from early discovery through to commercialization. In order to address these gaps, BVGH facilitates hosting and exchange programs for African scientists to gain first-hand knowledge and experience and learn from some of the world's largest pharmaceutical and biotechnology companies. Participating research institutions identify areas of weakness where they want to expand their capabilities and knowledge including learning about intellectual property management, the processes of research and development innovation, regulatory process management throughout the product life-cycle, cutting-edge manufacturing techniques, and knowledge management from pharmaceutical industry experts. Upon return to their home institution, the African researchers are able to apply what they have learned during their experience, thereby implementing new, much needed product research and development programs within their institutions.

Session observations and recommendations

1. It is necessary to map, document and assess the impact of training programmes that have been undertaken in Africa. Statistics should be assigned to such assessments in terms of who are being trained, attrition rates and which regulatory sectors are affected.
2. Partners should consider collaborating with academic institutions to aid in regulatory capacity development

3. Opportunities exist with partnerships at RECs level. RECs should be involved in the capacity building in countries.
4. Investment in training in pharmacovigilance should also target high level policy makers, and those in executive management in Regulatory Authorities and industry.
5. Capacity building initiatives should be in tandem with technological developments in industry
6. There is need to leverage private industry capabilities in drug discovery, regulatory processes, clinical trials and product life-cycle management in the design of capacity building programmes
7. Governments and policy makers should consider improving remuneration of regulatory personnel especially in public sector to prevent HR movements witnessed in most countries.
8. Health Canada HIV Vaccine Initiative (CHVI) Regulatory Capacity Building Approach that involves mentoring in the area of vaccine and clinical trial regulation that is tailored to the needs of participant NMRAs is a model that should be considered by other regulatory capacity building partners for establishing Regulatory Capacity Mentorship Programmes

1.11 Initiatives, country experiences and perspectives in regulatory capacity development

1.11.1 Increasing Access to Quality Essential Medicines and Services by Drug Shops in Uganda through Accreditation; Kate Kikule

Drug stores provide medicines and health care products to most of the rural population of Uganda. However, these shops are sometimes not licensed, have unqualified personnel and sell medicines that may be of uncertain quality. A project was therefore initiated to transform existing Class C drug shops into well regulated Accredited Drug Shops (ADS), so that people living in rural communities have access to quality medicines. The project supported setting standards for operations and the facility, training drug shop operators in drug management and support supervision was provided from district level. Advocacy campaigns were conducted to raise consumer awareness of the importance of buying medicines from licensed sources. The project resulted in a reduction in the percentage of drug stores that were not accredited and increased availability of essential medicines. This result indicate that accreditation of Class C drug shops into ADS improved access to quality products and services in retail drug shops that serve populations living in rural areas

1.11.2 Comparative dissolution profiling as a basic requirement for product licensing in the West African sub-region; Ndidi Ngwuluka

In vitro bioequivalence studies ought to be undertaken for product licensing and post-production by regulatory authorities and researchers in order to protect public health from substandard medicines. *In vitro* dissolution profiling is a more accurate approach than single point assay for bioequivalence studies. The provisions of the USFDA on biowaivers for bioequivalence studies were applied to three (3) brands of an antiretroviral, twelve (12) sulfadoxin-pyrimethamine and six (6) ciprofloxacin solid dosage forms available in Nigerian market. Dissolution apparatus II was employed for the antiretrovirals (ARVs) and sulfadoxin-pyrimethamine (SP) dosage forms while dissolution apparatus I was employed for the ciprofloxacin tablets/caplets using dissolution media (0.1 N hydrochloricacid and phosphate buffers at pH 4.5 and 6.8) at 37^{o}C and 50rpm. Samples were withdrawn at pre-determined intervals and assayed using liquid chromatography for ARVs and Ultra-Violet spectrophotometry for SPs and ciprofloxacin tablets/caplets. Similarity factor $f_2$and difference factor f_2 were utilized to compare the dissolution profiles for bioequivalence and ascertain if the different brands can be used interchangeably. Two ARVs were considered rapidly dissolving and bioequivalent; while both were bio-inequivalent to the reference product. The reference, prequalified by WHO did not exhibit greater than 85% in 15min and so was not considered a rapidly dissolving product. Furthermore, 5 out of 12 products of SPs compared favorably with the reference product. Three SPs brands released less than 30% of the active ingredient after 60min, while 3 of ciprofloxacin brands may not be used interchangeably with the innovator product. Dissolution profiling is a practical substitute for *in vivo* bioequivalence studies that African countries can utilize for product licensing and post monitoring of medicines. Consequently, it is suggested that regulatory authorities in Africa should implement the provisions of regulations or enact where they do not exist already.

1.11.3 Swaziland Ministry of Health and SIAPS Partnering in Strengthening Regulatory Capacity; Khontile Kunene

Medicines regulation in Swaziland is currently governed by the Pharmacy Act of 1929, which does not provide for the effective regulation and control of medicines. To address the gaps prevailing in the control of medicines, Management Sciences for Health, through the USAID funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program, supported the Ministry of Health in:

(i) Legislation review to develop the Medicines and Related Substances Control Bill (to establish the MRA) and Pharmacy Bill (to establish the pharmacy council).
(ii) Establishment of an interim MRA working desk to undertake some functions of the MRA and prepare for the establishment of the MRA upon the enactment of the Medicines Bill.
(iii) Building capacity of MRA desk through benchmarking consultative visits to more established SADC regulatory authorities.
(iv) Development of a Pharmaceutical Services Strategic Plan 2012-2016.
(v) Development of an MRA establishment plan.

As a result of these interventions, the following has been achieved:

a) The Medicines Bill was passed by the House of Assembly in July 2013 and is currently awaiting discussion by the House of Senate.
b) The MRA establishment implementation plan was developed to guide the formation of the MRA.
c) Draft regulations have been developed to facilitate the prompt implementation of the Medicines and Related Substances Control Act.
d) A medicines listing/registration database is under development to register all medicines imported, sold and used in Swaziland.

There is political will to establish the MRA in Swaziland and with Partner support, the Ministry has made commendable progress towards the establishment of the Swaziland Medicines Regulatory Authority (MRA).

1.11.4 Regulatory Capacity Building Efforts in NAFDAC, Nigeria; Monica Doo Eimunjeze; Nigeria

Realizing the need for strengthening regulatory capacity within NAFDAC, the Agency in collaboration with partners has initiated a number of capacity building efforts as well as participation at international fora to expose staff to best practices. A mentorship programme has been initiated between NAFDAC and Health Canada under the Canadian HIV Vaccine Initiative (CHVI) Regulatory Capacity Mentorship Program. The programme aims as building capacity in the six critical functions of vaccine regulation. In-house capacity building has become entrenched allowing for continuous sharing of information and knowledge dissemination. NAFDAC is also involved in the harmonization efforts being coordinated by the West African Health Organization (WAHO) within the West African Sub-region. We are involved in WHO programs such as the Paediatric Medicines Regulatory Network (PmRN), Collaborative

procedure for registration of WHO pre-qualified medicines, and the Expedited procedure for registration of WHO pre-qualified vaccines. We are also involved in the United Nations Commission Program for Life Saving Commodities for Women and Children.

1.12 Panel Discussion: Substandard & falsified medicines: what is Africa doing to combat the menace?

The panel discussion focussed on some of the key challenges that Africa is facing in combating substandard and falsified medicines, the prevailing opportunities for the continent to combat the menace and recommendations on strategic actions that can be taken. The panel comprised of Prof Jean Baptiste Nikiema (WHO-AFRO), Sybil Nana Ama Ossei-Agyeman-Yeboah (ECOWAS/WAHO), Margareth Ndomondo-Sigonda (NEPAD Agency) and Paul Botwev Ohrii (NAFDAC) also focused on some of the lessons being learnt in control of substandard and falsified medicines in Regional Economic Communities.

The panel noted that counterfeit medicines are a global problem that required Africa to cooperate and partner with international organisation in fighting against it. Networking will facilitate joint operations in detecting and alerting as well as sharing of good practices in fighting against counterfeit medicines. Some of the key challenges that Africa is facing in the fight against counterfeit medicines include:

1. Lack of access to safe and quality medicines to the majority of the African population has made sale of counterfeit medicines lucrative as they are filling the identified vacuum. Increasing access to safe and quality medicines to the majority of the population to have a positive impact on reduction of counterfeit medicines.
2. Most of the Africa countries do not have clear policies and legal framework to support the fight against counterfeit medicines. This has led to fragmented and uncoordinated efforts by the key sectors involved in the fight against counterfeit medicines. There is need for clear policies and legal frameworks that will facilitate coordinated efforts between key players such as the NMRAs, police, customs and trade as well as international partners including Interpol, World Customs etc.
3. The multiplicity of stakeholders in the medicines market at country level has increased complexity in the supply chain which requires strong monitoring. The increase in number of stakeholders in the supply chain has not been matched with increased capacity on the national regulatory authorities on the other hand resulting in the proliferation of counterfeit medicines.
4. Lack of coordination of effort in the fight against counterfeit medicines at the national, regional and continental levels has led to minimal strides being made at all levels.
5. Though the challenge of counterfeit medicines has a direct impact on the consuming population, not much is being done to educate patients. Not much can however be achieved without the involvement of the affected population.
6. Fighting counterfeit medicines required technological solutions. However, the tools developed at the international level do not always fit to work at the country level. There is therefore need to adapt such tools to fit country specific context and needs.

Recommendations

- AMRH Initiative should spearhead regional and continental coordination in strengthening capacity to address the global public health problem of substandard and falsified medical products drawing from the WHO member states mechanism
- NMRAs should consider the introduction of innovative technologies for detecting falsified and substandard medicines

1.13 Strengthening Pharmacovigilance Systems in Africa

1.13.1 Pharmacovigilance systems in developing countries: Dr. Shanthi Pal, WHO-HQ

World Health Assembly Resolution 16.36 invites Member States to arrange for a systematic collection of information on serious adverse drug reactions observed during the development of a drug and, in particular, after its release for general use. It is also noted that in building Pharmacovigilance system relevant to Africa there is need to focus on establishing minimum PV structures and functions; capacity building; public health focus; signal detection that is relevant to the region and that PV should be part of health system strengthening (HSS).

Currently in the African Region 32 countries are full members of the WHO Programme for International Drug Monitoring while 6 countries are Associate Members. 15 countries are not yet members of this Programme and are encouraged to join. Most PhV systems in Africa are extremely new and at their very early stages of development. Most members are still collecting data without any capability or capacity to turn that data into usable information. There is also lack of human and financial resources. Despite these challenges PV has been seen by most countries as critical and important for patient care and safety.

1.13.2 Improving patient safety: practical pharmacovigilance challenges: Prof. Alex Dodoo, Uppsala Monitoring Centre (UMC)

In a report on *Safety of Medicines in Sub-Saharan Africa: Assessment of Pharmacovigilance Systems and their Performance* it was noted that 59% of countries surveyed have no national policy on PhV; 70% have no legislation for ADR reporting; 83% still do not require post-marketing surveillance activities while requirements vary greatly across countries. Furthermore 26% have no PhV centre; 61% have no national guidelines; 61% have no drug safety advisory committees and many PV activities are vertical and/or individual project driven activities. Sustainability is also often threatened by lack of budget lines for PV. More challenges of reporting and managing ADRs in Africa include the fact that health care professionals and workers generally don't see the need and benefit to report side effects. There is also usually no immediate patient benefit. Aggregate results of ADR reports are not considered prior to revising treatment guidelines. There are also concerns of very questionable quality of reported cases via the common/traditional ADR spontaneous reporting approach. NMRAs are not equipped to contribute to case management and interventions. The specific aims of PV were reiterated as to improve patient care and safety; improve public health and safety in relation to the use of medicines; contribute to the assessment of benefit, harm, effectiveness, and risk of medicines; encourage their safe, rational, and more effective (including cost-effective) use.

1.13.3 Pharmacovigilance online reporting system in Kenya: Ali Arale, PPB-Kenya

Kenya NMRA Pharmacy and Poisons Board reported an improved PV situation since the launch of the PV system. The situation further improved as a result of adoption of innovative initiatives including a suite of software applications implemented for collection and processing of

information on suspected Adverse Drug Reactions (sADRs) and Poor Quality Medicinal Products (sPQMPs). This system enables electronic submission of sADR and sPQMP reports via a web portal using either a computer or mobile device. The innovative approach was developed due to challenges encountered in the use of manual forms and use of courier system for reporting suspected ADRs and poor quality medicines.

1.13.4 Setting up a pharmacovigilance centre: Experiences from Ghana: Delese Darko, FDB-Ghana

Ghana FDA reported several developments in the evolution of the PV system in the country. These include introduction of Institutional Contact Person (ICP) System from Healthcare Facilities where healthcare facility staff serve as vital link between institutions and the National PV Centre; inclusion of regional hospitals, clinics, private hospitals; and decentralization of PV activities with FDA Regional Contact Persons. Efforts have also been made to improve collaboration with Public Health programmes.

One of the key strategies adopted focuses on awareness creation and targeted training of primary reporters and collection of spontaneous reports. Active Monitoring is promoted where Cohort Event Monitoring (CEMs) for Public Health Programmes is conducted. It is noted that as a result of strengthening the PV system in Ghana some gains include identification of unregistered/counterfeit and sub- standard products through the spontaneous reporting system.

1.13.5 Improving ADR signal generation through a Patient-focused Pharmacovigilance Program in South Africa: Prof. Henry Fomundam, Howard University

The South Africa National Pharmacovigilance Centre, through its new and unique decentralized pharmacovigilance system currently being rolled-out throughout the country, continues to create strong links and networks with all healthcare programs at all levels. The Centre is collecting drug safety data from the National HIV/AIDS ART programme to be synthesized into information that will enhance patient safety. The information is also forwarded to the medicines regulatory authority on a continuous basis so that when necessary, they can take appropriate regulatory action.

The overall objectives of the decentralized pharmacovigilance programme are several-fold. Among others, they involve the establishment of the designed system at primary healthcare level, a first of its kind in South Africa. Secondly, the centre also aims at generating ADR signals in HIV/AIDS ART in SA; a platform envisaged to take on other indications in the near future.

A significant increase in ADR reports associated with the use of ART was observed as well as an immediate improvement in patient management and treatment outcomes. As the PV database grows, periodic review of the aggregate ADR data and local experience will inform clinical care, treatment guidelines and national policy. It will also play a key role in drug regulation by the medicines regulatory authority.

1.13.6 Post-Marketing Safety Measures: Lessons learnt in Africa: Jude Nwokike, MSH/SIAPS

MSH/SIAPS conducted an assessment of PV systems in sub-Saharan African and published a report in 2012. The survey targeted a representative sample of all stakeholders in the PV system including pharmaceutical industry, health facilities, public health programs, academic institutions, etc. Data was collected using local consultants; verifying and benchmarking systems capacity and performance. Countries were grouped by capacity of their PV systems. Lessons learnt include challenges of limited and disparate regulations for PV and for securing the supply chain; falsified and substandard medicines is a major concern and key source of medicines-related harm in Africa. Based on the survey results it was recommended that focus of active surveillance activities should be on quantifying and characterizing clinically significant risks. Information sharing on safety and quality of medicines within the regions is very limited. Electronic health records (EHR) are currently the most important source of information to capture the real-world setting, and should be used to assess the effectiveness (real-world effects) and safety of medicines, especially in populations that are not sufficiently included in clinical trials. Medicines quality and safety surveillance should be integrated into existing health surveillance structures.

Session observations and recommendations

1. There is need to build Pharmacovigilance systems that are relevant to the African region and signal detection that is relevant to the region
2. Pharmacovigilance should be integrated as one of the key building blocks of health system strengthening
3. Pharmacovigilance should be integrated as a core regulatory function for sustainability
4. Electronic Medical records should be introduced as a standard way of capturing longitudinal patient treatment data
5. The AMRH Platform should be utilized for harmonization of Pharmacovigilance systems in Africa
6. Pharmacovigilance Electronic Reporting System is recommended to enable electronic submission of suspected Adverse Drug Reaction (sADRs) and suspected poor quality medicines (sPQMs)
7. Decentralization of pharmacovigilance systems to improve the reach of pharmacovigilance services will stimulate the interest of Health Care Professionals (HCP) and other Health Care Workers (HCW) to freely and voluntarily report ADRs
8. Countries need to strengthen systems for pharmacovigilance including policies, guidelines, reporting forms and SOPs, and drug safety advisory committees
9. There is need for a concrete legislative and regulatory framework for pharmacovigilance systems in countries
10. Financing from partners should be invested in pharmacovigilance of medicines procured

1.14 Initiatives and country experiences in pharmacovigilance

1.14.1 Paediatric PV: Use of PV data mining algorithms for signal detection in paediatric phase IIIb clinical trial safety data set from 7 African Countries; Dan Kajungu

No drug is completely safe. Additionally children are not small adults, there may be unique ADRs that occur in children and not adults or with higher frequency or are more serious. Paediatric pharmacovigilance is still poor in Africa. Clinical trials safety data can be used to cover this gap. Furthermore, National Regulatory Authorities have huge drug safety databases from clinical trials. Regulatory authorities can use safety data reported in late phase clinical studies for key PhV activities like signal generation and evaluation.

1.14.2 Strengthening PMS in Africa The NAFDAC consumer safety Club (NCSC) Experience; Adeline Osakwe

The NAFDAC Consumer Safety Club (NCSC) is an innovative model being promoted as a platform for effecting behavioural change through enlightenment among the populace at a particular age group where they are expected to imbibe the culture of quality and propagate this value to the general public at large. The Club was formed as part of NAFDAC's PMS strategy for eradicating, fake and substandard products from circulation. It creates a forum for educating secondary school students on the circulation of fake products and promotion of quality products. It also empowers students to disseminate information on NAFDAC regulatory activities to their immediate communities.

Through this platform, a pool of young Nigerians who have good understanding of how to avoid fake, substandard regulated products, know how to read and understand product labels and are knowledgeable about adverse drug reaction reporting among other benefits has been nurtured. The club has also been used as a platform for conducting Knowledge, Attitude and Practice Survey on pharmacovigilance/post-marketing surveillance hence availing the Agency information on perception of the public on the impact of its activities and programmes.

1.14.3 Barriers and facilitators to suspected ADR reporting among HCP's in Uganda; Ronald Kiguba

Pharmacovigilance systems are relatively new in Africa and there is a paucity of published literature on adverse drug reactions (ADR) reporting in these settings. The study on barriers and facilitators to suspected ADR Reporting among HCP in Uganda employed a cross-sectional design with both descriptive and analytic components. The survey was conducted in purposively selected, geographically diverse health facilities in Uganda. Healthcare professionals in public, private for-profit and private not-for-profit health facilities in both rural and urban settings were selected. Among the study recommendations are that priority should be given to more private sector engagement and targeting older healthcare professionals in future interventions to improve ADR reporting. More engagement of Private For-Profit health facilities is critical to

strengthen PhV systems in countries. Active reporters are also found to be more informed about ADRs and are more likely to identify and report ADRs.

1.14.4 Strengthening PV systems in the Kingdom of Swaziland; Nomsa Shongwe

In the Kingdom of Swaziland, a number of activities were employed in strengthening pharmacovigilance activities. These include: capacity building for the pharmacovigilance unit; reviewing, printing and dissemination of Adverse Drug Reaction reporting forms and Standard Operation Procedures; development of tools (SSASSA & DCAT) for active surveillance of TB and HIV medicines; development of medicines safety watch newsletter for risk communication and the introduction of Active surveillance system at 6 pilot sites.
All the interventions are building blocks for a functional pharmacovigilance system. Several lessons have been learnt as a result of implementing these activities. The phased-in and participatory approach used in Swaziland has yielded a country-driven and owned process.

1.14.5 Strengthening monitoring of ADE in Nigeria; Adeline Osakwe

NAFDACs National Pharmacovigilance Centre (NPC) Pharmacovigilance Rapid Alert System for Consumer Reporting (PRASCOR) is an innovative tool that empowers a consumer who experiences ADR from use of a medicine to send a short text message to a prepaid short code using designated mobile network services. The network provider converts the message to an email and sends to the NPC where a trained NPC staff contacts the sender to facilitate completion of individual case safety reporting form.

1.14.6 Cohort event monitoring of artmether and lumafentrine in public facilities in Tanzania; Alambo Mssusa

Artemisinin combination therapies such as Artemether/Lumefantrine (ALu) are known to be effective for treatment of malaria and are used as first line treatment of uncomplicated acute falciparum malaria in Tanzania. However, the safety profile of ALu in large populations has not been fully assessed. The main objective of the study was to monitor adverse events associated with the use of ALu in public health facilities in Tanzania. The study conclusions were that the events observed were similar to those reported in literature. The safety profile of ALu for treatment of p. falciparum malaria continues to be favourable. Cohort Event Monitoring (CEM) as a pharmacovigilance tool requires sufficient resources and commitment of all involved stakeholders. CEM as a PhV tool provides safety data quickly and can be used to monitor new Public Health Programmes (PHP) medicines. CEM requires sufficient resources, commitment of healthcare providers and engagement of all stakeholders in order to meet its intended objectives.

Session observations and recommendations

1. Use of clinical trial drug safety data is recommended for use where pharmacovigilance systems are lacking

2. Regulatory authorities should consider using drug safety data reported in late phase clinical studies for key Pharmacovigilance activities like signal generation and evaluation
3. Data mining algorithms need to be considered and adopted for signal detection in spontaneous reports
4. Regulatory authorities should consider involvement of consumers and consumer groups in Pharmacovigilance activities. The NAFDAC Consumer Safety Club (NCSC) may be considered as a model for this purpose.
5. Using e-based approaches in information dissemination is recommended where consumers and consumer groups are involved in pharmacovigilance to reduce the cost of implementing programmes and activities
6. Regulatory authorities should engage for-profit health care facilities for pharmacovigilance reporting
7. Regulatory Authorities should consider subscription to Vigibase™ -WHO global Individual Case Safety Report (ICSR) database and tap into WHO UMC routine signal detection processes
8. It is recommended that pharmacovigilance data should collated, analysed and disseminated to all relevant stakeholders for decision making and development of risk management plans. Data collection tools & Database should be well developed ,validated and should include all key data elements
9. Cohort Event Monitoring (CEM) as a pharmacovigilance tool provides safety data quickly and can be used to monitor new Public Health Medicine (PHP) medicines
10. WHO should consider supporting countries to conduct Cohort Event Monitoring (CEM)

1.15 Providing an enabling environment for pharmaceutical production in Africa

1.15.1 Pharmaceutical Manufacturing Plan for Africa (PMPA): Its role in public health and development; Janet Byaruhanga

The Pharmaceutical Manufacturing Plan for Africa (PMPA) was adopted by the African Union to facilitate strengthening the continents ability to manufacture high quality, affordable pharmaceuticals across essential medicines. The PMPA is expected to directly contribute to increased access to affordable quality medicines, sustainable supply of essential medicines, improved public health outcomes and the realization of direct and indirect industrial and economic benefits. The key factors for enabling the achievement of the goals set within the PMPA include:

1. Strong independent and predictable regulatory system
2. Availability of the requisite human skills and access to know-how in the short term
3. Increased competition leading to continuous product improvements, increased production and distribution efficiencies, enhances sales and marketing efforts and service and business model innovation
4. Reduced demand uncertainty and accurate forecasting
5. Enhanced regulatory oversight
6. Investment and access to affordable finance
7. Provision of time-limited, easily understood, and accessible incentives

The PMPA has therefore been developed on the following pillars;

1. Human resource development
2. Access to product and technology
3. Access to affordable finance and time limited incentives
4. Regulatory systems strengthening and enforcement
5. Partnership, collaboration and fostering business linkages
6. Enhancing market data collection and facilitating market access

Three key essential conditions have been identified to form a solid foundation for the achievement of the PMPA including: (i) Sound sector strategy; (ii) policy coherence; and (iii) political commitment.

1.15.2 Industry perspective on medicines regulation and harmonisation; Emmanuel Mujuru

Federation of African Pharmaceutical Manufacturers Associations (FAPMA) was inaugurated in 2013 to facilitate collaboration between regional pharmaceutical manufacturing associations to address the common challenges faced by the industry and enhance opportunities towards self-sufficiency. FAPMA engages in advocacy and partnership with key stakeholders in promoting the production of quality, affordable medicines. The current membership of FAPMA includes FEAPMA, SAGMA and WAPMA which are regional pharmaceutical manufacturers' association.

According to Mr. Mujuru, one of the major challenges faced by the African manufacturers is the overly reliance on imports to meet the continent's essential medicines needs which is negatively impacting on the local industry. This translates to patients' vulnerability due to insecurity in supply and lack of long term sustainability. It is important to note that, the emerging pharmaceutical market in Africa is expected to be $20 billion by 2016. This therefore emphasizes the need to reorganize and strengthen local pharmaceutical industry and underscores the necessity of ensuring quality, safety and efficacy of the locally produced medicines. He indicated that lack of harmonized regulatory system poses challenges in hampering intra-regional trade, fighting the readily available fake and substandard medicines, causes fragmentation of markets and high cost of doing business. He indicated that harmonization will lead to growth of the Africa based pharmaceutical industry leading to increased access to affordable quality assured medicines across Africa. In this regards FAPMA strongly advocates for: (i) establishment of Regional Medicines Regulatory Agencies; (ii) standardization of registration and inspection procedures; (iii) development of NMRA to operate in accordance with international standards; (iv) competent regulatory affairs functions within the industry; (v) industry's participation and involvement in harmonization; (vi) consultative processes at all levels; and (vii) regular meetings between industry and MRAs

1.15.3 Mapping of the Pharmaceutical Manufacturing Capacity in the WHO Eastern Mediterranean (EM) Region; Mohamed Abdelhakim Farag

A study was conducted to map the current situation of pharmaceutical industry's manufacturing capacity in the 23 Member States of the WHO EM region. Primary data was collected from NMRA's from 23 Member States of the WHO EM region. Results of the study indicated that there are 74 local pharmaceutical manufacturers registered in the 12 responding countries ranging from public and private sectors, including joint ventures, and multinational manufacturers. The highest number of contract manufacturers was in Morocco. In 9 countries there were more than 3 companies in the process of licensing and planned to become operational in the period of 2012-2015. Out of the 714 manufacturers, more than 130 manufacturers produce at least one molecule for treatment of non-communicable diseases (NCD). 11 manufacturers in 4 countries produce anticancer medicines[1]. The study further noted that less than 20 manufacturers export to ICH markets[2] and production of active pharmaceutical ingredients (API) takes place only in 3 countries. The average time for issuance of manufacturing licenses was 5 months. There are efforts ongoing on harmonizing regulatory requirements, particularly among the member countries of the Gulf Cooperation Council.

1.15.4 WAHO Regional GMP scheme and access to finance by local manufacturers; Sybil Nana Ama Ossei-Agyeman-Yeboah

WAHO GMP Scheme and Access to Finance by Local Manufacturers has been set up with the following objectives:

[1] Iran, Jordan, Pakistan, Oman
[2] International conference on harmonization

a) To facilitate access to essential and quality medicines, vaccines and essential health products and reduce the use of uncertified medicines in Member States
b) To lead in the spirit of Public-Private-Partnership Initiative (PPP) since medicines are Public Health Commodity.
c) To establish Centers of Excellence in Pharmaceutical Production in ECOWAS Region
d) To establish Stock Security for ARVs and other Essential Medicines
e) To strategize to reducing poverty and achieve the Millennium Development Goals (MDGs)

The regional GMP scheme has encouraged the involvement of the local manufacturers through advocacy and training. Key advocacy points have been: (i) procurement of Anti-retroviral medicines worth over $1,000,000 from local pharmaceutical manufacturers (EVANS MEDICAL PLC, Nigeria, and DANADAMS, Ghana,) 2009-2010; (ii) support for pharmaceutical

Manufacturers /GMP upgrade worth about $500,000 (EVANS MEDICAL PLC, Nigeria, DAN – ADAMS, Ghana, MAY and BAKER, Nigeria and INPHARMA, Cape Verde); and (iii) Plan of Action and Legal Directive to combat counterfeit and fake medicines in ECOWAS. In order to achieve the goals of the project, WAHO has invested in GMP training for Regulatory Authorities and Pharmaceutical Manufacturers, initiated process of Medicine Registration Harmonization in ECOWAS Region and supported the WHO prequalification process. So far four training sessions have been conducted in Nigeria, Cape Verde, Benin and Ghana.

1.15.5 The Pharmaceutical Industry as a key Stakeholder in the Harmonisation process; William Mwatu

Varying regulatory capacities among African NMRAs poses challenges in determining the pathway for harmonisation of medicines regulation across economic zones. African pharmaceutical market comprises Local/Regional and Multinational manufacturers. The multinational manufacturers have been a key stakeholder in the ICH process, and involved in harmonisation initiatives within the European countries, Latin American countries and most recently in the ASEAN and Gulf states harmonisation initiatives. Learning from the other harmonisation initiatives, African harmonisation initiative can ensure a more effective process avoiding pitfalls encountered in the other regions. The African Medicines harmonisation needs to ensure that that there full industry input on the following areas:

1. The Development of agreed guidelines for medicine Registration and other affiliated guidelines
2. The strategy for implementation of the agreed guideline across the region to ensure that it does not negatively impact patient access
3. Development and agreement labelling requirements to take advantage of economies of scale and not result in increased cost of medicines.
4. Strategies to implement a GMP inspection to minimise inspection fatigue on the industry
5. Information management systems to ensure compatibility and increase efficiency using ICT infrastructure

6. Agreement of communication mechanisms to ensure transparency in regulatory processes

The engagement and input from the Pharmaceutical industry at the early stages is essential for the successful implementation of harmonisation within Africa.

1.15.6 What are the common elements of a good quality regulatory review process?; Prisha Patel

CIRS undertook a study to identify the key elements of all the processes and procedures undertaken to review a new medicines that are critical and that can be identified as enablers of the review. The study was conducted on the basis that regulatory agencies continuously evolve their process and practices to ensure use of the best tools and techniques. Primary data was collected from global pharmaceutical companies and regulatory agencies. The study results showed that characteristics that agencies and companies felt enable quality reviews differed. The top two characteristics that all 12 companies felt an agency should demonstrate were the ability to have dialogue with assessor for clarification of issues raised in a deficiency letter and the opportunity for pre-submission dialogue. All 11 agencies agreed that decision frameworks and internal training, for example, by experienced internal staff were the most important characteristics on which an agency should focus. However, there was one characteristic indicated by both agencies and companies as an enabler of regulatory review: a detailed description of each stage of the approval process including target times. Having this process in place would allow better transparency and predictability of the review, allowing companies to understand the process better and enabling agencies to adhere to target timelines by managing their workload more efficiently.

1.15.7 Harmonization of Good Manufacturing Practice Audit In Africa, A Key to creating an Enabling Environment for Quality Medicine Manufacturing and Regulation; Theophilus Ndorbor

Health care expenditure for Africa is expected to grow by 11% by the year 2020 with an estimated population of 1.3 billion. This makes the continent a high potential market for the pharmaceutical business. However, stringent regulation, lack of specialized skills in the pharmaceutical sciences and related disciplines, and strong downward price pressure in Africa, has made pharmaceutical manufacturing in Africa very difficult. Most African pharmaceutical manufacturers still find challenges in meeting Good Manufacturing Practice (GMP) in accordance with international standards due to the financial burden involve in meeting GMP requirement and maintenance. The financial burden increases further when the manufacturer is registering more products in several countries which may require several GMP inspections. In this regard, harmonisation of GMP Audits across Africa would be instrumental in improving the quality of pharmaceutical manufacturing in Africa and at the same time enabling African pharmaceutical manufacturers meet GMP compliance at a reduced cost. Harmonisation will enable member states to share audit findings and access audit findings from other Global pharmaceutical watch dogs thereby increasing quality of Medicine manufacturing and cutting

down of costs for the manufacturers. Harmonisation will also address the challenge of lack of GMP specialists in most African regulatory authorities.

Session observations and recommendations

- Pharmaceutical industry should be involved from the initial formulation of harmonized guidelines for regulation of medicines
- Medicines regulation harmonization should be an integral part of improving local production and creating a vibrant pharmaceutical industry

1.16 Closing

Remarks from AMRH Partners

World Health Organisation

In her closing remarks, Dr Ossy Kasilo emphasised that Africa is making progress in medicines regulation and that whilst there is some regulatory capacity in Africa, capacity utilisation in the major challenge. She stated that regional integration is thus the way forward via partnership, collaboration and harmonization between partner-states and RECs. She concluded by lauding collaboration of the stakeholders citing the Government of South Africa, NEPAD Agency, WHO, The Bill and Melinda Gates Foundation, the World Bank, USP, USFDA, DNDi, AERAS among others for supporting the organisation of the conference. She also thanked all participants, speakers, chairs, interpreters and rapporteurs for their key role in facilitating the success of the conference. She concluded with a vote of thanks to the conference organising committee for the preparation and implementation of the conference.

World Bank

Dr Eric Mallard gave brief closing remarks thanking all participants for good collaboration. He emphasised that the diversity of participants in the conference was a success factor that facilitated exchange of ideas and sharing of diverse experiences. He closed by stating that the World Bank is proud to be a partner of the Regional harmonisation initiative and expressed the hope that the institution will be able to expand the scope of their support.

NEPAD Agency

Prof Aggrey Ambali of NEPAD Agency thanked all for their participation. Admitting that the last few days were intense, he drew attention to the importance of making sure that the next steps decided at the conference should be clear and find their way into the African regulatory agenda at the 2014 January summit of the African Union HSOG. He closed by giving a vote of thanks to the Government of Republic of South Africa, and her peoples thanking them for hosting the conference.

Remarks by Dr Janet Byaruhanga African Union Commission (AUC)

Dr Byaruhanga commenced her closing remarks by pointing out that she was bringing with her to the conference greetings from Dr Dlamini Zuma, Chairperson of the African Union Commission, and H.E. Dr. Mustapha S. Kaloko, Commissioner of Social Affairs and that she will equally convey a message from the conference to them stating that this conference was an excellent forum of scientific information exchange and that building of partnerships has actually started taking place. Dr Byaruhanga said that the message she takes to the AU is clear and assured delegates that it will inform policy and assist the African continent in moving forward to a better place where the safety and quality of medicines for Africans will be a priority. In

conclusion she thanked the Republic of South Africa for hosting the conference and providing all with hospitality.

Closing Remarks by Prof Peter Eagles, Chairperson, Medicines Control Council, Department of Health – South Africa

Professor Peter Eagles, on behalf of the Minister, Ministry of Health and Director General of the Department of Health of the Republic of South Africa thanked all participants at the conference and applauded them for their informative and innovative approaches on how countries can come together and share and learn from one another.. He stated that a wide range of topics that were presented at the conference showed the wealth of knowledge that countries have at their disposal to move forward and noted that the regulatory curriculum development to capacitate and build a cadre of African regulatory professionals was right on time for the continent to make sure that all medical products that are manufactured or find their way into Africa are safe and are of good quality for the people of Africa. He concluded the conference by thanking the organising team and partners for pulling through the successful conference.

1.17 Conference Recommendations

After the two days conference deliberations, the following for key recommendations were made:

i. There should be a robust continental database and a platform for information sharing on medicines regulation and harmonization in Africa linked to regional platforms that will inform policy processes at national, regional and continental levels

ii. A robust M&E system should be established in order to track progress and impact in the implementation of AMRH programme.

iii. the *African Regulators Forum* should be established as a platform for informing AU policy organs on matters of medicines regulation in Africa

iv. There is need for strong advocacy for investment in strengthening medicines regulation and regulatory reforms in Africa

Annex 1: Conference Programme

Time	Topic	Presenter
Sunday 1 December 2013		
18:00-20:00	Pre-Conference Registration	
Monday 2 December 2013		
07:00-08:00	Registration & Welcome Coffee/Tea	
Opening Session Rapporteurs: Chimwemwe Chamdimba and Paul Tanui		
08:00 – 8:10	Welcome Remarks by Chairpersons Organizing Committee (NEPAD Agency & WHO AFRO)	Mrs Margareth Ndomondo-Sigonda and Prof Jean Baptiste Nikiema
08:10 – 8:20	Welcome Remarks	Prof H Leng, Medicines Control Council, Department of Health, South Africa
08:20 – 8:40	Keynote Address	Gugu Mahlangu, Director-General MCAZ , Zimbabwe
08:40 – 09:40	Remarks by AMRH Programme Partners	AUC, PAP, WHO, Gates Foundation, WB, FAPMA
09:40 – 09:50	Remarks from NEPAD Agency	Prof Aggrey Ambali, NEPAD Agency
09:50 – 10:10	Opening Speech	Hon. Dr Aaron Motsoaledi, Minister of Health, South Africa
10:10 – 10:20	Short Documentary/Video on Medicines Regulation in Africa	
10:20 – 10:30	Group Photo	All
10:30 – 11:00	**Tea/Coffee Break**	**All**
Plenary Session: *Global Regulatory Environment: Where is Africa?* **Session Chair: Dr Ossy Kasilo, WHO-AFRO** Rapporteurs: Paul Tanui and Chimwemwe Chamdimba		
11:00 – 11:05	Session Opening Remarks and Introduction	Session Chair
11:05 – 11:15	AMRH Programme: Continental Progress Update	Margareth Ndomondo-Sigonda, NEPAD Agency
11:15 – 11:25	Harmonization of medicines Regulation Requirements within the East African Community (EAC)	John Patrick Mwesigye, EAC
11:25 – 11:35	Impact Of Regional Regulatory Interventions in ECOWAS Region	Sybil Nana Ama Ossei-Agyeman-Yeboah, WAHO
11:35 – 11:45	Regulatory harmonization on the Economic and Monetary Union for West Africa	Traore Corneille, UEMOA
11:45 – 11:55	Position on the process of harmonising pharmaceutical policies and regulations in Central Africa: progress, issues and challenges	Emiliene Pola Yissibi; OCEAC
11:55 – 12:15	Q&A	Session Speakers
12:15 – 13:30 **Parallel Sessions**		
Regional initiatives for strengthening regulatory systems **Chair: Emiliene Pola Yissibi; OCEAC** Rapporteur: Chimwemwe Chamdimba and Mercy Fomundam 1. Perspectives on harmonized clinical research governance	***Leveraging Global Regulatory Interventions*** **Chair: Prof Jean Baptiste Nikiema, WHO AFRO** Rapporteur: Janet Okero and Grace Ramafi 1. Registering medicines for low income countries: how	***Case studies and country experiences in strengthening regulatory systems*** **Chair: Nadia Fenina, Head of NMRA, Tunisia** Rapporteurs: Paul Tanui and Tichaona Mangwende 1. NAFDAC e-Registration

Time	Topic	Presenter
	regulatory framework for Africa**; Solomon K. Sackitey** **2.** The IFPMA-African Regulatory Network (ARN) view on the African harmonization process, burden on the industry and its impact on patient access to medicines (aspirations/challenges); **Sharmila Parsotam and Mercè Caturla** **3.** Medicines Regulation in Africa – The Controversies and Way Forward: **Ben Botwe, Ghana** 4. Harmonization of Pharmaceutical regulation in West Africa: Realities and prospects; **Amari Antoine Serge**	suitable are the stringent review procedures of the Wold Health Organisation, the US Food and Drug Administration, and the European Medicines Agency?; **Joachim Yorokpa Doua** 2. Intersection of Public Policy and Regulatory Science: US and EU Efforts to Address Unmet Medical Needs from Serious Bacterial and Neglected Tropical Diseases: **Ekopimo Ibia** 3. Harmonisation and Beyond: The Case of Medicines Regulatory Systems in Africa; **Julius Mugwagwa**	process: **Babatunde Olajide Jayeola** 2. Medicines registration in Zimbabwe; **Luther Gwaza** 3. A unique regulatory perspective developing an NCE solely for the prevention of HIV-1 in African Women; **Elias Nyberg** 4. Assessment of the Policy and Legal Frameworks of the Ethiopian Pharmaceutical Supply Chain; **Edmealem Ejigu** 5. Providing a Conducive Regulatory Environment: The NAFDAC Perspective; **Paul Botwev Orhii**
13:30 – 14:30	**Lunch**	**All**
14:30 - 15:30 Plenary Session: ***Panel discussion on situation analysis and legal background for medicines policies and regulatory reforms in Africa*** **Panel Chair: Margareth Ndomondo-Sigonda, NEPAD Agency** Rapporteurs: Paul Tanui and Janet Okero Panellists: 1. **Samvel Azatyan, WHO-HQ;** Pharmaceutical legislation and regulatory harmonisation 2. **Marie-Hélène Pinheiro, EMA;** Legal Experience from EU in implementation of decisions: guidelines versus directives 3. **Hiiti Sillo, TFDA;** Country perspective on national legislation and regional harmonisation 4. **Jean Claude Loukaka, Central Africa, ECCAS;** Experiences in regional pharmaceutical policies 5. **Chimwemwe Chamdimba, AMRH/NEPAD Agency;** Need for Regulatory Reforms in Africa 6. **Celestine Kumire, SARPAM:** Strengthening regional capacity for regulatory reforms: Lessons learnt and experiences from the regional 'Flagship' course on Pharmaceutical Policy Reform in the Southern Africa Region		
15:30 – 16:30 Plenary Session: ***Panel Discussion on Regulatory oversight of clinical trials in Africa: Where are we?*** **Panel Chair: Dr Michael Makanga; Director, EDCTP** Rapporteurs: Chimwemwe Chamdimba and Mercy Fomundam Panellists: 1. **Dr. Nathalie Strub Wourgaft - DNDi;** The road to regulatory harmonization for Africa to accelerate access to essential medicines & vaccines: what is necessary to get there in the next decade? 2. **Christine Wasunna, KEMRI, IRB Representative;** Perspective of Ethics Committees/Institutional Review Boards (IRB); 3. **Mohamed Benslimane MANSOURI, NMRA Algeria;** Perspective of NMRAs 4. **Helen Ndagije, AVAREF**; Assessment of clinical trials regulatory oversight in Africa		
16:30 – 16:45	**Tea Break**	
Plenary Session: ***Presentations on improving efficiency of clinical trial applications review*** **Session Chair: Dr Michael Makanga, EDCTP** Rapporteurs: Chimwemwe Chamdimba and Mercy Fomundam		
16:45 – 16:55	1. Clinical Trials in Africa: Impediments and Opportunities	**Joseph Fadare; Nigeria**
16:55 – 17:05	2. Timelines for ethical and regulatory review of clinical trial applications in low- and middle-income countries: challenges and opportunities	**Loren Becker, USA**

Time	Topic	Presenter
17:05 – 17:15	3. Research for Health and Innovation organiser (RHInnO): Striving for Quality and Efficient Review of Clinical Trial Protocols	**Mary Kasule, Botswana**
17:15 – 17:45	Discussion	All
17:45	Closing	
18:30 – 21:30	Gala Dinner	**All**
Tuesday, 3 December 2013		
08:30 – 08:50	Recap of Day 1 Activities	**Chief Rapporteur**
Plenary Session: *Presentations on Regulatory Capacity Development & Partnerships* **Session Chair: Patrick Lukulay, USP** Rapporteurs: Janet Okero and Grace Ramafi		
08:50 – 09:00	Regional Centres of Regulatory Excellence (RCORE)	**Paul Tanui, AMRH/NEPAD Agency**
09:00 – 09:10	Regulatory Capacity Development: Role of Centers for Pharmaceutical Advancement and Training (CePAT)	**Kwasi Pokun Boateng, USP/PQM**
09:10 – 09:20	Role of Academia in medicines Regulation: Centre for Drug Discovery, Development and Production (CDDDP)	**Prof. Chinedum Peace Babalola**
09:20 – 09:30	EDCTP Networks of Excellence (NoEs)	**Dr Thomas Nyirenda, EDCTP**
09:30 – 09:40	Creating a Regulatory Profession in LMICs via a Global Regulatory Curriculum Framework	**Beverly Corey, US-FDA**
09:40 – 09:50	Capacity Building and Partnership in Regulation of Vaccines for Tuberculosis in Africa	**Michael Brennan; USA**
09:50 – 10:20	Q&A	All
10:20 – 10:40	**Tea/Coffee Break**	

10:40 – 11:40: **Parallel Sessions**

Partnerships in regulatory capacity development
Chair: Patrick Lukulay, USP
Rapporteur: Paul Tanui and Tichaona Mangwende

2. Health Canada's Regulatory Capacity Building Activities in Support of Developing National Regulatory Authorities; **Greg Monsour**
3. Role of a regional economic community in the harmonisation of pharmaceutical regulations at national level: the experience of the Economic and Monetary Community of Central Africa (CEMAC); **Helene Degui, Cameroon**
4. Strengthening regulatory and partnership regulation; **Mohamed Benslimane Mansouri**
5. Building capacity in African research institutions through facilitated partnerships and scientist exchange; **Jennifer Dent**

Initiatives, country experiences and perspectives in regulatory capacity development
Chair: Dr Eliangiringa Kaale
Rapporteur: Chimwemwe Chamdimba and Mercy Fomundam

1. Increasing Access to Quality Essential Medicines and Services by Drug Shops in Uganda through Accreditation; **Kate Kikule**
2. Comparative dissolution profiling as a basic requirement for product licensing in the West African sub-region; **Ndidi Ngwuluka**
3. Swaziland Ministry of Health and SIAPS Partnering in Strengthening Regulatory Capacity; **Khontile Kunene**
4. Regulatory Capacity Building Efforts in NAFDAC, Nigeria; **Monica Doo Eimunjeze; Nigeria**

11:40 – 13:00 **Plenary Session: *Panel discussion on substandard & falsified medicines: what is Africa doing to combat the menace?***
Panel Chair: Dr Marthe EVERARD, WHO-EMRO
Rapporteurs: **Janet Okero and Grace Ramafi**

Panellists:
1. **Prof Jean Baptiste Nikiema, WHO-AFRO:** Combating substandard & falsified medicines in Africa
2. **Sybil Nana Ama Ossei-Agyeman-Yeboah, ECOWAS/WAHO:** West African strategy on counterfeit medicines
3. **Margareth Ndomondo-Sigonda, NEPAD Agency:** Global Public Health Implications of Substandard & Falsified Medicines – Recommendations of the IOM Committee
4. **Paul Botwev Ohrii, NAFDAC:** Using mobile technology for product quality monitoring – to combat

Time	Topic	Presenter
	Substandard/Falsified medicines	
13:00 – 14:00	**Lunch**	
Plenary Session: *Strengthening Pharmacovigilance Systems in Africa* **Session Chair: Joseph Mthetwa, SADC** Rapporteurs: Paul Tanui and Tichaona Mangwende		
14:00 – 14:10	Pharmacovigilance systems in developing countries	**Dr. Shanthi Pal, WHO-HQ**
14:10 – 14:20	Improving patient safety: practical pharmacovigilance challenges	**Prof. Alex Dodoo, Uppsala Monitoring Centre (UMC)**
14:20 – 14:30	Pharmacovigilance online reporting system in Kenya	**Ali Arale, PPB-Kenya**
14:30 – 14:40	Improving ADR signal generation through a Patient-focused Pharmacovigilance Program in South Africa	**Prof. Henry Fomundam, Howard University**
14:40 – 14:50	Post-Marketing Safety Measures: Lessons learnt in Africa	**Jude Nwokike, MSH/SIAPS**
14:50 – 15:00	Setting up a pharmacovigilance centre: Experiences from Ghana	**Delese Darko, FDB-Ghana**
15:00 - 15:20	Q&A	All
15:20 – 15:40	**Tea/Coffee Break**	
15:40 – 17:00: Parallel Session		
Initiatives and country experiences in pharmacovigilance **Chair: Dr Fred Siyoi, PPB (Kenya)** Rapporteur: Paul Tanui and Tichaona Mangwende 6. Pediatric PV: Use of PV data mining algorithms for signal detection in pediatric phase IIIb clinical trial safety data set from 7 African Countries; **Dan Kajungu** 7. Strengthening PMS in Africa The NAFDAC consumer safety Club (NCSC) Experience; **Adeline Osakwe** 8. Barriers and facilitators to suspected ADR reporting among HCP's in Uganda; **Ronald Kiguba** 9. Strengthening PV systems in the Kingdom of Swaziland; **Nomsa Shongwe** 10. Strengthening monitoring of ADE in Nigeria; **Adeline Osakwe** 11. Cohort event monitoring of artmether and lumafentrine in public facilities in Tanzania; **Alambo Mssusa**		***Providing an enabling environment for pharmaceutical production in Africa*** **Chair: Dr Paul A. Lartey** Rapporteur: Chimwemwe Chamdimba and Mercy Fomundam 1. Pharmaceutical Manufacturing Plan for Africa(PMPA): Its role in public health and development; **Janet Byaruhanga** 2. Industry perspective on medicines regulation and harmonisation; **Emmanuel Mujuru** 3. Mapping of the Pharmaceutical Manufacturing Capacity in the WHO Eastern Mediterranean (EM) Region; **Mohamed Abdelhakim Farag** 4. WAHO Regional GMP scheme and access to finance by local manufacturers; **Sybil Nana Ama Ossei-Agyeman-Yeboah** 5. The Pharmaceutical Industry as a key Stakeholder in the Harmonisation process; **William Mwatu** 6. What are the common elements of a good quality regulatory review process?; **Prisha Patel** 7. Harmonization of Good Manufacturing Practice Audit In Africa, A Key to creating an Enabling Environment for Quality Medicine Manufacturing and Regulation; **Theophilus Ndorbor**	
Closing Session **Session Chair: Margareth Ndomondo-Sigonda, NEPAD Agency** Rapporteurs: Janet Okero and Grace Ramafi		
17:00 – 17:20	Presentation of Conference recommendations	**Chief Rapporteur**
17:20 – 17: 40	Discussion of conference recommendations	**All**
17:40 – 17:50	Remark on behalf of AMRH Partners	**Dr Ossy Kasilo, WHO-AFRO**
17:50 – 18:00	Official Closing	**Prof. Peter Eagles, Chairperson, Medicines Control Council, DoH-SA**
18:00	**End of Conference**	

Annex 2: List of Participants

1st Scientific Conference on Medicines Regulation in Africa					
#	Name	Surname	Job Title	Organisation	Email
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