2nd Biennial Scientific Conference on Medicines Regulation in Africa

Regulatory Systems Strengthening for Advancing Research, Innovation and Local Pharmaceutical Production in Africa

CONFERENCE REPORT

AFRICAN UNION

NEPAD
TRANSFORMING AFRICA

World Health Organization

2nd Biennial Scientific Conference on Medicines Regulation in Africa

Regulatory Systems Strengthening for Advancing Research, Innovation and Local Pharmaceutical Production in Africa

AFRICAN UNION

NEPAD
TRANSFORMING AFRICA

World Health Organization

CONTENTS

List of abbreviations and acronyms 3

Acknowledgements 7

Executive summary 8

Conference objectives 9

Conference outcomes 10

Conference observations and recommendations 10

Conference proceedings 11

1. Opening session 11
2. Plenary session I: experiences on regulatory networking and information sharing in the advent of regional integration and regulatory harmonisation 17
3. Parallel Session 2: medical products regulatory systems in Africa in the advent of regional integration and regulatory harmonisation 20
4. Parallel session 1: Innovative Post-Marketing Surveillance Interventions in resource-limited settings 22
5. Plenary Session II: advancing local production of medical products for Africa – where are we? 26
6. Plenary session III: Clinical trial oversight in Africa: promoting research and development 30
7. Parallel session 3: ICT for advancing regulation of medical products in Africa 32
8. Parallel session 4: The future of regulation of medical devices and technologies in Africa 39
9. Plenary session IV: the future of medical products regulation in Africa: post-2015 development agenda 44
10. Closing Session 47

Annexes 49

LIST OF ABBREVIATIONS AND ACRONYMS

A	AfDB	African Development Bank
	AMA	African Medicines Agency
	AMRC	African Medicines Regulators Conference
	AMRH	African Medicines Regulatory Harmonization
	AMU	Arab Maghreb Union
	ANDI	African Network for Drugs and Diagnostics
	ART	Antiretroviral Therapy
	ASLM	African Society for Laboratory Medicine
	AU	African Union
	AUC	African Union Commission
	AVAREF	African Vaccine Regulatory Forum
B	BMGF	Bill and Melinda Gates Foundation
C	CAMD	Coalition Against Major Diseases
	CAS	Country Assistance Strategy
	CEMAC	Central African Economic and Monetary Community
	CENSAD	Communauté des États Sahélo-sahariens
	CHAI	Clinton Health Access Initiative
	CIRS	Centre for Innovation in Regulatory Science
	COHRED	Council on Health Research for Development
	COMESA	Common Market for Eastern and Southern Africa
	CT	Clinical Trials
	CTA	Clinical Trials Applications
D	DFID	UK Department for International Development
	DNDi	Drugs for Neglected Diseases Initiative
E	EAC	East African Community
	EAC-HRH	East African Community Medicines Regulatory Harmonization
	ECCAS	Economic Community of Central African States

	ECOWAS	Economic Community of West African States
	EMA	European Medicines Agency
F	FAPMA	Federation of African Pharmaceutical Manufactures Associations
	FIND	Foundation for Innovative New Diagnostics
	FMHACA	Food, Medicine and Health Care Administration and Control Authority
	FSCA	Field Safety Corrective Actions
G	GAVI	Global Alliance for Vaccines and Immunization
	GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
	GMP	Good Manufacturing Practice
H	HIV	Human Immunodeficiency Virus
	HNP	Health, Nutrition and Population
	HPPN	Harmonised national drug policies
I	IAVI	International AIDS Vaccine Initiative
	ICT	International Conference on Harmonisation
	IGAD	Intergovernmental Authority on Development
	IMS	Information Management Systems
	IRB	Institutional Review Boards
	IRS	Institute for Regulatory Science
	IVD	In-Vitro Diagnostics
M	MA	Marketing Authorization
	MCC	Medicines Control Council
	MCU	Malaria Control Unit
	MDGs	Millennium Development Goals
	MDR	Multi-drug Resistant
	MDTF	Multi Donor Trust Fund
	MER	Medicines Evaluation and Registration
	MHRA-UK	Medicines and Healthcare products Regulatory Agency
	MMV	Medicines for Malaria Venture
	MOF	Ministry of Finance

N	NAFDAC	National Agency for Food and Drug Administration and Control
	NAPAMS	National Automated Product Administration and Management System
	NCD	Non-Communicable Diseases
	NDA	National Drug Authority
	NEPAD	New Partnership for Africa's Development
	NFDAC	Nigeria Food and Drugs Administration and Control
	NHLS	National Health Laboratory Service
	NMRA	National Medicines Regulatory Authority
	NQCL	Kenya National Quality Control Lab
	NTDs	Neglected Tropical Diseases
O	OCEAC	**O**rganisation de **C**oordination et de **C**oopération pour la lutte contre les **G**randes **E**ndémies en **A**frique **C**entrale
	OI	opportunistic infections
P	PAP	Pan African Parliament
	PAHWP	Pan African Harmonisation Working Party
	PBSL	Pharmacy Board of Sierra Leone
	PPB	Pharmacy and Poisons Board
	PDPs	Product Development Partnerships
	PEPFAR	US President's Emergency Plan for AIDS Relief
	PFSCM	Partnership for Supply Chain Management
	PMPA	Pharmaceutical Manufacturing Plan in Africa
	PMS	Post-market surveillance
	PQP	Prequalification Programme
	PQT	Prequalification Team
Q	QA/QC	Quality assurance
	QES	Quality Management Systems

R	RAPS	Regulatory Affairs Professionals Society
	RCOREs	Regional Centres of Regulatory Excellence
	R&D	Research and Development
	RECs	Regional Economic Communities
S	SADC	Southern African Development Community
	SAHPRA	South African Health Products Regulatory Authority
	SDGs	Sustainable Development Goals
	SIAPS	System for Improved approach for Pharmaceuticals and Service
	SPS	Strengthening Pharmaceutical Systems
	SRA	Stringent Regulatory Authorities
	SSFFC	Sub-standard, Spurious, Falsely-labelled, Falsified or Counterfeit
	STC-HPDC	AU Specialised Technical Committee on Health, Population and Drug Control
T	TB	Tuberculosis
	TFDA	Tanzania Food and Drugs Authority
	TOPRA	The Organization of Professional in Regulatory Affairs
	TRIPS	Trade-Related Aspects of Intellectual Property Rights
U	UCT	University of Cape Town
	UEMOA	Union Economique et Monétaire Ouest Africaine
	UN	United Nations
	UNAIDS	Joint United Nations Programme on HIV/AIDS
	UNIDO	United Nations Industrial Development Organization
	USFDA	United States Food and Drug Administration
	USP PQM	United States Pharmacopoeia Promoting the Quality of Medicines
W	WAEMU	West Africa Economic and Monetary Union
	WAHO	West African Health Organization
	WB	World Bank
	WHO	World Health Organisation
	WHO-AFRO	World Health Organisation Regional Office for Africa
	WHO-EMRO	World Health Organisation Eastern and Mediterranean Region

ACKNOWLEDGEMENTS

The conference organising committee, comprising the NEPAD Agency, as well as the AUC WHO-AFRO and WHO-EMRO, thanks those who participated in the second Biennial Scientific Conference on Medicines Regulation in Africa. The conference would not have been a success without the active participation of representatives of the AU member states' NMRAs and RECs, as well as representatives from the international pharmaceutical industry, academic and research fraternity, plus its development and technical partners.

Special gratitude is also extended to speakers who prepared insightful presentations at the event.

In addition, the committee is grateful for the efforts of the reviewers of the abstracts for the time they spent reviewing presentations and their constructive input.

It also acknowledges the work of the conference chairpersons and rapporteurs who led structured sessions.

Furthermore, this meeting would not have been possible without the financial support from NEPAD agency's partners, including the BMGF, WHO, WB and IAVI.

The Conference Organising Committee also appreciates the role played by the AUC in hosting the conference and the hospitality it afforded participants and delegates.

EXECUTIVE SUMMARY

Products for preventing, diagnosing and treating medical conditions are an essential component of any public health system. Availability and access to medical products ensure confidence in the system, and are essential for a sustainable response to the public health challenges Africa faces. Availability and access to new medical products developed over the last century have transformed medical science and have had a meaningful impact on prevention, treatment and cure of many illnesses and diseases. This has led to a significant rise in the quality and life-span of many people. WHO estimates that more than two-thirds of new HIV infections occur in the sub-Saharan region. However, 4,8 million deaths in the region have been averted by increasing the availability and access of ART.

Despite this progress, millions of people still lack access to important healthcare services. Statistics show that only 37 per cent of people living with HIV in sub-Saharan Africa received treatment from 2013. Meanwhile, there are a number of other diseases that also challenge the public health system on the continent, including TB, malaria and NTDs, which all have a profound negative impact on poor populations of the continent.

Ensuring access to medical products in Africa is a complex conundrum that requires multifaceted solutions. The AU heads of state have therefore committed to promoting R&D of microbicides, vaccines, diagnostics and treatment for HIV and AIDS, as well as TB and malaria. This intervention includes traditional medicines in line with the Abuja Call for accelerated action towards universal access to treatment for these diseases.

R&D for health is an essential step towards delivering new medical products for Africans. While some progress has been made in terms of R&D for health in Africa, there are still significant hurdles that hinder improved access to medical products for populations on the continent. Investment in innovation in health technologies is essential for Africa to deliver on its public health objectives. The second pillar of the AU Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa prioritises actions needed to ensure accelerated access to affordable and quality medicines, as well as health-related commodities. This is complemented by the adoption of the, PMPA which will enhance local production of pharmaceuticals to ensure sustainable access by Africans.

The third SDG focuses on ensuring healthy lives and promoting the wellbeing of all. This means African countries have to strengthen their health systems and ensure sustainable access to important medical products. Increased access to and improved innovation in the provision of quality medical products is highly dependent on the effectiveness of prevailing regulatory systems. However, a number of studies have identified bottlenecks in most African country's regulatory systems, highlighting varying levels of human, institutional and infrastructural capacities. This is compounded by fragmented systems with different legal basis for the regulation of medicines, further hindering harmonisation and collaboration to bolster regulatory capacity.

Efforts are being taken by different stakeholders

to respond to the challenges to regulating medical products at national, regional and continental levels. For example, partners of the AMRH embarked on a programme to support AU member states harmonise technical requirements and processes for regulation of medical products through their RECs. The initiative complements existing work on harmonisation and work-sharing in RECs, and experiences from countries that have stronger regulatory systems. It is for this reason that the second Biennial Scientific Conference on Medicines Regulation in Africa reviewed progress made by Africa in strengthening regulatory systems. With a theme of Medical Products Regulatory Systems Strengthening: Promoting Research, Innovation, Manufacturing and Increased Access to Medicines, the conference provided a platform for stakeholders to highlight the importance of medical products regulation to effectively contribute to the post-2015 development agenda.

Conference objectives

The scientific conference was convened to:

- take stock of the progress made to strengthen medical products regulatory systems in Africa and share advances and best practices in strengthening regulatory systems,
- provide a platform to deliberate on the role of medical products regulation in the implementation of Africa's post-2015 development agenda,
- establish a forum for sharing lessons and best practices in regulatory systems to deliver necessary new medical products and innovations.
- deliberate and agree on approaches for accelerating regional and continental collaboration in medicines regulation, and
- provide a platform to foster collaboration and networking among regulators, policymakers, academia, scientific community, private sector and civil society.

Conference outcomes

More than 200 people participated in the conference. They were policymakers, parliamentarians, regulators from African and international NMRAs and other countries, members of ethics committees, or IRBs, clinical trials sponsors, industry representatives and AMRH partners. The event also garnered participation from other stakeholders in regulatory endeavour on the continent, REC representatives, researchers and academia, as well as development partners. They used this forum to exchange information from diverse disciplines and to share best practices to bolster regulatory systems at national, regional and continental levels.

Conference observations and recommendations

Participants called upon AMRH partners to strengthen research capacity for medicines regulators as a fundamental component of the harmonisation agenda. It was noted that the RCORES could be used to build research and regulatory capacity. In addition, the important role of African governments and development partners in supporting collaborative research and drug discovery to achieve the goals of the PMPA was emphasised.

Participants noted the significant progress made in the implementation of the AMRH through RECs, while calling for continued collaboration among member states to ensure the efficient functioning of regional harmonisation. They urged NEPAD Agency and its AMRH partners to establish a platform to share knowledge and promote best practices in advancing the harmonisation of medicines regulation on the continent.

Key recommendations made by participants include:

- A need to support the strengthening of PMS capacity and adopt strategies that will incorporate product safety and quality monitoring, as well as ensure scientific-based regulatory action.
- A need for AMRH partners to grow the scope of regulatory functions to cover pharmacovigilance activities.
- The requirement for an AMRH platform and AVAREF activities. AMRH partners were asked to facilitate collaboration and alignment in the review of clinical trial oversight and ethics to avoid competition and duplication, while ensuring efficient deployment of scarce African resources.
- Promoting the use of technology by NMRAs to bolster their regulatory systems to ensure effective and efficient delivery of regulatory services.
- A need for a regional GMP scheme to promote production of quality products by local manufacturers.
- The important role African countries are able to play in strengthening regulatory capacity for medical devices and diagnostics by participating in regulatory harmonisation schemes and aligning the PAHWP's efforts into the AMRH initiative to minimise duplication.

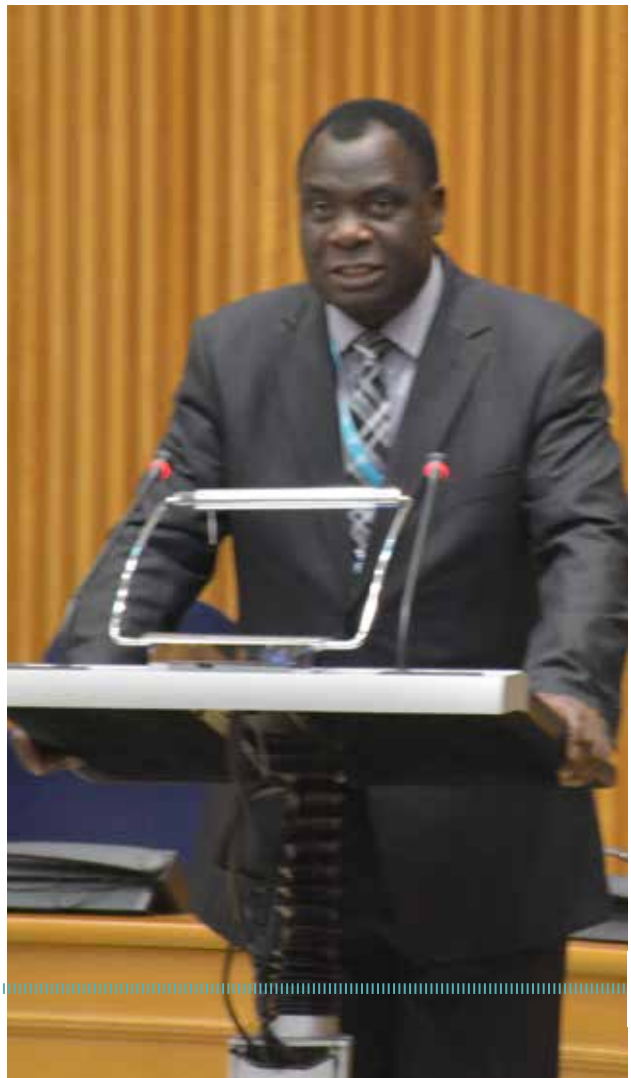
CONFERENCE PROCEEDINGS

1. Opening session

1.1 Welcome remarks

NEPAD Agency's Prof. Aggrey Ambali welcomed delegates and acknowledged the efficacy of the partnership that contributed towards the hosting of the conference. The head of the **NEPAD** Science, Technology and Innovation Hub, acknowledged the role of the Conference Organising Committee in working tirelessly in preparing the conference, which enjoyed financial contribution from the BMGF, WHO and the WB. He indicated that the conference mirrored existing commitments to strengthening medical products regulatory systems at a national level and advancing regulatory harmonisation in Africa. Prof. Ambali reminded delegates that the NEPAD Agency, the secretariat of the AMRH initiative, is committed to working with partners, including the AUC, PAP, WHO, BMGF, WB and other stakeholders in advancing Africa's harmonisation agenda.

He added that the conference would help participants assess progress Africa had made in bolstering medical products regulatory systems and allow for sharing of best practices. This is critical for strengthening regulatory systems to contribute towards the achievement of the continent's post-2015 development agenda. Prof. Ambali concluded that the agency was very hopeful that the outcomes of the conference would contribute towards shaping a positive future for medical products on the continent.



1.2 Remarks by FAPMA

Vice-Chairperson of FAPMA, Nazeem Mohamed, thanked the AU, NEPAD, WHO and its other partners for inviting the pharmaceutical manufacturers to the conference. Mohamed explained that the association was established to facilitate the collaboration of African manufacturers to tackle common challenges, while

representing the needs of its member companies. He noted that about 80 to -90 per cent of medicines used in most African countries were imported. Mohamed said that African manufacturers faced technical challenges in maintaining equipment and developing products, in addition to other impediments, including limited access to finance their operations.

He said that healthcare on the African continent would not improve until the private and public sectors, as well as civil society collaborated across a series of programmes. At present, most countries, especially those in sub-Saharan Africa, are struggling to cope with infectious diseases, as well as the rise in NCDs. As such, Mohamed thanked the AU for prioritising the development of an African pharmaceuticals manufacturing industry – the third-highest sector to receive priority on its agenda after agriculture and mining. The adoption of the PMPA and its business plan reflects political will to advance pharmaceutical manufacturing capacity on the continent. He urged partners to work together to foster more support for the implementation of the PMPA and its business plan throughout Africa. Mohamed also acknowledged the commitment made by those stakeholders who had already started collaborating to support regulatory harmonisation on the continent which, he said, was essential for advancing local manufacturing capacity.

He concluded by reiterating the commitment made by local manufacturers to improve quality systems to comply with global standards. The industry has also confirmed that it will continue working with several agencies, including the UNIDO and WHO, to improve African quality systems.

1.3 Remarks by the WB

Apollo Muhairwe, representing the WB, thanked the Ethiopian government for hosting the second Biennial Scientific Conference at the headquarters of the AU and AU/NEPAD. Muhairwe reiterated that the WB wanted to eradicate poverty and improve peoples' lives, and that the bank recently underwent internal reorganisation and established 14 global practices, in addition to other cross-cutting solutions to deliver its mandate. HNP is one of the areas that address regulatory issues.

The bank works together with clients, usually MOFs, to prepare a CAS, based on national development plans that guide the design of country-specific projects and their execution. This ensures the desired reforms and strengthens systems. Country programmes are usually relevant to all sectors of the economy, but focus on priority areas at a national level. In terms of the AMRH programme, the WB is a trustee for the MDTF and responsible for the fiduciary oversight of the programme. The largest contributor to the fund is the BMGF, while contributions have also been received from the US government, UK DFID and GAVI. Muhairwe detailed that the bank had also started using some of its own resources to support AMRH activities, including leveraging the existing RECs, to strengthen systems and processes of regulatory functions within the NMRAs. Muhairwe identified key areas that would lead to success, including MER, GMPs, IMS and QMS.

Successful implementation and availability of additional funds in the MDTF would also determine expansion of the existing scope of the AMRH to include other functions for effective medicine regulation at national, regional and continental levels.

He also said that the EAC was the first REC to benefit from the AMRH project for a number of reasons. The region had demonstrated political commitment and

pursued an agenda of regional integration. Other factors that played in the REC's favour was its size, proximity, homogeneity and culture. These factors are complemented by the EAC Treaty, which also details the its desire to implement a common system for the registration of medicines in the region. There has also been increased collaboration in the EAC especially in terms of sharing of related work and regulatory information, while attending to other functions to ensure effective medicine regulation. By developing a mutual recognition framework, the region is now helping countries legally share and exchange regulatory decisions. The bank is also supporting a study on financial sustainability of NMRAs, in line with the MRH. This study will inform the activities in the other RECs as they start to implement MRH.

1.4 Remarks by the WHO

Dr Paul Mainuka, acting WHO Country Representative for Ethiopia, spoke on behalf of organisation's Regional Director for Africa, Dr. Matshidiso Rebecca Moeti.

Mainuka reminded delegates about the call for greater commitment to ensure that Africans have access to quality-assured affordable medicines. He said member states were committed to developing robust pharmaceutical sectors with effective policies and plans. Over the past decade, countries have also made significant progress in strengthening their regulatory systems to ensure that medicines, vaccines, diagnostics and medical devices are of a sound quality, safe and efficient.

He said well-resourced medicines regulatory authorities that performed critical functions, such as market registration and surveillance, quality control, monitoring of adverse drug reactions and oversight of clinical trials, were reference points for emerging systems. Other examples include WHO Collaborating Centres and RCOREs, over-and-above the pre-qualification of eight quality-control laboratories in the WHO African Region.

Despite this progress, Mainuka said there is a need to accelerate the establishment of the AMA and intensify the fight against the increasing inflow of SSFFC medical products. The WHO African Region is the second-highest, after Europe, to report SSFFC medical products to the organisation's Global Monitoring System. The lack of regulation and quality assurance for medical devices and in vitro diagnostics compounds the situation.

Mainuka called on delegates to focus on emerging regulatory challenges brought about by new technologies, including "e-commerce", which may have a negative impact on African health by facilitating access to unregulated products.

He concluded that academic and research institutions, as well as regulatory networks in the region needed to work together to improve the regulation of medical products, especially in terms of health emergencies.

1.5 Remarks by BMGF

BMGF's Dr. Dan Hartman said that the foundation was supporting the strengthening of regulatory systems for the entire product chain. In terms of clinical development, the director of Integrated Development said that the foundation had been backing the AVAREF platform for many years. It recently approved a new tranche of funding to support AVAREF and directly funded the WHO-AFRO for the next three

years, a first for the foundation. The latter includes a new work plan and set of principles in an effort to strengthen efficiency in conducting clinical trials on the continent.

It is also backing the AMRH programme with tremendous progress having been made in the EAC, in terms of registration. Hartman elaborated that the AMRH is now expanding to other regions, as well as in other regulatory areas and product streams. An important example is the foundation's involvement in pharmacovigilance, where, he told delegates, significant progress had been made.

Hartman said he was satisfied with the progress made by the AMRH, and announced that the foundation therefore decided to make a second significant contribution to its Trust Fund. Hartman indicated that progress, in terms of strengthening regulatory systems, was made possible with the support and commitment from a large number of stakeholders and partners.

He believed that the joint efforts to enhance the regulatory landscape through AMRH, AVAREF and WHO PQ was the best global health project to have received support from the BMGF over the past three years – a sentiment that is also shared by top-brass of the foundation.

1.6 Remarks by PAP

Hon. Dr Bala Saratou Boukarl, Chairperson of the Committee on Health, Labour and Social Affairs of the PAP, said that harmonising regulation of medical products on the continent was on top of the PAP's agenda. The February 2009 conference, the architect of this initiative, was jointly organised by NEPAD, and the PAP, as well as its partners, the WHO, GMGF, DFID, UNAIDS, Clinton Initiative on Access to Health and WB.

To ensure countries implemented a comprehensive legislation that strengthens regulatory systems and supports harmonisation, the PAP adopted recommendations on the development and adoption of a Model Law on medical products regulation at its regular session in May 2011. In July 2011, a workshop on capacity building of the members of the Committee on Health, Labour and Social Affairs was held to equip parliaments with the capacities they needed to enable them to advocate harmonisation of medicines registration in Africa. Participants then recommended the development and advocated the adoption of such an initiative, according to WHO standards.

As such, the NEPAD Agency, together with PAP, AUC and development partners, has backed a participatory process to develop a Model Law on medical products regulation.

Boukarl said that the law was intended to be approved by Heads of State and Government of the AU in January 2016, and urged all partners to collaborate on the project to save lives by improving the health of African populations. She also emphasised the need to adopt a strategy that would educate leaders and other participants in the African political and social landscapes on the benefits and values of harmonisation of medicines regulation.

1.7 Opening statement by the AUC

Ambassador, Dr. Olawale Maiyegun, the AUC Director of Social Affairs, noted that the conference was timely and relevant, considering the credence placed on advancing the AU Agenda 2063 and the post-2015 Development Agenda.

Maiyegun said that the PMPA Technical Committee and relevant partner agencies had assessed progress made over the past decade in implementing the Abuja 2005 Assembly Decision on promoting pharmaceutical manufacturing on the continent. The Technical Committee had identified both gaps and opportunities for improving the sector.

He highlighted that member states, RECs and partner agencies would continue to collaborate to pursue their commitments to the agenda. Maiyegun reaffirmed that the AUC recognised the importance of science, technology and innovation as critical to the development of all sectors, and that the conference was therefore a fundamental platform for outlining a research focus for the African pharmaceutical industry.

1.8 Keynote presentation: regulatory systems strengthening for advancing research, innovation and local pharmaceutical production in Africa

Dr. Paul Lartey highlighted the key AU policy frameworks and declarations that govern pharmaceutical R&D, local production and access to medicines. They include the Abuja call for action to ensure universal access to HIV/AIDS, tuberculosis and malaria healthcare in Africa; PMPA and AMRH as an integral part of the PMPA; and an AU roadmap for shared responsibility and global solidarity for AIDS, TB and malaria.

Lartey reaffirmed the need to invest in combating priority diseases affecting Africa, including HIV, TB and Malaria. He also reminded delegates about imminent health threats, such as dengue and Lassa fever, as well as the recent Ebola shock. The latter started in West Africa, and infected 15 215 persons and killed 11 299 people in 10 countries on three continents. Meanwhile, he also highlighted the threat of many other diseases, which did not yet have an effective cure, such as Schistosomiasis, Lymphatic filariasis, Buruli ulcer, Trypanosomiasis, Onchocerciasis and Sickle cell disease.

Lartey raised concerns about the lack of major sustainable efforts to develop new drugs in the pharmaceutical industry, while stressing the need for African governments to build capacity in the entire pharmaceutical value chain.

Key to the success of a robust African pharmaceutical industry are a strong technology base, such as Genomics, proteomics, CAMD and combinatorial chemistry; superlative infrastructure; and a rich pool of scientists. He added that funding was also critical, considering that USD49,4 billion/year is spent on R&D1 by US pharmaceutical companies. At the same time, it receives significant government support to the value of USD30 billion a year2 in the form of tax credit for research and funding of basic biomedical research. Lartey said research institutions, regulators, industry and government, which provided policy, political and financial support, needed to partner for discovery and development.

He cited examples of drug discoveries that occurred on the continent, including an antimalarial drug, H3d, which was discovered at the University of Cape Town's (UCT) Drug Discovery & Development Center. It is the first novel structural and mechanistic class to be based on traditional African herbal medicines. This new antimalarial, Novel lipid kinase, is active against chloroquine-resistant Plasmodium falciparum blood and liver forms, offering a potential radical cure. This development is as result of collaboration between the UCT, the MMV and a Swiss-based PDP, and they received support from the South African government's Department of Science & Technology.

Lartey emphasised Africa's biodiversity, untapped source of diverse chemical entities and rich history of herbal and traditional medicines, providing it with a significant competitive advantage. Extensive studies conducted on African medicinal plants, in terms of structures and mechanism of actions, as well as work published in peer-reviewed journals demonstrate a significant potential for discovery and development through collaboration between research and academic institutions, governments and non-governmental organisations.

He noted progress made in the promotion of local production in Africa, regional regulatory harmonisation efforts and the AU vision for establishment of an AMA.

2. Plenary session I: experiences on regulatory networking and information sharing in the advent of regional integration and regulatory harmonisation

2.1 AMRH Programme: continental progress update

Margareth Ndomondo-Sigonda explained that AMRH is a partnership that was formalised in 2009 to improve the fragmented regulatory system for product registration in Africa. It is behind the development of simplified collaborative regional approach, as opposed to cumbersome country-focused initiatives. The first regional project was launched in the EAC countries in 2012 and has since been introduced to other regions, including ECOWAS, UEMOA and SADC. AMRH activities have also been initiated in central and north-north east African regions.

The AMRH has also made strides to help strengthen legal frameworks for the regulation of medical products. The AU Model Law on Medical Products Regulation was developed to address gaps in the existing legal frameworks in member states. This reference guide is to be used by countries to help them develop or review their legislations, and has been considered by the AU STC-HPDC and the AU Specialised Technical Committee on Justice and Legal Affairs.

Significant progress has been made in strengthening regulatory capacity, knowledge generation and leveraging, all activities which have been designated to 11 RCOREs. The AMRH Implementation Toolkit and Monitoring and Evaluation Framework was also developed to help documentation and adoption of lessons learnt in scaling up AMRH activities. The establishment of the AMA has also taken shape. A joint secretariat comprising NEPAD Agency, AUC and WHO has been designated and a task team established to oversee the development of a legal and institutional framework, while a business plan has been drafted for the agency.

2.2 The role of research in informing policy and advancing regulatory science in Africa

Chimwemwe Chamdimba told conference delegates that sciences geared at developing new medical products, such as nanotechnology, biotechnology and synthetic biologicals, creates new regulatory demands and drives the need for co-evolution of medicines regulation. It is therefore important to increase the role of harmonisation of regulatory requirements and work sharing at regional, continental and international levels.

African medicines regulators are faced with impediments when responding to new demands from patients. This is considering new innovative therapies and the rapid rate of scientific change. While regulators are conducting research daily, the scientific documentation of experiences and outcomes and sharing of these experiences is limited. For example, the experiences garnered in organising this conference revealed that most papers submitted for review lacked scientific basis for making recommendations. This stresses a need to increase this capability, evolving and remaining current with new developments, as well as ensuring that regulatory decision making is based on science and evidence.

In line with the framework of AMRH, there is also a need to enhance the role of RCOREs to support research. This can be done by focusing on training NMRA staff in research techniques, as well as facilitating collaboration in advancing knowledge generation and sharing of findings and experiences at scientific conferences. The recommendations of the scientific conferences will be presented to the AMRC, STC-HPDC and AU for policy and decision making.

2.3 WHO collaborative registration procedures as a model for regulatory cooperation

Milan Smid said the WHO collaborative registrations accelerate national registrations, facilitate availability of the organisation's prequalified medicines and provide assurance that nationally-registered medicines were of the same standard as their prequalified counterparts. Registration dossiers in countries are similar to those approved by the PQP. The WHO PQT shares with interested regulators detailed outcomes of its assessment and inspections to support their decision making in exchange for accelerated registration within 90 days.

Since its establishment, 26 countries from Africa, Europe and Asia have participated in the WHO-PQT collaborative registration process. By 20 November 2015, 98 registrations in 15 countries were obtained and 54 applications were being processed. A total of 77 per cent of all approved products were obtained within four months, with the observed median time to registration 56 days in 2015.

There is a growing number of manufacturers and NMRAs that are accepting the WHO collaborative procedure.

Meanwhile, the procedure has been revised to include vaccines and in vitro diagnostics. A similar model of the procedure has been piloted to facilitate registrations of medicines approved by SRAs to enable registration of innovator and generic products. This process is being developed together with industry associations, relevant SRAs and companies.

2.4 Experience in regulatory harmonisation and joint assessment in the EAC region: impact and lessons learnt

David R. Matle said the EAC-MRH Programme was officially launched in 2012 to improve access to safe, efficient and quality essential medicines in the region. It wants to implement a harmonised and functioning medicines regulatory system within the EAC – in line with national and internationally recognised policies and standards, including those of WHO and ICH.

The EAC-MRH programme has recorded significant milestones since its launch. For example, harmonised technical requirements for registration of medicines and GMP inspection were approved in September 2014 and became effective in partner states in January 2015. The region has also received applications for joint assessments. In terms of capacity building, EAC experts continue to benefit from training and learning by participating in WHO PQP. In 2014, four RCOREs were designated in the region and two are now operational.

Despite the challenges experienced during implementation, the EAC has demonstrated that regulatory harmonisation and joint regional activities are feasible and achievable. These processes have

facilitated swift registration leading to improved access to safe, efficient and quality medicines. More manufacturers are choosing the EAC joint assessment and inspection processes. What is more, the medicines registration harmonisation has opened the window to other regulatory harmonisation programmes. These include the harmonisation and strengthening of regulation of medical devices and diagnostics, pharmacovigilance and post-marketing surveillance, control of clinical trials and registration of vaccines.

2.5 Experience and lessons learnt from the ZAZIBONA Collaborative Medicines Registration model

Luther Gwaza said the ZAZIBONA Collaborative Medicines Registration programme was established in the SADC to collaborate in the assessment of applications and inspections of medicine makers. The programme initially focused on four countries, namely Zambia, Zimbabwe, Botswana and Namibia. It aimed to reduce workload and timelines to registrations, develop mutual trust and confidence in regulatory collaboration and build a platform for training and collaboration in other regulatory fields in these countries.

Since its establishment in June 2013, the model has improved efficiencies, in terms of registration timelines, raised the quality of work, enhanced technical capacity and driven down costs. Plans are underway to expand this model to include other SADC member states and adopt sustainable financing. Experiences gained from the initiative prove that the future is bright for Africa, in terms of joint activities and sharing of outcomes.

3. Parallel Session 2: medical products regulatory systems in Africa in the advent of regional integration and regulatory harmonisation

3.1 Collaborative procedure in assessment and accelerated approval of pharmaceutical products

Mercè Caturla reported that the first pilot-facilitated registration between the IFPMA and WHO-PQP was undertaken on 25 milligram (mg) Intelence tablets for paediatric HIV treatment, and approved by the EMA. The applicant, Janssen, EMA, 11 African NMRAs and WHO were involved in the process. A similar dossier was submitted by the applicant to EMA which, together with the manufacturer, agreed to share details of the full assessment and inspection reports with the NMRA. The registration timelines for this pilot was reduced from two years and no less than three to eight months in all participating NMRAs.

Experience has shown that the accelerated registration procedure for medicines already approved by SRA is possible. Simple improvements in administration in future trials may result in accelerated registration processes at a country level. Based on the encouraging results and experiences garnered to date, it may be beneficial to expedite this procedure to bolster access to SRA-approved medicines.

3.2 Establishment of a regional process for medicines registration for drugs in Central Africa

Alexandre DE LA Volpiliere said a treaty of the CEMAC laid the foundations for the adoption of HPPN in the region. The HPPN aims to provide the population with quality, safe, effective and affordable medical products.

This was initiated in the region in 2007 and the technical guidelines were adopted in 2013 Joint assessment activities involve submitting medicines MA dossier in the six countries of the sub-region. This is achieved by following a technical reference document, before joint assessment and approval processes is undertaken by member states. Two annual joint reviews a have been scheduled from 2016 onwards to build confidence and cultivate a culture of collaboration. The establishment of a regional Medicines Agency has also been proposed to facilitate sustainable harmonisation activities, according to AU guidelines.

3.3 WHO prequalification and market access of an innovator product: an industry experience

Fabienne Benoist says the WHO-PQP, offers countries an opportunity to make quality priority medicines available for their patients. In addition to its evaluation and inspection activities, WHO-PQP builds national capacity for sustainable manufacturing and monitoring of quality medicines. A procedure for collaboration between the WHO-PQP and interested NMRAs was established to facilitate and accelerate

national registration of products, which have already been assessed and prequalified by the programme. A product that is qualified by the WHO will ensure faster approval of quality products to integrated and harmonised African markets.

WHO-PQ for Coartem 80/480 mg (an additional dosing strength) occurred 20 months after approvals were received from Swissmedic and 21 African NMRAs. The WHO Prequalification dossier format was not fully harmonised with the dossier format that was approved by SRAs, leading to complexity in the life-cycle management. It is therefore important to enhance transparency on WHO-PQP and NMRAs procedures to optimise functioning and accelerate access.

3.4 The role of regulatory interventions in improving access to quality pharmaceutical services: lessons learnt from accredited drug seller initiatives in Tanzania, Uganda, and Liberia.

Eliphace Christopher Mkumbo told delegates that access to quality medicines from retailers is a challenge for most of the population in low-income countries. Accredited drug seller initiatives in Tanzania, Uganda and Liberia were launched to raise availability to quality medicines and pharmaceutical services from drug stores. This public-private partnership is based on accreditation, standards and regulation. An accreditation programme was initiated in Tanzania in 2003 and scaled up in Uganda and Liberia, resulting in remarkable improvements in service delivery in in all three countries.

To sustain medicine sales, local stakeholders need to be involved from the beginning to develop and execute the mix of public- and private-sector responsibilities. National and local-level strategies are important to increase regulatory capacity, including boosting human and financial resources, improving accessibility and deployment of regulatory tools, incorporating regulatory activities into local plans and budgets and strengthening coordination and reporting among regulatory entities and retail outlets.

RECOMMENDATIONS ON REGULATORY NETWORKING AND INFORMATION SHARING IN THE ADVENT OF REGIONAL INTEGRATION AND REGULATORY HARMONISATION

With the significant progress in the implementation of the AMRH through RECs, there is need for continued collaboration among member states to enhance proper functioning of regional harmonisation projects. The following has been recommended:

- ***The NEPAD Agency should facilitate the establishment of a platform for AU Regional Economic Communities to work and engage in the sharing of information and promotion of best practices in advancing medicines regulation harmonisation on the continent.***

- *AMRH partners should include a component focused on strengthening research capacity for medicines regulators within the AMRH activities.*
- *NEPAD Agency and Partners should facilitate the use of RCOREs to build research and regulatory capacity for medicine regulators.*
- *African governments and funding agencies should support collaborative research and drug discovery to facilitate achievement of PMPA goals.*
- *Experiences gained in collaborative procedures have proved to be useful in expediting access to WHO-prequalified and SRA-approved medicines. African NMRAs are therefore encouraged to use these procedures to accelerate registration and improve access. This will lead to the raising of the knowledge and skills base of medicines assessors and GMP inspector.*
- *To improve the quality of pharmaceutical services and products in low-income countries, AMRH partners should support advocacy in scaling-up innovative approaches, such as the Accredited Drug Seller Initiatives implemented in Tanzania, Uganda and Liberia.*

4. Parallel session 1: Innovative Post-Marketing Surveillance Interventions in resource-limited settings

4.1 Post Marketing Surveillance of Antimalarial Medicines in Tanzania

TFDA is the body responsible for regulating the safety, quality and effectiveness of medicines in Tanzania, noted Sophia Ally Mziray at the event. One of its core regulatory functions is PMS to ensure that medicines retain their quality specifications throughout their shelf life. The authority undertook PMS of antimalarial medicines in 24 regions of Tanzania between 2012 and 2014.

The survey involved collecting and reviewing samples of selected anti-malarial medicines available on the market and then undertaking quality control testing in laboratory conditions. Sampling was done by public and private sectors according to pre-approved plans.

There was a failure rate of 62,29 per cent due to labelling defects. Discoloration was noted in 1,82 per cent of quinine tablets and five per cent of sulfamethoxaxole/pyrimethamine tablets that were sampled. In addition, chipping occurred in 2,94 per cent of sulfamethoxaxole/pyrimethamine tablets. One batch of quinine tablets failed confirmatory assay tests and 2,68 per cent did not comply with weight uniformity and appearance specifications.

This intervention allowed TFDA to better understand the quality profile of the selected products and discover means of improving monitoring of other products on the market.

4.2 Detecting product quality problems and protecting public health using pharmacovigilance data: the Ethiopian experience

Hailu Tadeg detailed that the objective of the research was to demonstrate how Pharmacovigilance data can be used to detect medicines with quality problems to safeguard public health systems in resource-constrained environments.

Research resulted in the revision of an adverse drug event reporting guideline and form to document medication errors, product defects and adverse drug events. In-service training was provided to increase adverse drug events awareness and reporting among healthcare providers. The reporting tools were made available and the Pharmacovigilance center provided regular feedback on adverse drug events reports. In addition, reports on suspected product quality problems were reviewed by the Pharmacovigilance forum, which consisted of experts from registration, inspection and quality control directorates.

There was a marked increase in the detection and reporting of adverse drug events from 79 to 411 between 2012 and 2015. Up to 77,6 per cent of the adverse drug events were reported by pharmacy professionals and 5,95 per cent by physicians.

The incorporation of product quality reporting into the regular spontaneous reporting system can be an effective means of detecting the circulation of medicines with quality problems, especially where poor post-marketing quality surveillance systems abound.

4.3 Regulatory assessment of pandemic (A)H1N1 influenza vaccine and narcolepsy safety issue: lessons for resource-limited countries.

Joachim Doua disclosed that eight influenza A (H1N1) vaccines were authorised for global markets, following a breakout of the epidemic in Mexico in March 2009. Widespread use of H1N1 vaccines resulted in reports of narcolepsy, especially in children and adolescents, in the EU in August 2010. The vaccines were therefore withdrawn by some Nordic countries. However, a review by EMA concluded that more data was needed to further assess causalities as the rise of narcolepsy was confined to Nordic countries.

It was concluded that spontaneous data is suited to the generation of safety signals, but makes a minor contribution to the evaluation of attributable risk, while requiring extensive resources. Mechanistic and biologic studies are the best tools for causality assessment, but there are challenges, in terms of research design and costs. Doua also highlighted the need for pharmacoepidemiology research capabilities to strengthen national MRAs.

4.4 Medication error disclosure and attitudes to reporting by healthcare professionals in a sub-Saharan African setting: a survey in Uganda

Ronald Kiguba noted that medication errors were largely under reported, undermining quality improvement and medication risk management in healthcare. Little was known about the attitudes of Ugandan healthcare providers towards medication error reporting. Therefore, investigating the practice of Pharmacovigilance by healthcare providers was necessary to provide a useful platform for assessing

and then promoting medication safety in Uganda and, possibly, other African countries.

A pretested questionnaire was used to assess the attitudes of healthcare providers involved in prescribing, transcribing, dispensing and administering medications.

A total of 91,1 per cent of healthcare providers supported the establishment of national medication error reporting systems and 58,2 per cent supported integration of medication error reporting with Pharmacovigilance. A total of 64,6 per cent believed that it was important for patients to report medication errors to support root-cause analysis and 73,8 per cent share the view that reporting of medication errors should be mandatory. Service providers, who disclosed that they had committed medication errors, emphasised the need for mechanisms to protect themselves in the event of an accident, which they mainly attributed to stressful working conditions.

More reporting of medication errors can be encouraged by protecting healthcare providers from adverse litigation, encouraging patient involvement, integrating medication error reporting in existing Pharmacovigilance systems and increased collaboration between academic and policy-implementing institutions.

4.5 Assessment of substandard/counterfeit medicines in the Ethiopian pharmaceutical market

The effects of substandard and counterfeit medicines are devastating, and Dawit Dilbeto pointed out that developing countries had felt the full brunt of the situation, especially in terms of lives lost.

Up to 2,5 per cent of products sampled in Ethiopia were not registered, while 7,8 per cent failed to meet pharmacopeia specification. The study assessed 19 product categories with 319 samples analysed.

The study showed that there were no incorrect, or fake active ingredients. However, variations in content of active ingredients were found in about eight per cent of the samples – problems that can be attributed to GMP, deliberate counterfeiting or poor retail management.

The following recommendations were made:

- There is a need to strengthen enforcement of pharmacy regulations to trace sources of drugs in formal and informal markets, enabling sanctions to be implemented when appropriate.
- There is a need to deploy cutting-edge technologies, such as TruScan, Minilab and mobile authentication services, to help combat counterfeit medicines.
- Routine PMS on life-saving products is required.

4.6 Surveillance of medical devices and in-vitro diagnostics in resource-limited settings: Tanzania experience

Agnes Sitta Kijo told delegates that the TFDA monitors the quality of medical devices after registration, via a structured PMS programme. Defective devices may lead to a failure of the treatment cycle because of incorrect diagnosis and medication. Due to six porous entry points to the country, PMS of devices is critical in Tanzania, a country that is dependent upon medical imports and which was previously alerted to international reports about poor quality devices and its inadequate capacity to assess the number and variety of systems being used by its populates.

Between 2012 and 2015, 2 483 samples, including 20 malaria and 80 HIV rapid-diagnostic tests, as well as 2 383 medical devices, were collected. Laboratory test results revealed a 100 per cent compliance rate for all the diagnostics samples tested, while only 0,08 per cent of syringes and intravenous-giving sets failed sterility tests. It was noted that many HIV test kits were stored in inappropriate conditions and several deficiencies were also observed in product literature.

As such, there is a need to implement more extensive sampling and testing of sterile products. In addition, the TFDA also identified a lack of awareness of healthcare personnel, in terms of regulatory requirements and the handling of rapid diagnostic tests. Storage requirements were also a point of concern. TFDA's PMS programme has since been reviewed to improve monitoring of product quality and performance.

RECOMMENDATIONS ON INNOVATIVE POST-MARKETING SURVEILLANCE INTERVENTIONS IN RESOURCE-LIMITED SETTINGS

- *NMRAs should establish comprehensive post-marketing surveillance strategies that incorporate product safety and quality monitoring, supported byoperational governance structures that facilitate scientific guidance for regulatory action.*
- *AMRH partners should expand the scope of regulatory functions to also cover pharmacovigilance activities.*
- *Pharmaco-epidemiology research abilities should be promoted alongside the current African harmonisation and regulatory systems. Strengthening initiative.*

5. Plenary Session II: advancing local production of medical products for Africa – where are we?

5.1 Status of pharmaceutical manufacturing in Africa: PMPA +10 where are we?

With NCD on the rise and infectious diseases continuing to take a heavy toll on people's health, George Makateto noted that Africa is confronted by a significant challenge. Access to safe and effective treatment and care for the majority of Africans is far from being guaranteed. Considering Africa produces only three per cent of international medicines, the AU heads of state and government set out to modernise the African pharmaceutical sector in 2005. The PMPA was adopted by the African heads of states and government in 2007 and, in2012; they adopted its business plan. The PMPA supports local pharmaceutical manufacturing to improve African public health systems, raising access to essential medicines that are of a high quality and affordable, while contributing towards the industrial and economic development agenda of the continent.

To gain important insights on the status of production capacities in Africa, various publications were reviewed and interviews conducted with selected member states and RECs.

Preliminary results showed that the pharmaceutical market size, in terms of value increased steadily from USD 4,2 billion in 2000 to USD20,8 billion in 2013. This is projected to reach USD 45 billion by 2020. The number of pharmaceutical firms has increased tremendously with more than 900 pharmaceutical manufacturers operating on the continent. Up to 500 of these are situated in seven countries, including South Africa, Algeria, Nigeria, Morocco, Egypt, Tunisia and Kenya and the balance distributed throughout the rest of the member states.

EAC, SADC and ECOWAS have developed programmes that are in various stages of implementation that will stimulate more African pharmaceutical manufacturing. They are also implementing regional medicines regulatory harmonisation programmes, including harmonising standards for GMP to improve the quality of products manufactured locally.

However, a number of challenges hamper progress, including financial limitations to operate the project, lack of a clear roadmap, a weak PMPA governing structure, unavailability of important data, and a shortage of skills in the manufacturing sector.

The following recommendations were proposed:

- There is a need to develop a robust continental database and platform for knowledge transfer on pharmaceutical manufacturing in Africa.
- Strong advocacy is required to encourage investment into strengthening the African pharmaceutical sector and the pharmaceutical regulatory system.
- Technology transfer must be facilitated to access new technologies, skills and product development through south-south and north-south collaborations.
- The flexibility of the TRIPS should be used accordingly.

5.2 Barriers to pharmaceutical production in Uganda

David Nahamya Onen Solomon said the divide in domestic manufacturing on the continent was a concern. It is estimated that more than 80% of drugs used in Uganda are imported, with domestic production only accounting for less than 20%.

The National Drug Policy/Authority Act, Cap 206, laws of Uganda supports production of medicines in the country, and the NDA has implemented measures to help local manufacturers. Measures geared at stimulating domestic production include technical support, a waiver of verification fees on imported pharmaceutical raw materials and accelerated market authorisation of locally produced medicines.

This study was conducted to assess the barriers to local production of medicines. Literature reviews were undertaken and interviews with key stakeholders conducted.

The study identified the following constraints:

- small markets in individual countries,
- weak policy environment and limited government support to the local pharmaceutical industry,
- weak or non-existent capacities for R&D, and
- a dearth of capital and skills, including scientists and industrial pharmacists.

Locally-produced drugs also tend to be more costly than those imported in large quantities from India and China.

The study recommended the following measures to overcome these barriers:

- Models that have achieved significant levels of success in other countries, such as Ghana and India, must be reviewed,
- Tax incentives are necessary, and could involve relinquishing duties on imports of raw and packaging materials, as well as manufacturing-related equipment and their spare parts.
- Price preference, such as a favored margin of 20 per cent for locally produced medicines and medical devices in national tenders, will stimulate local manufacture.
- Import classification will add value. This intervention should include free importation of specialised medicines where there is no locally-manufactured equivalent; banning of importation of certain medicines and levying up to a 30 per cent tax on certain foreign-manufactured drugs.

5.3 The implementation of 350 - 2500 nm reflectance spectroscopy and high performance thin layer chromatography to rapidly assess manufacturing consistency and quality of Co-trimoxazole tablets in Tanzania

Eliangiringa Kaale said that the pilot study was supported by PEPFAR. The PFSCM procures pharmaceutical products for HIV/AIDS sufferers and OI in developing countries. Medicine procurement was prioritised from sources that had stringent regulatory approvals or WHO PQ in place. This approach guaranteed the provision of high quality products. The PFSCM established a “consignment” procurement model to further improve access to products that were purchased from local manufacturers in the same country as the destination health facilities or clinics. Meanwhile, suppliers were assessed through SCMS quality audits, and due diligence undertaken via risk-based drug sampling and testing. All lots

were securely quarantined at the manufacturer's site and product purchased only if they complied with testing standards, although this is not intended to replace stringent regulatory approvals, or WHO pre-qualification.

This work has resulted in the deployment of diffuse reflectance spectral technology, allowing rapid and cost-effective screening of all locally purchased cotrimoxazole tablets. The time required for screening is less than an hour per sample, which is sent to the testing laboratory in less than a day as due to the elimination of import/export-related shipping challenges in the process.

These quality assessments have been implemented at more than 100 Zentrim (cotrimoxazole tablets) production lots to support local manufacture, while improvements in the quality of product have also been achieved.

It is believed that this approach could be applied elsewhere by establishing a spectral database of acceptable products for comparative assessments. Provided proper reference materials are developed, it could also be deployed for various liquid formulations.

The risks associated with extending this programme to other product types needs to be assessed on a case-by-case basis to determine where additional quality assurance activities need to be implemented.

5.4 GMP roadmap for implementation of the AU Pharmaceutical Manufacturing Plan for Africa (PMPA): a regional approach

At the STC-HPDC-1 in April 2015, ministers of health declared that the Commission and the NEPAD Agency, in collaboration with other partners, would "facilitate implementation of the first phase of activities, especially the development and implementation of a GMP roadmap via regional and national certification schemes".

Pharmaceutical manufacturers will benefit from agreed GMP roadmaps in the RECs.

A compendium was developed to provide guidance to the NMRAs to manage applications for registration of human medicinal products in the EAC. With technical assistance from UNIDO and WHO, Kenya and Ethiopia have developed country-specific roadmaps to help their pharmaceutical industries meet international GMP standards. The WAHO also recently developed a Regional and National GMP Roadmap for ECOWAS, with the remaining RECs advised to also develop GMP roadmaps.

Aligning efforts of RECs and development partners to develop a common approach for attaining acceptable GMP status will avoid duplication of efforts by partners in implementing the AU PMPA Business Plan.

An implementation plan of the GMP Regional Roadmaps, which is aligned to PMPA and AMRH Frameworks, will be developed under the coordination of NEPAD Agency and AUC, while the RECs and NMRAs are the implementing agencies. Technical guidance will be sought from WHO, UNIDO and other partners already supporting GMP activities in Africa. Implementation takes a consultative approach and undertaken in three phases, starting with a baseline survey/assessment on the status of GMP compliance by local manufacturers, based on an agreed assessment tool. Stakeholder meetings will then be held to discuss results and to agree on a roadmap for compliance to regionally harmonised GMP standards, followed by monitoring and evaluation to assess progress.

RECOMMENDATIONS ON ADVANCING LOCAL PRODUCTION OF MEDICAL PRODUCTS FOR AFRICA – WHERE ARE WE?

- *Member states need to take the lead in implementing the PMPA business plan, using the proposed solution package, such as human-resource development, policy coherence, tax incentives AND trips flexibilities.*
- *AUC, together with NEPAD Agency and technical support from WHO, UNIDO and other partners, should develop the GMP road map for Africa. THIS needs to be achieved via national and regional roadmaps that align to PMPA and AMRH Frameworks to meet universal and international standards.*
- *AUC should facilitate South-South and North-South cooperation to help achieve the PMPA goals.*
- *AUC and NEPAD Agency should establish monitoring and evaluation frameworks to assess progress and impact in the implementation of the PMPA.*

6. Plenary session III: Clinical trial oversight in Africa: promoting research and development

6.1 Ethics clearance and joint reviews of Ebola vaccines and therapies in Africa: AVAREF experience

Dicky Akanmori observed that Ebola vaccine R&D has mainly been driven by public-private partnerships, to date.

Accelerating timelines for different phases of clinical trial was a major challenge. However, this was being overcome by working with different partners making it possible to achieve unprecedented timelines in the first and second phases of development of unique vaccines for Ebola. At times, different phases occurred simultaneously.

Human resources of each agency were bolstered to reduce clinical trial authorisations.

There were a host of key enabling factors, including the number of products in the pipeline for Ebola vaccines and availability of a network of ECs and NRAs. Importantly, BMGF was also willing to re-purpose the AVAREF meeting of affected countries, namely Guinea, Liberia and Sierra Leone. This was complemented by the willingness of sponsors to share plans openly, while sites and African scientists were available, while efforts received significant support from the FDA, Health Canada and EMA.

6.2 Country experiences on clinical trial authorisations and oversight of therapies and vaccines against Ebola and other Neglected Tropical Diseases: Ghana

This presentation by the head of NMRAs detailed Ghana's implementation of legal mechanisms to undertake clinical trials, of which 55 have been undertaken. Four Ebola vaccine trial applications were received, including one for the first phase and three for the third phase. The first phase study was not undertaken due to the withdrawal of sponsors, while the second-phase trials are ongoing and await review.

The Ebola vaccines CT reviews were undertaken by the Expert Committee on Clinical Trials. Joint reviews were then conducted with organisations, such as the NRAs, in other countries. Each NRA then decided to adopt the expert committee and joint reviews.

Challenges associated with the approval of these CTs included significant anxiety and fears among the population of the affected countries for many unspecified reasons. This was exacerbated by the spreading of negative rumours by members of the scientific community.

Lessons learnt included the need to adhere to the principles of science and law and form alliances to ensure that socio-cultural, economic or political considerations do not override them. Effective communication is also key to educating the public and assertion helps in this type of crisis scenario.

Charting the way forward involves acknowledging the importance of stringent regulation and strong collaboration and Optimum communication tools and channels. Parliament or legislature and sections of professional communities also need to be engaged, while regular updates need to be communicated to a wider audience to improve proactive stakeholder engagement for CT.

6.3 Country experiences on clinical trial authorisations and oversight of therapies and vaccines against Ebola, and other Neglected Tropical Diseases

Sierra Leone Head of NMRAs reminded delegates that the Ebola outbreak started in Guinea and then spread to Liberia, Sierra Leone and other countries. More than 27 000 cases were reported, while the outbreak resulted in more than 11 000 deaths, while HCWs caused untold suffering for many more. Health systems were overwhelmed and there were no vaccines or treatment available. In Sierra Leone, alone, more than 10 000 people were affected and the disease claimed the lives of 4 000. In addition, Ebola had an adverse impact on the socio-cultural behaviour of the affected countries. The Sierra Leonean government tackled the situation through emergency intervention, coordination and command. Stakeholders helped address the acceptability of the disease and established diagnosing and clinical-management facilities.

At the same time, the PBSL and College of Medicine and Allied Health Sciences of the University of Sierra Leone strengthened the country regulatory capacity for CTA evaluation, approval and monitoring.

The country expedited the review of all CTAs within 10 working days by collaborating with WHO, AVAREF and other partners, such as the WHO (GENEVA and AVAREF), Health Canada, FDA Ghana, NAFDAC-Nigeria, USFDA and MHRA-UK.

6.4 Regulatory challenges and opportunities for TB drugs and regimens

Martha A. Brumfield provided an update on new TB treatments. The Critical Path to TB Drug Regimens initiative is a partnership that unites drug developers, academic scientists, global regulatory authorities and civil society organisations to accelerate the development of new drug regimens for TB. The initiative is jointly led by the BMGF, Critical Path Institute and Global Alliance for TB Drug Development.

For the first time in more than 40 years, there are two new treatments for MDR TB:Sirturo (bed aquiline). It received swift approval from the USFDA in December 2012, and was included in the WHO Interim Treatment Guidance in June 2013. It also received conditional approval by EMA in March 2014 and approval by the South African MCC in October 2014. The second drug, Deltyba (delamanid), received conditional approval by EMA in November 2013. Both drugs were included in the WHO List of Essential Medicines in May 2015.

Licensing applications for these new drugs will be presented to national regulatory authorities for review and approval in the foreseeable future.

6.5 The role of regulatory oversight in advancing R&D on Neglected Tropical Disease: PDP experience

Nathalie Strub Wourgaft provided insights on the DNDi. This collaborative non-profit drug R&D organisation develops new treatments for neglected diseases. DNDi wants to deliver up to 18 new treatments by 2023; establish a robust pipeline of new medicines; and use and strengthen existing capacity in disease-endemic countries. In addition, it raises awareness and advocates for increased public leadership. The initiative is funded by several global organisations and has delivered six new treatments since 2003.

The DNDi acknowledges that there is an increasing number of CTs for products developed by PDPs

to address unmet medical needs. It also recognises that there is a degree of overlap between ethical committees and NRAs, compounded by the lengthy and resource-demanding reviews by NRAs. In addition, new mechanisms, such as those promoting joint reviews, by ethics committees and NRAs have proved to be of value. These could be initiated for priority products and support faster access to safe and effective treatments.

RECOMMENDATIONS ON CLINICAL TRIAL OVERSIGHT IN AFRICA: PROMOTING R&D

- *AMRH partners should facilitate collaboration and alignment in CT oversight to avoid competition and duplication, while guaranteeing optimal use of scarce resources on the continent.*
- *AMRH partners must strengthen joint assessments and collaboration among NMRAs, as well as Ethics Committees through the regional platforms.*
- *Governments, public funders and private donors should invest in clinical practice research and regulatory-support services on the continent.*
- *The AUC, through the CDC, must provide early-warning systems to monitor and inform decision makers on emerging public health threats affecting Africans.*
- *NMRAs in Africa should use available resources, such as European Public Assessment Reports, and opportunities for international regulatory collaboration. This will accelerate the reviewing of new medical products and technologies.*

7. Parallel session 3: ICT for advancing regulation of medical products in Africa

7.1 Monitoring quality of anti-malarial medicines in Kenya by using Minilab technology: a five year analysis

George Muthuri presented on collaborative studies on malaria medicines involving the PPB of Kenya, MCU, NQCL and USP PQM programme.

The main aims of the studies, which have been underway since 2010, were to determine the proportion of unregistered products and medicines in selected sites that conform to quality standards. Information on the quality of medicines is then disseminated to stakeholders involved in medicines procurement, use and regulation.

Initial testing was done with Minilabs at sentinel sites. Additional testing was undertaken at the National Drug Quality Control Laboratory on failed test results – first using a minilab and then the compendia method. Regulatory actions, such as product recall, were applied if a product batch failed to conform to acceptable quality standards.

Results from the four study rounds reveals improved quality of antimalarial products in Kenya. This is due to regulatory actions that have been implemented based on the failed batches.

The initiative has proved that Minilab testing offers an affordable and cost-effective means for monitoring quality of medicines in countries that have limited resources.

7.2 The impact of management information systems in strengthening regulatory systems: experience from Tanzania Food and Drugs Authority

Ambele Mwafula informed the conference delegates that, since 2014, the TFDA had been operating an electronic management information system to register medicines, medical devices, cosmetics and food. It also uses it to register premises, clinical trials, GMP and inspect import and export controls.

It has resulted in the introduction of online import and export applications, as well as approvals. In addition, it has facilitated the preparation of reports and reduced response time to customers. The system has also improved efficiency and revenue collection capabilities of the TFDA, while mitigating human errors in data capture.

7.3 Deployment of ICT as a tool in advancing medicinal products regulation in Nigeria: development of NAPAMS Version 2.0 Africa

Jayeola Babatunde Olajide explained that NAPAMS is a platform for electronic registration of regulated products that was developed by the NAFDAC. It was introduced in 2011 and since then, more than 4 000 registration applications have been managed electronically. The ICT system was deployed to improve efficiency and transparency in managing the large number of registration applications handled by NAFDAC and to improve transparency. The original version is being upgraded to Version 2.0 with more user-friendly features and the capability to process variations to registered product details.

The system has improved efficiency and therefore been very well received. This is despite challenges faced in its implementation, including difficulties in change management, limited computer skills of staff, the digitisation of manual work flows and classification of data.

7.4 Drugs, data and technology: developing electronic systems for drug registration in Bangladesh, Ethiopia and Mozambique

Kyle Duarte said the implementation of SIAPS was geared at strengthening pharmaceutical sector governance; building individual or institutional capacity for supply management and services; improving pharmaceutical service to account for health outcomes; and bolstering financial strategies and mechanisms to improve access to medicines and address information for decision making.

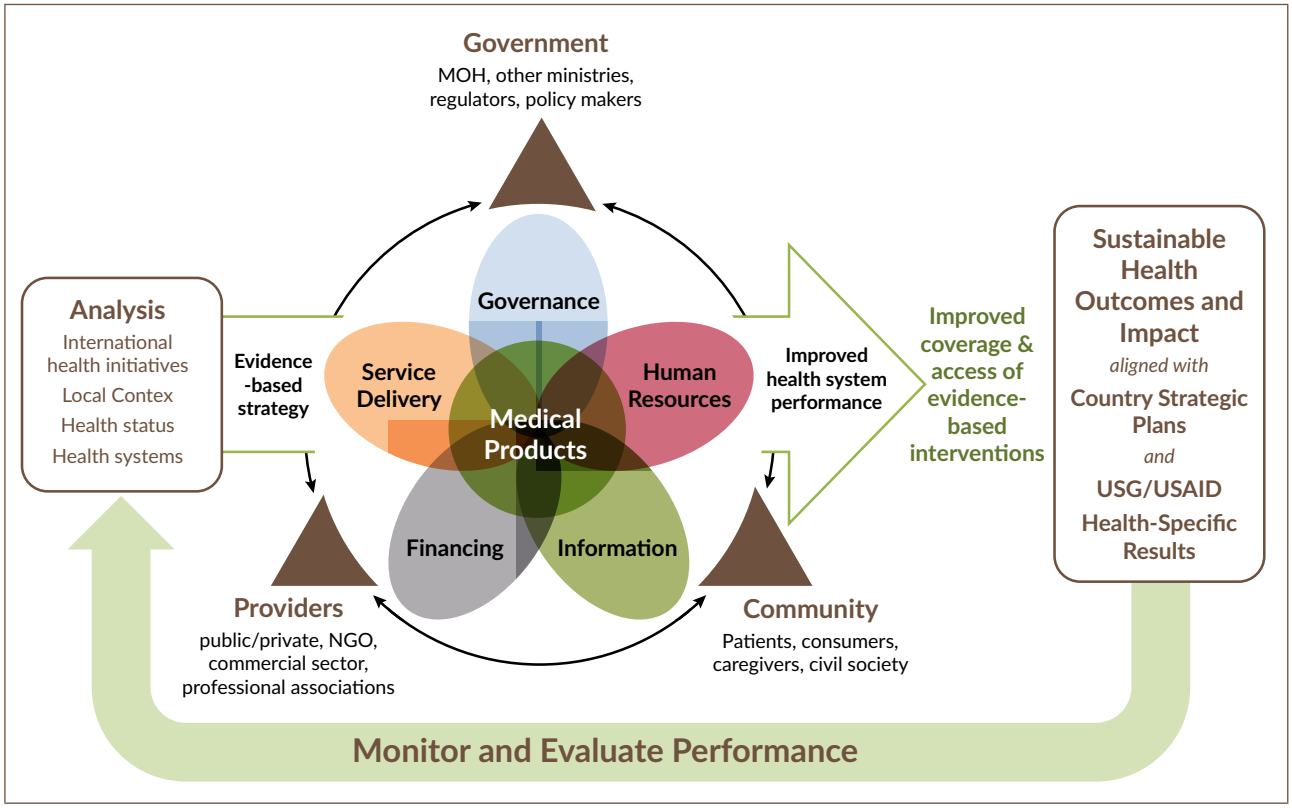


Figure 7.4.1 SIAPS system strengthening approach *(Source Duarte, Kyle and Aboagye-Nyame, Francis, 2015)*

Regulation systems are a key component of the pharmaceutical system to ensure health outcomes are attained.

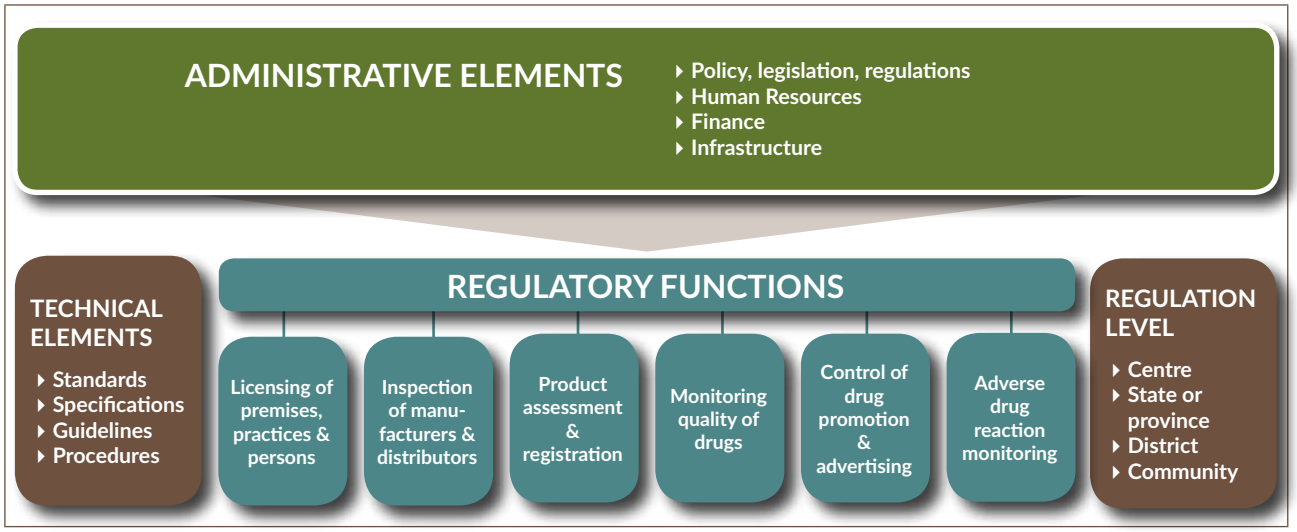


Figure 7.4.2 An approach to regulatory systems strengthening *(Source Duarte, Kyle and Aboagye-Nyame, Francis, 2015)*

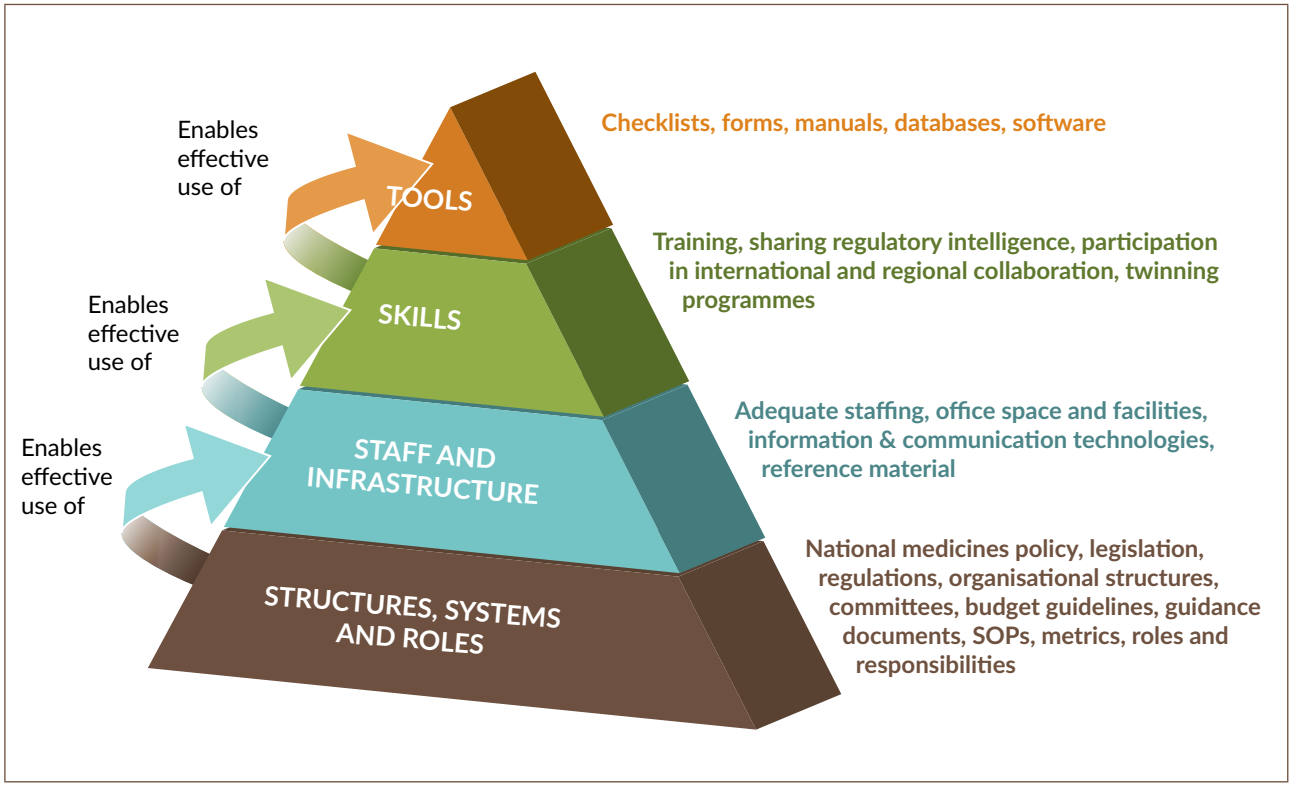


Figure 7.4.3 Capacity building for regulatory authorities *(Source Duarte, Kyle and Aboagye-Nyame, Francis, 2015)*

Capacity building is modelled in an inverted-pyramid structure. The basis of the model is structures, systems and roles, followed by staff and infrastructure, then skills and tools. In terms of research undertaken, only six out of 26 NMRAs had coherent networked computerised systems for medicines regulation in place, while nine relied upon manual systems.

Pharmadex is a web-based tool developed by the USAID-funded SPS programme and expanded under its successor, the SIAPS Programme. Pharmadex helps streamline and manage regulatory information throughout an NRA.

It is being implemented in Namibia, Mozambique, Ethiopia and Bangladesh.

Past experience has shown that there is a need to imbed governance issues when developing an automated system, while mapping and optimisation of the process is critical before implementing automation.

The implementation process (Figure 7.4.4) resulted in cross-fertilisation of best practices and ideas across countries. More than 60 key processes across three countries have been optimised and international standards and best practices adopted. Task-shifting data heavy steps reduces the burden on NRAs.

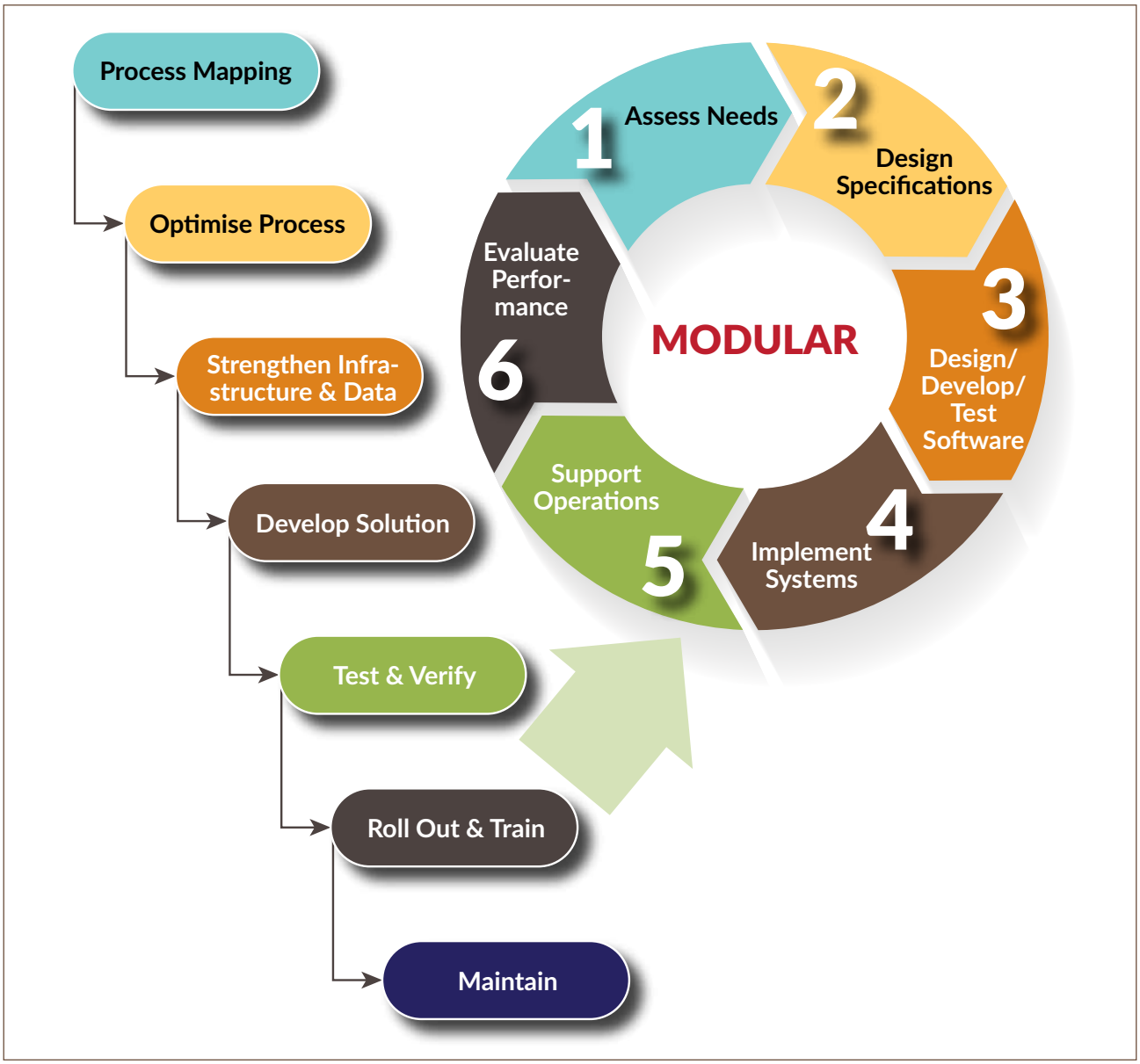


Figure 7.4.4 Implementation process *(Source Duarte, Kyle and Aboagye-Nyame, Francis, 2015)*

7.5 Strengthening regulatory systems by implementing electronic medicine registration data management system (PharmaDex) in Mozambique

Dr. Nazalie Macuvele Nazália Leonardo Macuvele said the organogram of the Pharmaceutical Department of Mozambique was enumerated, showing that it comprised 64 staff, nine of which were pharmacists, three chemists, 12 technicians and 25 finance and administration staff.

The PD experienced challenges in terms of regulatory tools, technical capacity and data management, and uses the PharmaDex medicine registration data management system to improve access to pharmaceuticals and services. The SIAPS provides effective communication and sound review capabilities.

7.6 Advancing medicine registration through process optimisation and automation

Endalk Gebrie of the FMHACA of Ethiopia identified a need to improve the efficiency of its medicine registration system by institutionalising transparency and accountability by deploying ICTs. The first step involved optimising medicine-registration processes and tools, followed by automation with support from USAID's SIAPS. The improved processes and tools have been incorporated into software that will introduce an electronic medicines registration information system in the next phase of implementation.

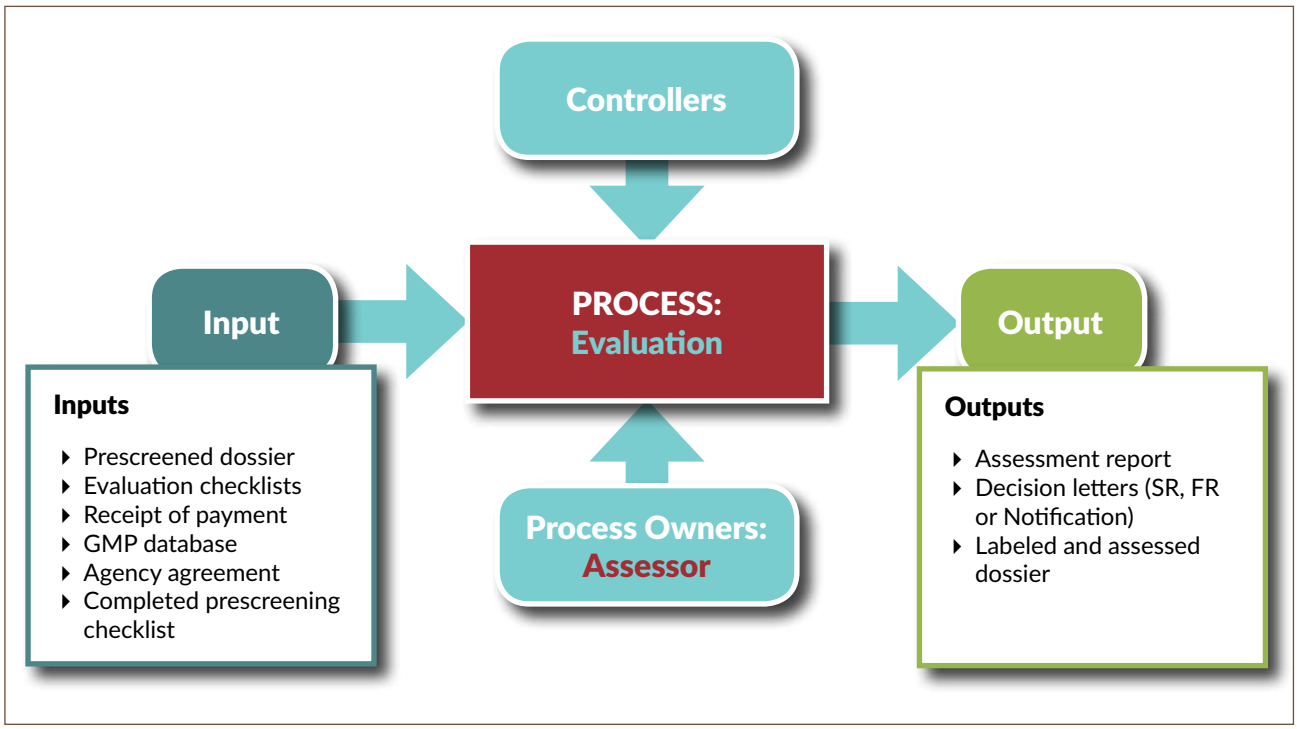


Figure 7.6.1 Processes and tools reviewed *(Source: Tadeg H.; Gebrie E.; Ejigu E.; Thumm M.; Duarte K.; Mengistu, A. (MSH) and H. Gebra (FMHACA) 2015)*

The figure above shows the results of the processes and tools that have been reviewed.

A total of 28 out of 38 of the 46 tools were modified during the optimisation phase. They included guidelines, SOPs, checklists and forms. Eight new tools were also developed, including evaluation guidance checklists for variations.

Table 7.6.1 Results of optimisation

Development, customisation, or optimisation of tools			
Types of tools	**No. of tools accepted**	**No. of tools modified**	**No. of new tools developed**
Guidelines/SOPs	2	3	2
Checklists	1	15	2
Templates	4	4	4
Forms	3	6	0
Total	**10**	**28**	**8**

Source: Tadeg H.; Gebrie E.; Ejigu E.; Thumm M.; Duarte K.; Mengistu, A. (MSH) and H. Gebra (FMHACA) 2015

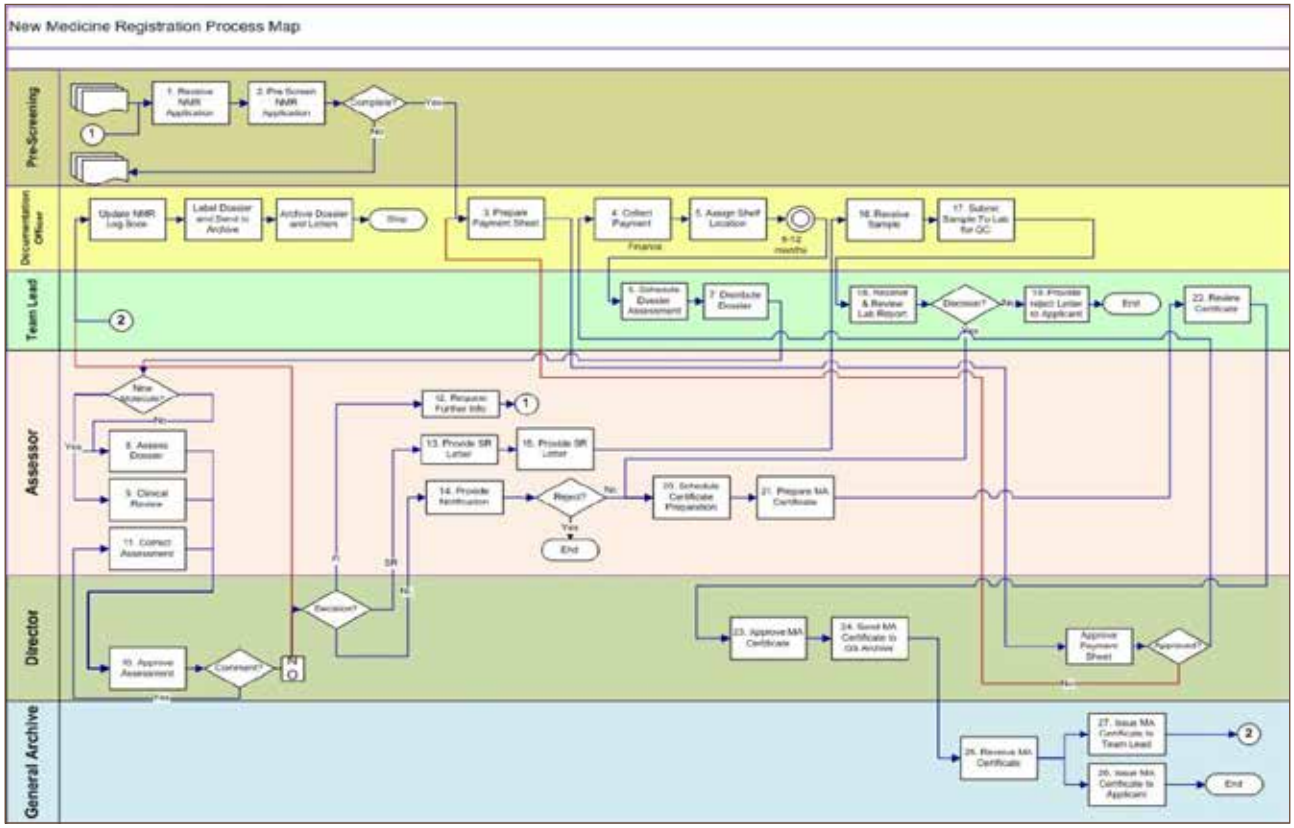


Figure 7.6.2 Sample redesigned process map for new medicines registration *(Source: Tadeg H.; Gebrie E.; Ejigu E.; Thumm M.; Duarte K.; Mengistu, A. (MSH) and H. Gebra (FMHACA) 2015)*

Figure 7.6.2 details the redesigned process map sample for new medicines registration.

Before NMRAs advance to automation, manual operational processes need to be well developed, stable and owned.

RECOMMENDATIONS ON ICT FOR ADVANCING REGULATION OF MEDICAL PRODUCTS IN AFRICA

- *NMRAs should ensure the deployment of technology to strengthen their regulatory systems. A phased approach to migration from manual to electronic systems should be adopted to avoid disruption of operations.*
- *NEPAD Agency, in collaboration with its partners, should facilitate the development of basic requirements for instituting ICTs to support Member States as they transition into the digital phase.*

8. Parallel session 4: The future of regulation of medical devices and technologies in Africa

8.1 ANDI: Facilitating technology development and market access in Africa: regulatory implications

Dr. Solomon Nwaka's presentation detailed that ANDI is a network that focuses on creating a sustainable platform for health innovation in Africa. It aims to promote and sustain African-led innovation to address the continent's public health requirements through the efficient use of local knowledge, assembly of research networks and building capacity to support development.

Compounding the host of challenges that blight the African health sector is limited resources for diagnostics, which are often inadequate for field use. Investments in R&D of diseases are also grossly inadequate and not profitable.

R&D into health innovation is also lagging. Africa represents a small subset, in terms of innovation, mirrored by the fact that only about 0,22 per cent of patents are filed on the continent. Intra-African networks are not well articulated, national clusters are common place and foreign universities are a bridge between African countries. According to the UNESCO Science Report of 2005, Africa spent about 0,3 per cent of its gross-domestic product on R&D in 2002, compared to the global benchmark of 1,7 per cent.

ANDI identifies and assesses the relevance of technology for local use, incorporates QA/QC and regulatory measures into its programme and provides catalytic funding where appropriate. It also brokers technology transfer, public- and private- as well as philanthropy-based partnerships to implement projects. Meanwhile, it integrates cross-cutting capacity building and training, complemented by its M&E efforts.

ANDI continues to report significant milestones.

These include the mapping of the health innovation landscape, as well as identifying and recognising pan-African centres of excellence and regional hubs that are can fund projects. It also advocates innovation, facilitates partnerships for AUC members, the WHO, UNOPS, AfDB, UNICEF and WB, while strengthening capacity of south-south and north-south partnerships.

However, it still faces several challenges. These include current regulatory systems that prioritise pharmaceuticals, as opposed to medical devices and diagnostics. Separate standards for "local" and "external" products are also hampering regulatory approvals, delaying product access to patients.

8.2 Global strategy on regulation of medical devices and technologies

Josephine MM Hansen said there are many issues to be considered in regulating medical devices and also differences and commonalities between medicines and medical devices. The WHO has developed a model regulatory framework for medical devices. WHA 60.29 defines the application of organised knowledge and skills of health technologies. This is in the form of devices, medicines, vaccines, procedures and systems.

There are therefore differences between medicines and medical devices in the regulatory framework, including assessment of the benefit or risk, nomenclature, industry composition and sales. Differences and commonalities can also be observed in clinical trials, marketing authorisation, uses and post-market surveillance.

The framework for medical devices includes IVDs. They were developed with international input, and reflect a modular approach to regulating medical devices. It guides in the processes involved in commencing regulating; determining what needs to be regulated by providing harmonised definitions and guiding principles; and explains how to regulate, as well as undertake stepwise methods of development and implementation. The framework also details when to regulate by highlighting priority areas and defining the transitional period.

The stepwise approach comprises basic elements. These include the establishment of essential principles of safety and performance and issuing guidance documents on regulatory requirements. They include the registration of manufacturers, importers and distributors and the listing of medical devices introduced to the market. It also consists of import, market surveillance, supply-chain control, traceability, labelling and instruction-for-use controls, while highlighting serious adverse events, recalls, and FSCAs, or withdrawal from market in exchange with other NRAs. The framework provides for exemptions from regulatory requirements, such as donations and humanitarian use, and the enforcement regulations.

8.3 The role of the pan-African Harmonisation Working Party on strengthening the capacity of regulation of medical devices and technologies

Agnes Kijo elaborated that the PAHWP is a voluntary body that aims to improve access to safe and affordable medical devices and diagnostics in Africa via harmonised regulation.

Its membership comprises Tanzania, Nigeria, South Africa, Burundi, Kenya, Ethiopia, Ghana, Malawi, Mozambique, Senegal, Sierra Leone, Uganda, Zimbabwe and Zambia.

PAHWP was conceived in 2012 following stakeholder meetings in East Africa with an interim secretariat within the EAC. It raises of awareness and advocates the strengthening of regulatory frameworks, preparing common registration files and reducing duplication in clinical-performance studies and PMS.

It studies and recommends ways of harmonising medical devices and diagnostics regulation in Africa. The current chair is the TFDA and vice-chair is the NAFDAC. The secretary is South Africa's NHLS.

It has achieved a number of milestones since its inception. This includes participating in the first African Regulatory Forum on Medical Diagnostics in July 2013 in Nairobi; a joint workshop with the Asian Harmonization Work Party in Taiwan in 2013, the AMRH Advisory Committee meeting in March 2014 in South Africa; the second African Regulatory Forum on Medical Diagnostics in January 2014 in South Africa; the third African Regulatory Forum on Medical Diagnostics in November 2014 in South Africa; and the Advanced workshop on Clinical Performance Studies in October 2014 in Tanzania.

PAHWP wants to enrol more member states to help it continue working with WHO, AHWP and other partners to regulate medical devices and diagnostics on the continent. It expects countries to adopt a stepwise approach to harmonised regulation of medical devices and in vitro diagnostics and has identified up to three priority areas for implementation. Countries are also expected to review their laws and adopt the Model Law for Medical Products that has been prepared in collaboration with the AU and NEPAD Agency to avoid duplication by multiple institutions.

8.4 The role of the African Society for Laboratory Medicines in the regulation of medical devices and technologies in Africa

Sagie Pillay says the ASLM was launched in 2011 as a pan-African professional body to advocate for the critical role and needs of laboratory medicine and networks on the continent.

In December 2012, a landmark Ministerial Call for Action was endorsed by African Health Ministers. It reinforced the commitment from multiple governments to enhance laboratory medicine throughout Africa. While pledging government support for ASLM and the ASLM2020 Strategic Vision, the Call for Action document outlines tangible steps that can be taken to improve laboratory systems at all levels.

The ASLM 2020 Strategic Vision provides for the certification of laboratory professionals and clinicians through standardised frameworks and enrols laboratories in quality-improvement programmes to achieve accreditation by international standards. It develops strong, harmonised regulatory systems for diagnostic products as defined by the Global Harmonization Taskforce and builds a network of national public health reference laboratories to improve early disease detection and collaborative research.

Regulatory control of diagnostics results in safety, quality, relevance, value for money, transparency of risk and other benefits. Importantly, science should be a driver in formulating regulations.

On the other hand, harmonisation prevents duplication, promotes the efficient use of scare skills and resources, enhances equity, promotes swift access to innovation and the sharing of experiences and data.

ASLM therefore fulfils several roles, including close

collaboration between WHO AFRO, NEPAD and regional structures to strengthen laboratory systems and harmonisation of regulatory requirements for diagnostics. It also coordinates clinical trials through the ASLM Centres of Excellence, convenes workshops to develop strategies and provides training in developing policy and regulations. It also shares data and provides information on evaluations, as well as clinical performance studies undertaken on the continent. In addition, it develops guidelines and draft templates for policies and regulations, while lobbying for the development of relevant regulation and regulatory harmonisation.

8.5 Country experience in regulation of medical devices and technologies: the case of Ghana

Hudu Mogtari noted that the regulation of medical devices in Ghana is governed by the Public Health Act, 2012, Act 851, Part 7. It comprises 70 sections including 14 sections on food, 19 on drugs, cosmetics, medical devices and household chemicals; 17 on administration; and 20 on general provisions. Section 80(1) establishes the FDA, while section 81 defines the objectives of the authority. This includes providing and enforcing standards for the sale of food, herbal medicinal products, cosmetics, drugs, medical devices and household chemical substances. Section 82 details the functions of the authority.

Section 117 provides for the application process for medical devices.

Apart from application for registration of a medical device, the law also provides for the registration of medical devices; cancellation or suspension of registration and importation of medical devices; handling of counterfeit medical devices; registration of premises, licenses and permits; closure of premises and safe disposal of unwholesome regulated products. It also details penalties, guidelines and codes of practice, Power of Authority to prosecute and Power of Court to suspend or cancel the licence.

The registration or approval process starts with the submission of the application. An applicant submits the completed application form, samples and fees. Evaluation of the application starts with a dossier evaluation committee meeting, before laboratory evaluation of samples is undertaken. Then GMP/QMS audit is undertaken of the facility, followed by a product registration committee meeting. Recommendations for approval, deferral or rejection are then made, before the CEO of the FDA makes a final decision, which is communicated to the client. An applicant can then appeal against the decision.

Operational documents include guidelines for the registration of medical devices and registration as an importer, as well as application forms for the registration of medical devices and for the registration as an importer of medical devices. Other operational documents in draft form include guidelines for the donation of medical devices, registration of combination products and group registration of medical devices, as well as guidance documents for the registration of medical devices.

RECOMMENDATIONS ON THE FUTURE OF REGULATION OF MEDICAL DEVICES AND TECHNOLOGIES IN AFRICA

- *Member States should promote and strengthen policy and regulatory frameworks for medical devices and diagnostics, as well as participate in regulatory harmonisation schemes and networking.*
- *Member States should strengthen research, development and innovation of medical devices and diagnostics, while ensuring swift access to novel technologies.*
- *Member states should invest in building technical expertise and capability for regulation of medical devices and diagnostics.*
- *AMRH partners should incorporate PAHWP's efforts into the AMRH initiative to minimise duplication of efforts.*

9. Plenary session IV: the future of medical products regulation in Africa: post-2015 development agenda

9.1 Strengthening health R&D and regulatory harmonisation in the Sustainable Development Agenda

Claire Wingfield reminded delegates that the UN adopted the SDGs in 2015, which replace the MDGs that expired during the same period. The MDGs had three health goals that were developed using a top-down approach as a blueprint for development aid. Meanwhile, the SDGs were driven by member states and provide a universal agenda for all countries and sectors. Out of the 17 SDGs, there is one health goal focusing on maternal, newborn, communicable diseases and nutrition, plus NCDs, mental health and injury. In addition, they provide more ambitious goals to eliminate disease and ending preventable deaths.

The SDGs will not be achieved without investing in R&D and regulation of new health technologies. As such, the role of R&D, and strengthening of regulatory systems has been included in targets under three goals. However, there are no corresponding targets on R&D and regulatory systems. For this reason, PATH, MMV, Global Health Technologies Coalitions, TB Alliance, AVI, COHRED and FIND partnered to find indicators and methods to measure global health R&D for the post-2015 development agenda. The global indicators will track the progress of all countries toward the SDGs and represent the core set that will be monitored on a regular basis.

9.2 A Summary of agency model and quality management systems of National Medicines Regulatory Agencies in Africa

Benjamin Kwame Botwe highlighted that medical products regulatory systems in many African countries are at different levels of development. This is despite the existence of national health or medicines policies to ensure that products are of the correct quality, safe and efficient. Regulatory systems in different countries have been designed according to their country's legal frameworks. Differences exist in medical products regulatory infrastructure, with some countries having regulatory agencies and others not. Against the backdrop of harmonisation, it is important for countries that do not have regulatory agencies to create one.

A study was conducted to analyse the medical products regulating infrastructure in 47 African countries to propose a model medicines agency for those countries that want to establish new ones or review available options. More than 90 per cent of the 47 countries surveyed have documented national medicines, or drug policies which have been reviewed in the last 10 years. Results further identified two main categories of regulatory systems. The first comprises autonomous agencies and the second institutions that are a function of a ministry responsible for health. Regulatory systems that fall under the ambit of ministries responsible for health are mainly financed from national consolidated funds. Fees charged for services are paid to finance-related ministeries. However, these institutions receive direct financial and technical assistance from bilateral and multilateral agencies, such as the WHO, UNICEF, Global Fund, WB, USAID, GIZ and DFID, to name a few. On the other hand, independent NMRAs' budgets are determined by funds that are generated from fees charged for the services that they render. A few of the NMRAs retain all the fees, paying their own staff salaries and financing their operations. Others are permitted by law to only retain a certain percentage of their fees, while central government pays salaries and allowances. They also undertake various projects funded from bilateral and multilateral sources. The study also assessed the different legal provision, as well as governance structures in different countries.

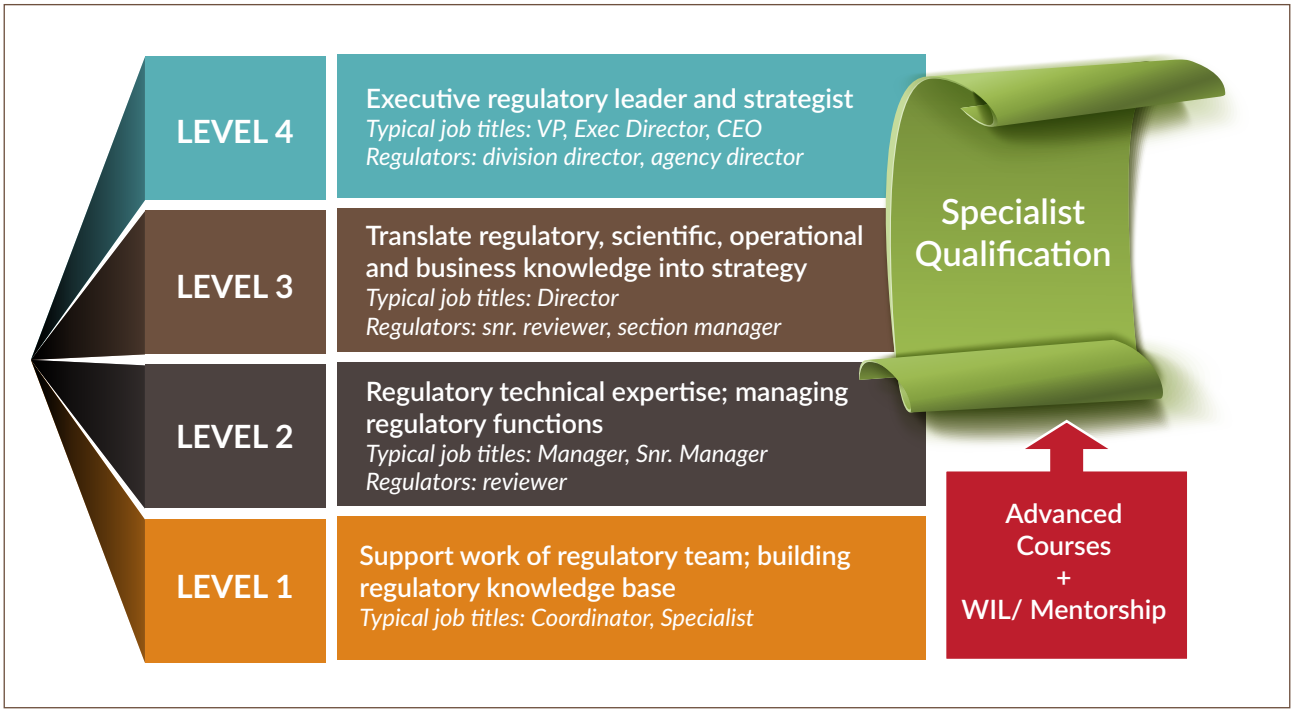
It was recommended that policies of countries make provision for medicines regulatory systems and, more specifically, specialised autonomous or semi-autonomous agencies. The study also suggested that comprehensive legislation be passed to support all medicines-regulatory activities, including for the provision of existing harmonisation efforts – either on a bilateral or multilateral basis. A clear governance structure, together with other operational plans, quality management and information and knowledge management systems is needed to create efficiency.

9.3 The Institute for Regulatory Science: a model for building regulatory capacity in Africa

Desmond Johns detailed South African government's efforts in establishing the IRS to develop national regulatory capacity to support the country's SAHPRA that is being established. The institute will focus on ensuring access to safe and effective health products by enabling the "leapfrogging" of existing regulatory practice to bring the country on par with its international peers. The institute will also provide training in regulatory capacity that is urgently required throughout the sector. It will deploy collaborative solutions that facilitate the best use of available solutions. This will enhance capacity to support the reorientation from an external evaluation model deployed in the MCC to an internal model that will be used by SAHPRA.

The IRS will provide flexible access to quality assured, basic and advanced courses in regulatory science; support the development and deployment of structured work-integrated learning, or mentorship programmes; and offer a "think-tank" function to monitor, or engage the development of global policy and mobilise the appropriate constituencies and responses. It will use occupational qualifications to deliver "work-ready" graduates, who can be further trained. The core competencies and accredited web-based post-graduate programmes (NQF 8) structure will be developed by consulting national and international stakeholders . The IRS model will facilitate consistent, coherent and cross-learning elements for corresponding functions in the national regulator and industry. It will initially focus on medicines regulation by adopting a model that can be replicated for regulation of medical devices, in vitro diagnostics and complementary medicines. Although the initial focus will be on responding to the needs of SAHPRA and South African industry, the project is scalable with established coherence with regional, such as SADC, and continental (AMRH) endeavours.

Competency-based skill levels for IRS



9.4 Partnership platform for advancing medical products regulation in Africa

Chimwemwe Chamdimba said the AU frameworks provide policy guidance to member states to advance a particular sector. This avails a common goal that unites different stakeholders to support implementation and facilitate collaboration and partnerships. The PMPA operated for 10 years as an AU Strategic Framework for addressing public health challenges by ensuring sustainable access to necessary medical products. It unlocks key bottlenecks hampering sustainable local production and access to medical products.

In addition, the PMPA has led to the emergence of collaborative efforts in different areas. It is working with different institutions at a continental level to support an array of activities. However, there is still need to strengthen collaboration and coordination of the actions by different participants to minimise duplication of effort and competition for resources, while eliminating confusing steps in advancing the agenda.

As such, the Partnership Platform will support dialogue and exchange among stakeholders, including African governments, private sector, financing institutions, development partners, research and academic institutions, as well as civil society. In addition, it will facilitate the alignment and harmonisation of development partners' support, actions and commitments, while ensuring mutual accountability in achieving its mandates. Membership of the platform will comprise representatives from different sectors, including health, trade and industry, finance and legal affairs, as well as science, technology and innovation.

The Regulatory Systems Strengthening Partnership Platform will focus on GMP registration; PMS and safety monitoring; and CT oversight, policy and legislation, medical devices and diagnostics, inspections and enforcement, vigilance and risk management.

10. Closing Session

THE FUTURE OF MEDICAL PRODUCTS REGULATION IN AFRICA: POST-2015 DEVELOPMENT AGENDA

- *AMRH partners should explore modalities to facilitate the inclusion of the South African Institute of Regulatory Authority and the Ethiopean Bioequivalence Centre as part of the RCOREs.*
- *The AUC and NEPAD Agency should institute a platform to facilitate coordination of partners.*
- *AUC and NEPAD Agency should ensure the integration of R&D and regulatory strengthening indicators into the au M&E system – in line with the SDGS and Agenda 2063.*

10.1 Remarks from WHO

Dr. Ossy MJ Kasilo reiterated WHO's commitment to continue working with partners, including the NEPAD, AUC and BMGF to support African countries in strengthening regulatory systems. Importantly, WHO/AFRO said it appreciated the contribution of the Conference Organising Committee, consisting of NEPAD, AUC, AFRO, EMRO and others, for their efforts. Kasilo also acknowledged the role EMRO had played in attracting Eastern Mediterranean countries to share their experiences and learn from their counterparts elsewhere on the continent.

Dr. Kasilo noted that the objectives of the second Biennial Scientific Conference on Medicines Regulation in Africa with its Regulatory Systems Strengthening

for Advancing Research, Innovation and Local Pharmaceutical Production in Africa theme had been achieved. This was mirrored by the recommendations of the conference, as well as the active participation and contribution from representatives of African regulators and scientific bodies, as well as from training and research institutions.

She said that the strong presentations demonstrated that Africa had skilled personnel with sound regulatory capacity, and observed that there had been very rich exchange of experiences during the four plenary sessions.

Kasilo emphasised the theme of the keynote presentation on Research, Innovation and Local Pharmaceutical Production in Africa, namely Yes! We Africans Can. She agreed that Africa had a very rich biodiversity, which can become a platform for drug discovery. There is need to invest in scientists and researchers to develop plant-based medicines within the framework of the PMPA to improve access to essential medicines. This will aid the building of regulatory systems as requested by the African Summit of the AU Heads of States and government, WHO and RECs.

Kasilo reminded that the African Union Summit of Heads of State and Government, as well as the 60th and 63rd sessions of the WHO Regional Committee for Africa in 2012 supported the establishment of an AMA. Subsequently, the AU Executive Council endorsed a roadmap for the establishment of the AMA, based on the recommendation of the first African Ministers of Health meeting that was convened by the AUC and WHO. The AUC, NEPAD and WHO has established the task team and developed a draft business plan and regulatory framework for its launch. She said that the WHO would continue its work with these partners to launch the AMA in 2018.

10.2 Remarks from NEPAD Agency

On behalf of NEPAD Agency and AU institutions, Prof. Aggrey Ambali of NEPAD expressed his satisfaction that the second Biennial Scientific Conference on medicines Regulation in Africa had produced sound recommendations that need to be implemented. He also called upon AU member states to intensify the improvement of regulatory strengthening at national, regional and continental levels, via public and private institutions.

ANNEXES

Annex 1: Conference programme

Time	Topic	Presenter
Monday, 30 November 2015		
07:00-08:30	Registration	
08:30 – 10:40: Opening session **Session co-Chair:** Margareth Ndomondo-Sigonda of NEPAD and Ossy Kasilo of WHO **Rapporteurs:** Chimwemwe Chamdimba and Paul Tanui		
08:30 – 8:40	Welcome remarks by NEPAD Agency	Prof. Aggrey Ambali
08:40 – 08:50	Remarks by Federation of African Pharmaceutical Manufacturers Association	Mr. Nazeem Mohamed
08:50 – 09:00	Remarks by World Bank	Mr. Apollo Muhairwe
09:00 – 09:10	Remarks by World Health Organization (WHO)	WHO representative, Ethiopia
09:10 – 09:20	Remarks by Bill and Melinda Gates Foundation	Dr. Dan Hartman
09:20 – 09:30	Remarks by Pan African Parliament	Hon. Dr. Saratou Balla
09:30 – 09:50	Opening speech	Ambassador Dr. Olawale Maiyegun
09:50 – 10:00	Short video on medicines regulation in Africa	
10:00 – 10:30	Keynote presentation: regulatory systems strengthening for advancing research, innovation and local pharmaceutical production in Africa	Dr. Paul A. Lartey
10:30 – 11:00	Group photo and tea/coffee break	All

Time	Topic	Presenter
11:00 – 13:00: Plenary Session I: Experiences on regulatory networking and information sharing in the advent of regional integration and regulatory harmonisation **Session Co-Chairs:** Marthe Everard of WHO and Corneille TRAORE and WAEMU **Rapporteurs:** David Matle and Nancy Ngum		
11:00 – 11:20	AMRH Programme: Continental progress update	Margareth Ndomondo-Sigonda, NEPAD Agency
11:20 – 11:40	The role of research in informing policy and advancing regulatory science in Africa	Chimwemwe Chamdimba, NEPAD Agency
11:40 – 12:00	WHO collaborative registration procedures as a model for regulatory cooperation	Milan Smid, WHO
12:00 – 12:20	Discussion	
12:20 – 12:40	Experience in regulatory harmonisation and joint assessment in the EAC region: impact and lessons learnt	Hiiti Sillo, Tanzania
12:40 – 13:00	Experience and lessons learnt from ZAZIBONA Collaborative Medicines Registration model	Luther Gwaza, Zimbabwe
13:00 – 13:30	Discussion	
13:30 – 14:30	Lunch	All
14:30 – 16:30: Parallel sessions		

Time	Topic	Presenter
Parallel session 1: innovative post-marketing surveillance interventions in resource limited settings		
Co-chairs: Patrick Lukulay of USP and Fred Siyoi of KPPB		
Rapporteurs: Imene Chergui and Apollo Angole		
Post Marketing Surveillance of antimalarial medicines in Tanzania by Sophia Ally Mziray		
Detecting product quality problems and protecting public health using pharmacovigilance data: the Ethiopian experience by Hailu Tadeg		
Regulatory assessment of pandemic (A)H1N1 influenza vaccine and narcolepsy safety issue: lessons to learn for resources limited countries by Joachim Doua		
Medication error disclosure and attitudes to reporting by healthcare professionals in a sub-Saharan African setting: a survey in Uganda by Ronald Kiguba		
Assessment of substandard/counterfeit medicines in the Ethiopian pharmaceutical market by Dawit Dilbeto		
14:30 – 16:30: Parallel sessions		
Surveillance of Medical Devices and In-Vitro Diagnostics (IVDs) in resource limited settings: Tanzania Experience by Agnes Sitta Kijo		
Parallel session 2: medical products regulatory systems in Africa in the advent of regional integration and regulatory harmonisation		
Co-chairs: Ben Botwe and Stanley Sonoiya, EAC		
Rapporteurs: David Matle and Bonaventure Nyabenda		
Collaborative procedure in assessment and accelerated approval of pharmaceutical products by Mercè Caturla, Pharma		
Establishment of a regional processes for medicines registration for drugs in Central Africa by Alexandre DE LA Volpiliere		
WHO Prequalification and market access of an innovator product. An industry experience by Fabienne Benoist		
The role of regulatory interventions in improving access to quality pharmaceutical services: «lessons learned from accredited drug seller initiatives in Tanzania, Uganda and Liberia». by Eliphace Christopher Mkumbo		

Time	Topic	Presenter
16:30 – 16:45	Tea break	All
16:45 – 18:00: Plenary session II: Advancing local production of medical products for Africa – Where are we? **Co-Chairs:** Janet Byaruhanga of theAfrican Union Commission **Rapporteurs:** Imene Chergui and Nancy Ngum		
16:45 – 17:05	Status of pharmaceutical manufacturing in Africa: PMPA +10: where are we?	George Makateto
17:05 – 17:25	The implementation of 350-2500 nm Reflectance spectroscopy and high performance thin layer chromatography to rapidly assess manufacturing consistency and quality of Co-trimoxazole tablets in Tanzania	Eliangiringa Kaale, MUHAS
17:25 – 17:45	GMP roadmap for implementation of the AU Pharmaceutical Manufacturing Plan for Africa (PMPA): a Regional Approach	Paul Tanui, NEPAD Agency
17:45 – 18:05	Discussion	
Tuesday, 01 December 2015		
08:30 – 10:40: Plenary Session III: Clinical trial oversight in Africa: promoting research and development **Session Chair:** Dan Hartman of the Bill and Melinda Gates Foundation **Rapporteurs:** Apollo Angole and Ali Arale		
08:30 – 08:50	Ethics clearance and joint reviews of Ebola vaccines and therapies in Africa: AVAREF experience	Dicky Akanmori
08:50 – 09:10	Country experiences in clinical trial authorisations and oversight of therapies and vaccines against ebola, as well as other neglected tropical diseases: Ghana	Heads of NMRAs Ghana
09:10 – 09:30	Country experiences on clinical trial authorisations and oversight of therapies and vaccines against Ebola, and other neglected tropical diseases: Sierra Leone	Heads of NMRAs Sierra Leone

Time	Topic	Presenter
09:30 – 09:50	Country experiences in linical trial authorisations and oversight of therapies and vaccines against Ebola, and other neglected tropical diseases: Liberia	Heads of NMRAs Liberia
09:50 – 10:10	Discussion	
10:10 – 10:30	Regulatory challenges and opportunities for TB drugs and regimens	Martha A. Brumfield
10:30 – 10:50	The role of regulatory oversight in advancing R&D on neglected tropical disease: PDP experience	Nathalie Strub Wourgaft
10:50 – 11:10	Discussion	
11:10 – 11:30	Tea/coffee Break	
11:30 – 13:30**: Parallel sessions**		
Parallel session 3: ICT for advancing regulation of medical products in Africa Co-chairs: Monica Doo Eimunjeze of NAFDAC and Francis Aboagye-Nyame of MSH-SIAPs Rapporteurs: George Makateto and Apollo Angole Monitoring quality of anti-malarial medicines in Kenya by using minilab technology: a five year analysis by George Muthuri The impact of a management information system in strengthening regulatory systems: experience from Tanzania Food and Drugs Authority by Ambele Mwafula Deployment of ICTs as a tool in advancing medicinal products regulation in Nigeria: development of NAPAMS Version 2.0 Africa by Jayeola Babatunde Olajide Drugs, data and technology: developing electronic systems for drug registration in Bangladesh, Ethiopia and Mozambique by Kyle Duarte Strengthening Medicine Regulatory Systems by implementing electronic medicine registration data management systems (PharmaDex) in Mozambique by Dra. Nazalie Macuvele Advancing medicine registration through process optimization and automation by Endalk Gebrie		

Time	Topic	Presenter
Parallel session 4: the future of regulation of medical devices and technologies in Africa Co-chairs: Jean Baptiste Nikiema, WHO and Sybil Nana Ama Ossei-Agyeman-Yeboah, WAHO Rapporteurs: Paul Tanui and Hidaya Juma Hamad ANDI: facilitating technology development and market access in Africa, regulatory implications by Solomon Nwaka Global strategy on regulation of medical devices and technologies by Josephine MM Hansen The role of pan-African harmonisation working party on strengthening the capacity of regulation of medical devices and technologies by Agnes Kijo The role of African society for laboratory medicines in regulation of medical devices and technologies in Africa by Sagie Pillay Country experience in regulation of medical devices and technologies: the case of Ghana by Hudu Mogtari Industry perspective on regulation of medical devices and technologies in Africa by Madeleine Pearce		
13:30 – 14:30	Lunch	
Plenary Session IV: The future of medical products regulation in Africa: post-2015 development agenda **Chair:** Gugu Mahlangu of the Medicines Control Authority of Zimbabwe **Rapporteurs:** Chimwemwe Chamdimba and Marthe Everard		
14:30 – 14:50	Strengthening health R&D and regulatory harmonisation in the sustainable development agenda	Claire Wingfield
14:50 – 15:10	A summary of agency models and quality management systems of National Medicines Regulatory Agencies in Africa	Benjamin Kwame Botwe
15:10 – 15:30	The Institute for Regulatory Science: a model for building regulatory capacity in Africa	Desmond Johns
15:30 – 15:50	Partnership platform for advancing medical products regulation in Africa	Chimwemwe Chamdimba
15:50 – 16:10	Discussion	
16:10 – 16:30	Tea/coffee Break	
Closing session **Session co-Chair:** Margareth Ndomondo-Sigonda of NEPAD and Ossy Kasilo of WHO **Rapporteurs:** Paul Tanui and Ali Arale		

Time	Topic	Presenter
16:30 – 16:40	Presentation of conference recommendations	Chief Rapporteur
16:40 – 16:50	Discussion of conference recommendations	All
16:50 – 17:00	Remarks from WHO	WHO Representative
17:00 – 17:10	Remarks from NEPAD Agency	Prof. Aggrey Ambali, NEPAD Agency
17:10 – 17:20	Closing Remarks from AUC	Ambassador Dr. Olawale Maiyegun, AUC
17:20	End of Conference	

Annex 2: Conference Participants

S/N	Name	Country	Organisation	Contact Details
1	Ayenew Ashenef	Ethiopia	Addis Ababa University	ayenew.ashenef@aau.edu.et
2	Benmakhloud Madjid	Algeria		msdphm@ibnsina.ands.dz; majbendoc@yahoo.fr
3	Takele Geressu	Ethiopia	ANDI	takeleg@unops.org
4	Abel Sunda	Angola		abelsunda@gmail.com
5	Sagie Pillay	South Africa	ASLM	spillay@aslm.org
6	George Makateto	Ethiopia	AUC	gmakateto@yahoo.com
7	Hailu Kidu	Ethiopia	AUC	kiduhailu@yahoo.com
8	Imene Chergui	Ethiopia	AUC	imene.chergui@gmail.com
9	Janet Byaruhanga	Ethiopia	AUC	ByaruhangaJ@africa-union.org
10	Ndayishimiye Medic	Ethiopia	AUC	mndayish@yahoo.ca
11	Robert Ndieka	Ethiopia	AUC	ndiekar@africa-union.org
12	Serkdaniel Solomon	Ethiopia	AUC	serkdaniel@africa-union.org

S/N	Name	Country	Organisation	Contact Details
13	Sheila Shawa	Ethiopia	AUC	shawas@africa-union.org
14	Somda Paulin	Ethiopia	AUC	paulinesimda@yahoo.com
15	John Mwangi		Bayer	john.mwangi@bayer.com
16	Agathe Assankpon	Benin	Media	assauline@gmail.com
17	Dan Hartman	USA	Bill & Melinda Gates Foundation	Dan.hartman@gatesfoundation.org
18	Samantha Galvin	USA	Bill & Melinda Gates Foundation	samantha.galvin@gatesfoundation.org
19	Samuel Martins	USA	Bill & Melinda Gates Foundation	samuel.martins@gatesfoundation.org
20	Vincent Ahonkhai	USA	Bill & Melinda Gates Foundation	Vincent.Ahonkhai@gatesfoundation.org
21	Abdoulaye Nikiema	Burkina Faso		abdoulniki@gmail.com
22	Samdrine Gampini	Burkina Faso		samdy2bf@yahoo.fr
23	Bonaventure Nyabenda	Burundi		bonaventurenyabenda@gmail.com
24	Emmanuel Bamenyekanye	Burundi		bamenyekanye@hotmail.com
25	Ndayishimiye Medic	Canada		mndayish@yahoo.ca
26	Angela Silvestre	Cape Verde		angela.silvestre@ms.gov.cv
27	Innocent Makwiramiti	COMESA		imakwiramiti@comesa.int
28	Said Fazul Ahamada	Comoros (the)		sfazul@yahoo.fr
29	Jean Aimé EKAKA	Congo (Republic of)		dpmcongo@gmail.com
30	Joachim Y. Doua		Consortium for African Regulatory Expertise Development	y.j.doua@gmail.com
31	Anastasie Mulumba	Democratic Republic of the Congo (the)		mulumbaa@who.int

S/N	Name	Country	Organisation	Contact Details
32	Daniel Ngeleka Mutolo	Democratic Republic of the Congo (the)		dangelemutolo@yahoo.fr
33	Hassan Moussa Hassan	Djibouti		libahsakatabte@yahoo.fr
34	Nthalie Strub Wourgart	Switzerland	DNDi	nstrub@dndi.org
35	Jane Mashingia	Tanzania	EAC	jmashingia@eachq.org
36	John Patrick Mwesigye	Tanzania	EAC	jmwesigye@eachq.org
37	Stanley Sonoiya	Tanzania	EAC	ssonoiya@eachq.org
38	Jean Claude Loukaka		ECCAS	jcloukaka@yahoo.fr
39	Osama Ahmed Mohamed Ali Badary	Egypt		obadary@yahoo.com
40	Habtamu Beyele	Ethiopia		skeennaa@gmail.com
41	Heran Gerba	Ethiopia		eghna2013@gmail.com
42	Zerlealem Tesfaye	Ethiopia		zerlealem8@hotmail.com
43	Martin Harvey Allchurch		European Medicines Agency	Martin.Harvey@ema.europa.eu
44	Nazeem Mohamed		FAPMA	nazeem@kpi.co.ug
45	Dhirendra Shah		FEAPM	drshah@biodealkenya.com
46	Osaretin Jaiyeola		Fensyl MHP Consulting Limited	osaretin.jaiyeola@fensyl.com
47	Aida Cancel		FHI360	acancel@fhi360.org
48	Hien Dinh		FHI360	hdinh@fhi360.org
49	Hudu Mogtari	Ghana		fda@fdaghana.gov.gh; hudu.mogtari@fdaghana.gov.gh
50	Robert Afriye	Ghana		
51	Wesley Ronoh	Tanzania	GIZ - EAC	wesley.ronoh@giz.de
52	Kemal Hussein		Global Fund	kemalfenet@yahoo.com

S/N	Name	Country	Organisation	Contact Details
53	Francis Karanja		GSK/KAPI	francis.m.karanja@gsk.com
54	Nagnouma Sano	Guinea		snagnouma@yahoo.fr
55	Magassouba Koman		Guinea Embassy	komanmaga@yahoo.fr
56	Guillermo Lopez Rozada		i+solutions	grozada@iplussolutions.org
57	Boitumelo Mokgatla	Botswana	IAVI	bmokgatla@iavi.org
58	Caroline Mendy	Switzerland	IFPMA	c.mendy@ifpma.org
59	Fatuma Adan	Kenya	IGAD	fatuma.adan@igad.int
60	Johan Venter		International Partnership for Microbicides	jventer@ipmglobal.org
61	Judy Coates	South Africa	IPASA	judy@ipasa.co.za
62	Dr Thomas LAPNET-MOUSTAPHA		IST/ESA	lapnett@who.int
63	Merce Caturla		Jansen	mcaturla@its.jnj.com
64	Ali Arale	Kenya		aliarale@yahoo.com
65	Fred Moin Siyoi	Kenya		fmsiyoi@gmail.com
66	George Muthuri	Kenya		
67	Paul Lartey		Lagray	paul.lartey@lagray.org
68	Hanan Benashar	Libya		hananbenashar@yahoo.com
69	Nagi Mohamed	Libya		
70	Ronald Kiguba		Makerere University	kiguba@gmail.com
71	Yaya Coulibaly	Mali		couliyaya2003@yahoo.fr
72	Nazalia Maculuve	Mozambique		nasaliamacuvele47@gmail.com
73	Robyn Daniel		MRA Regulatory Consultants	robyn@mra-regulatory.com
74	Edmealem Ejigu		MSH	eejigu@msh.org
75	Eliphace Mkumbo	Tanzania	MSH	emkumbo@msh.org

S/N	Name	Country	Organisation	Contact Details
76	Suleiman Kimatta	Tanzania	MSH	skimatta@msh.org
77	Yewedalem Tesfaye Tiruneh		MSH	ytesfaye@et.pfscm.org
78	Yodit Admasu		MSH	yadmasu@msh.org
79	Robert Tuala Tuala		MSH/SIAPS	
80	Mulu Legesse		MSH/USAID	mlegesse@msh.org
81	Eliangiringa Kaale		MUHAS	elia.kaale@muhas.ac.tz
82	Chimwemwe Chmadimba	South Africa	NEPAD	chimwemwec@nepad.org
83	Flore Kamdong	South Africa	NEPAD	florek@nepad.org
84	Manana Mashologu	South Africa	NEPAD	mananam@nepad.org
85	Margaret Mahlomuza	South Africa	NEPAD	margaretr@nepad.org
86	Margareth Ndomondo-Sigonda	South Africa	NEPAD	margarets@nepad.org
87	Mercy Fomundam	South Africa	NEPAD	mercyf@nepad.org
88	Millicent Seganie	South Africa	NEPAD	millicents@nepad.org
89	Nthabiseng Moiloa	South Africa	NEPAD	nthabisengL@nepad.org
90	Paul Tanui	South Africa	NEPAD	paulk@nepad.org
91	Prof Aggrey Ambali	South Africa	NEPAD	aggreya@nepad.org
92	Babatunde Jaiyeloa	Nigeria	NAFDAC	tundejay@gmail.com
93	Colette Ifudu	Nigeria	NAFDAC	coletteifudu@yahoo.com
94	Monica Hemben EIMUNJEZE	Nigeria	NAFDAC	eimunjeze.m@nafdac.gov.ng
95	Mohamed Elhassan Imam	North Sudan	NMRA	imam@nmpb.gov.sd
96	Wijdan Khalid Elfil	North Sudan	NMRA	wijdan02@yahoo.com
97	Zehour Yahia Shamseldin	North Sudan	NMRA	zehor.yayha@yahoo.com
98	Anne Grobler	South Africa	North West University	anne.grobler@nwu.ac.za

S/N	Name	Country	Organisation	Contact Details
99	Elishiba Mwangi		Novartis	elishiba.mwangi@norvatis.com
100	Sarah Muthuri		Novartis	sarah.muthuri@novartis.com
101	Dakshina Reddy		Novartis South Africa	dakhshina.reddy@novartis.com
102	Libandra Reddy		Novartis South Africa	libandra.reddy@novartis.com
103	Aime Djitafo Fah	Cameroon	OCEAC	aimedjitafofah@yahoo.fr
104	Alexandre de La Volpilière	Cameroon	OCEAC	a.delavolpiliere@gmail.com
105	Emilienne Pola Yissibi	Cameroon	OCEAC	Pola54@yahoo.fr
106	Marie Bebey	South Africa	Pan African Parliament	bebeymarie@yahoo.fr
107	Saratou Bala	Niger	Pan African Parliament	bala_saratou@yahoo.fr
108	Claire Wingfield	USA	PATH	cwingfield@path.org
109	Hesbon Simba	Kenya	PATH	hsimba@path.org
110	Tapiwa Mupereki		PFSCM	tmupereki@pfscm.org
111	Tobias Diergardt		PTB	tobias.diergardt@ptb.de
112	Charles Mangwiro		Radio Mozambique	mangwiroc@gmail.com
113	Tsige Marcam		Regional Bioequivalence Centre	tsigegmwm@gmail.com
114	George Mhango		SABC	
115	Madicke Diagne	Senegal		dmadicke@yahoo.fr
116	Bilkis Mia		Serenus Biotherapeutics	bmia@serenusbio.com
117	Prakhash Chetty		Serenus Biotherapeutics	pchetty@serenusbio.com
118	Francis Aboagye-Nyame		SIAPS	fnyame@msh.org

S/N	Name	Country	Organisation	Contact Details
119	James Komeh	Sierra Leone	NMRA	kompjames@yahoo.com
120	Mr Wiltshire C.N. JOHNSON	Sierra Leone	NMRA	marvic@hotmail.com;
121	Sitta Kamara	Sierra Leone	NMRA	sittakamara904@yahoo.com
122	Desmond Johns	South Africa	Department of Health	johnsd@health.gov.za
123	Portia Nkambule	South Africa	Medicines Control Council	nkambp@health.gov.za
124	Mawien Atem Mawien	South Sudan	NMRA	mamarik200@yahoo.com
125	Sophia Mziray	Tanzania	TFDA	sophia.mziray@gmail.com
126	Maurice Bolo		The Scinovent centre	bolo@scinnovent.org
127	Atany Nyansa	Togo		bnyansa@yahoo.fr
128	Corneile Traore		UEMOA	ctraore@uemoa.int
129	Kate Kikule	Uganda	National Drug Authority	katkikul@nda.or.ug
130	Apollo Angole	Uganda	National Drug Authority	aangole@nda.or.ug
131	Mutyaba Michael Romeo	Uganda	National Drug Authority	rmutyaba@nda.or.ug
132	Onen Solomon	Uganda	National Drug Authority	sonen@nda.or.ug
133	Victoria Namujju	Uganda	National Drug Authority	namujjuvicky@nda.or.ug
134	Dawit Dikasso	Ethiopia	UNFPA	dikasso@unfpa.org
135	Guy Njambong		UNIPEX	guy.njambong@unipex.com
136	Ambele Mwafula	United Republic of Tanzania (mainland)	TFDA	ambeleso@gmail.com

S/N	Name	Country	Organisation	Contact Details
137	David Matle	United Republic of Tanzania (mainland)	TFDA	drmatle@hotmail.com
138	Rose Muhangwa Shija	United Republic of Tanzania (the) (mainland)	WHO	shijar@who.int
139	Hidaya Juma Hamad	United Republic of Tanzania (Zanzibar)	Zanzibar Food and Drugs Board	hiddayya@gmail.com; h_hidaya@yahoo.com
140	Antoine Amari		Universite Felix Houphouet Boigny	amarias_03@yahoo.fr
141	Mary Kasule	Botswana	University of Botswana	mary.kasule@mopipi.ub.bw
142	Michael Adewale Durowaiye	Nigeria	University of Ibadan	mstand2000@yahoo.com
143	Jane NWANGI	USA	USAID	jamwangi@usaid.gov
144	Elizabeth Woldemariam		USAID/SIAPS	ewolswmariam@msh.org
145	Hailu Tader	Ethiopia	USAID/SIAPS	htadeg@msh.org
146	Eshetu Wondemagegnehu	Ethiopia	USP	euw@usp.org
147	Patrick Lukulay	USA	USP	phl@usp.org
148	Timothy Nwogu	USA	USP	
149	Kwasi Poku Boateng	Ghana	USP-CePAT	kpb@usp.org
150	Agnes Yeboah		Valient	sengahaobey@gmail.com
151	Kent Briggs		Vector Life Sciences	kent@vectorls.co.za
152	Kofi Busia	Burkina Faso	WAHO	kofi_busia@hotmail.com
153	Ben Botwe	Ghana	WAHO/World Bank	benbotwe@gmail.com
154	Abraham Giorgisa	Ethiopia	WHO	gebregiorgisa@who.int

S/N	Name	Country	Organisation	Contact Details
155	Daniela Vasile		WHO	vasiled@who.int
156	David Woo	Switzerland	WHO	wood@who.int
157	Josephina Hansen	Switzerland	WHO	hansenj@who.int
158	Lawrence Nzumbu	Switzerland	WHO	nzumbul@who.int
159	Milan Smid	Switzerland	WHO	smidm@who.int
160	Thomas Lapnet-Moustapha	Zimbabwe	WHO	
161	Dicky Akanmory	Congo-Brazzaville	WHO AFRO	akanmorib@who.int
162	Jean Baptiste Nikiema	Congo-Brazzaville	WHO AFRO	nikiemaj@who,int
163	Ossy Kasilo	Congo-Brazzaville	WHO AFRO	kasiloo@who,int
164	Arsene Ouedraogo	Burkina Faso	WHO	arsene.ouedraogo@gmail,com
165	Donatien BIGIRIMANA	Burundi	WHO	bigirimanad@who.int
166	Florentine Sylvie MBERYO YAAH	Central African Republic	WHO	mberyosy@who.int
167	Alexander Dodoo	Ghana	WHO Collaboration Centre	alexooo@yahoo.com
168	Haggar Ampadu	Ghana	WHO Collaboration Centre	ampaduhh@gmail.com
169	Ray MANKELE	Ghana	WHO Congo (Republic of)	mankeler@who.int
170	Marthe Everard	Egypt	WHO EMRO	everard@who.int
171	Paul Manhe	Ethiopia	WHO	manhe@who.int
172	Okouyi Ndakassa	Gabon	WHO	okednda@gmail.com
173	Edith Andrews Annan	Ghana	WHO	andrewse@who.int
174	Cece Vieux Kolie	Guinea	WHO	vkcece@yahoo.fr

S/N	Name	Country	Organisation	Contact Details
175	Regina Mbindyo	Kenya	WHO	mbindyor@who.int
176	Djibrila Minkaila Maiga	Mali	WHO	maigam@who.int
177	Ana Fernades	Mozambique	WHO	fernandesa@who.int
178	Messan Halimatou	Niger	WHO	docmeshali@yahoo.fr
179	Ogori Taylor	Nigeria	WHO	tayloro@who.int
180	Stella Tuyisengue	Rwanda	WHO	tuyisenges@who.int
181	Mamadou Ngom	Senegal	WHO	ngomma@who.int
182	Stanley Midzi	Zimbabwe	WHO	midzis@who.int
183	Apollo Muhairwe	Uganda	World Bank	amuhairwe@worldbank.org
184	Esnat Mwape	Zambia	NMRA	Emwape@pra.gov.zm; emwape@zamra.co.zm
185	Bridget Dube	Zimbabwe	Medicines Control Authority of Zimbabwe (MCAZ)	bdube@mcaz.co.zw
186	Gugu N Mahlangu	Zimbabwe	MCAZ	gnmahlangu@mcaz.co.zw
187	Luther Gwaza	Zimbabwe	MCAZ	lgwaza@mcaz.co.zw
188	Priscilla Nyambayo	Zimbabwe	MCAZ	pnyambayo@mcaz.co.zw
189	Adil Mohamed			

AFRICAN UNION

NEPAD
TRANSFORMING AFRICA

World Health Organization

NEPAD Contact Information

230, 15th Road, Randjespark,
Midrand, Gauteng, South Africa

Telephone: +27 (0) 11 256 3600

Twitter: @NEPAD_AMRH

Email: amrh@nepad.org