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A Programme of the African Union

Harmonizing Drug Registration in Africa

Proceedings of a Workshop held at Birchwood Hotel and OR Tambo International Conference Center, Johannesburg, South Africa from 24-26 February, 2009

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Acronyms

ACAME	Association of Central Medical Stores for Generic Essential Medicines
AIDS	Acquired Immunodeficiency Syndrome
AMU/UMA	Arab Maghreb Union
APEC	Asia-Pacific Economic Cooperation
ASEAN	Association of South East Asian Nations
AU	African Union
BMGF	Bill and Melinda Gates Foundation
CAPA	Central Administration of Pharmaceutical Affairs
CAT	Committee for Advanced Therapies
CDP	Common Drug Policy
CEEAC	Communauté Economique des États de L'Afrique Centrale
CEMAC (CEAC)	Economic and Monetary Community of Central Africa
CEN-SAD	Community of the Sahel Sahara States
CEO	Chief Executive Officer
CHM	Conference of Health Ministers
CHMP	Committee for Medicinal Products for Human Use
CHRCP	Cellule pour l'harmonisation de la réglementation et de la coopération pharmaceutiques
COMESA	Common Market for Eastern and Southern Africa
COMP	Committee for Orphan Medicinal Products
COMRAC	COMESA Regulatory Affairs Conference
CTD	Common Technical Document
CVMP	Committee for Medicinal Products for Veterinary Use
DGF	Development Gap Fund
DFID	Department for International Development
DGPML	Direction Générale de la Pharmacie, du Médicament et des Laboratoires
DJCC	Directors Joint Consultative Committee

DPM/MS	Direction de la Pharmacie et du Médicament/Ministère de la Santé
DRAs	Drug Regulatory Authorities
EAC	East African Community
EACMFSC	East African Community Food Safety Commission
EACHPA	East African Community Health Professionals Authority
ECOWAS	Economic Community of West African States
ECSA-HC	East, Central and South Africa Health Community
eCTD	Electronic Common Technical Document
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFTA	European Free Trade Association
EMEA	European Medicine Evaluation Agency
ESTRI	Electronic Standards for the Transfer of Regulatory Information
EU	European Union
FDA	Food and Drug Administration
GCC	Gulf Cooperation Council
GCC-DR	Gulf Central Committee for Drug Registration
GCG	Global Cooperation Group
GCP	Good Clinical Practice
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GTZ	German Technical Agency (Deutsche Gesellschaft fur Technishe Zusammenaarbeit)
HIV	Human Immunodeficiency Virus
HMA	Heads of Medicines Agencies
HPPN	L'harmonization des Politique Pharmaceutiques
ICDRA	International Conference of Drug Regulatory Authorities
ICH	International Conference on Harmonization
IFPM	International Forum on Pain Medicine

IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IGAD	InterGovernmental Authority on Development
JPMA	Japanese Pharmaceutical Manufacturers Association
LMRC	Liberia Medicine Regulatory Committee
MCC	Medical Control Council
MD	Medical Doctor
MHLW	Ministry of Health, Labor and Welfare
MOU	Memorandum of Understanding
MP	Member of Parliament
MRAs	Medicines Regulatory Authorities
MRH	Medicine Regulation Harmonization
MTA	Medical Treatment Act
NAFDC	National Advisory Food and Drug Committee
NDoH	National Department of Health
NDRAs	National Drug Regulatory Agencies
NEPAD	New Partnership for Africa's Development
NEPAD-OST	NEPAD Office of Science and Technology
NMRAs	National Medicines Regulatory Authorities
NTA	Notice to Applicants
OCCGE	Organisation de Coordination et de Cooperation pour la Lutte Centrex les Grandes Endemies
OCEAC	Organisation de Coordination pour la lutte contre les Endémies en Afrique Centrale
PAP	Pan African Parliament
PANDRH	Pan American Network for Drug Regulation Harmonization
PDCO	Pediatrics Committee
PhRMA	Pharmaceuticals Research and Manufacturers of America
PMS	Personal Medical Services
PQP	Pre-Qualification Program
PRSAO	Program Régional Santé en Afrique de l'Ouest

QA	Quality Assurance
QCL	Quality Control Laboratories
R&D	Research and Development
RECs	Regional Economic Communities
SC	Steering Committee
S&T	Science and Technology
SADC	Southern African Development Community
SAIIA	South African Institute of International Affairs
SATCI	SADC Tuberculosis Control Initiative
SWOT	Strengths, Weaknesses, Opportunities and Threats
TB	Tuberculosis
TRM	Thoroughbred Remedies Manufacturing (Traditional Medicine)
UEMOA	Union Economique et Monétaire Ouest Africaine
UNIDO	United Nations Industrial Development Organisation
UK	United Kingdom
USA	United States of America
USFDA	United States Food and Drug Administration
WAHC	West African Health Community
WAHO	West African Health Organization
WHO	World Health Organization
WHO/AFRO	WHO Africa Regional Office

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The organizing team is also grateful to the Minister of Health of the Government of the Republic of South Africa for opening the workshop and the people of the Republic of South Africa for hosting; all Heads of NMRAs and RECs secretariat staff, and resource persons for participating actively in the workshop. Finally, the organizers wish to thank the technical team comprising Professors Abolade Awotedu, Leonard Kamwanja, John Saka and Frank Teng-Zeng for producing the original manuscript of the report.

Executive Summary

This report concerns the proceedings of a conference and workshop held from 24-26 February, 2009.The workshop was organized by the African Union's program, the New Partnership for African Development (NEPAD) in collaboration with the Pan African Parliament, and on behalf of a consortium of partners including the Bill and Melinda Gates Foundation (BMGF), the UK Department for International Development (DFID), the William J. Clinton Foundation and the World Health Organization (WHO). The workshop was opened by the South African Minister of Health, the Honorable, Barbara Hogan and closed by the NEPAD Science and Technology Adviser, Professor Aggrey Ambali. The purpose of the conference was to explore the possibilities of supporting medicine the process of registration harmonization within the African Regional Economic Communities (RECs) and also to initiate a strategic approach to the development of project proposals for mobilizing the necessary financial and technical resources to support RECs undertaking medicine registration harmonization. The specific objectives were to:

i. engage with RECs and member state National Drug Regulatory Authorities on the proposed approach to drug registration harmonization, solicit their feedback and agree on the next steps;
ii. promote the public health benefits of improved regulatory harmonization (including standardization, communication and collaboration) with an initial focus on drug registration and regulatory documentation package; and
iii. mobilize and structure donor community support for drug registration harmonization within and across African Regional Economic Communities.

The conference was attended by delegations from the Pan African Parliament, Regional Economic Communities and Inter-Governmental Health Forums, 39 National Drug Regulatory Authorities, the German Technical Development Agency (GTZ), UNIDO, experts from the European Commission, the Arab Gulf Cooperation Council and academic institutions in Africa.

Several technical papers and RECs reports were presented on issues relating to harmonization of medicine registration, as well as three case studies from the European Union, the International Conference on Harmonization and the Arab Gulf Cooperation Council (GCC). The workshop undertook a SWOT analysis (Strengths, Weaknesses, Opportunities and Threats) and developed a first outline of RECs plans for the future.

The workshop participants reaffirmed the importance of harmonizing drug registration to promote quicker access to priority essential medicines of ensured quality (e.g. new fixed-dose combinations against HIV/AIDS or malaria). The participants further agreed that this would lead to better effectiveness and cost-efficiency of national drug regulatory agencies. In addition, they agreed that more rapid market approval of quality generic medicines promotes competition and will reduce prices for governments and international donors, and the general public.

The participants observed that there is wide political support for collaboration in public health in general and for harmonization of medicine registration in particular, within the continental and regional economic communities and organizations. Many RECs have received full political mandates in this respect and have already developed common pharmaceutical policies and operational plans; several RECs have developed common medicine registration standards. However, in most RECs the national implementation of these common policies and standards has been rather limited due to a lack of technical, human and financial resources both at REC and national level. The lack of a dedicated technical secretariat in the RECs was often seen as a critical bottleneck.

Donor partners, NEPAD and WHO confirmed their interest in supporting the RECs in this regard, including the necessary actions aimed at promoting national implementation, strengthening national regulatory agencies, promoting inter-REC and continental exchange of information, coordination and technical consistency. Their strategic approach is to invite summary project proposals from committed RECs and seek financial and technical support for the most sound and promising proposals among them.

In this regard the workshop participants agreed on the following timelines:

i. RECs to submit summary project proposals in support of regional medicine registration harmonization by 31st May 2009;
ii. the project consortium1 to inform RECs of the outcome by 30th June 2009;
iii. selected RECs to submit full project proposals by 31st October 2009;

[1] The current consortium partners include: New Partnership for Africa's Development (NEPAD), Pan African Parliament (PAP), Bill and Melinda Gates Foundation (BMGF), UK Department for International Development (DFID), William J. Clinton Foundation and World Health Organization (WHO).

iv. the project consortium, to review, select and recommend the full proposals to interested donors by 31st December 2009;
v. approved projects to be initiated within the first half of 2010 (depending on funding).

The workshop participants recommended that:

i. African governments should strengthen legislative systems which support drug registration harmonization and also provide adequate human and financial resources;
ii. NEPAD and its partners should work with RECS to develop fundable project proposals;
iii. NEPAD, WHO and RECs should engage with partners such as DFID, BMGF, GTZ and other development partners for adequate resources for both project development and subsequent implementation;
iv. RECs and National Medicines Regulatory Agencies should aggressively lobby policy and decision makers in the various RECs and member states for optimum support; and
v. Africa should adopt good practices from elsewhere such as Europe, the Gulf Cooperation Community as well as within the continent of Africa for harmonizing drug regulation at regional level.

Chapter 1: Introduction

1.1 Background

Essential medicines save lives and improve health when they are available, affordable, of assured quality and properly used. However, the lack of access to essential medicines remains a major impediment to public health in most African countries, particularly in the case of medicines used for priority and neglected tropical diseases.

Before a drug can legitimately be used in-country, it is generally evaluated by the National Medicines Regulatory Authority (NMRA) to ensure acceptable standards of quality, safety and efficacy. A positive decision leads to the issuance of a marketing authorization and the product is included on a list of authorized products - the register. This process is known as drug registration and the number and type of products for which registration status is sought, as well as the speed and effectiveness of the registration system, has a direct impact on patient access to quality essential medicines.

It is well recognized that for any medicine to become available in-country, it depends on the speed of registration and the time taken to meet the requirements for technical information (the dossier) needed by NMRAs to register a product. This can greatly be reduced by standardizing country-specific technical requirements and dossier formats, which would, in turn, increase the attractiveness of national markets by reducing the incremental cost to industry furthermore, common documentation would enable and facilitate collaborative mechanisms at the regional-level (such as information sharing and joint inspections/evaluations) that should translate into improved registration processes and operational efficiencies at the national level, thereby reducing actual registration times whilst enhancing the quality of the registration decision. In this regard, cross-country standardization, communication and collaboration (collectively referred to as harmonization for the purposes of this paper) would support NMRAs expansion of their technical and administrative capacity to strengthen, streamline and expedite drug registration.

The harmonization of drug registration is expected to contribute the following benefits:

i. Communities and patients in Africa will enjoy quicker access to priority essential medicines including important new treatment options (such as generic fixed-dose combinations) of assured quality and at more affordable prices.
ii. National Medicines Regulatory Authorities will be better equipped to register medicines in a cost-effective and timely manner, leading to increased efficiencies across NMRAs. Capacity building will enhance the quality of the registration decision, whilst streamlined processes and improved information management will lead to more effective medicines control.
iii. Governments can enjoy substantial savings and/or increased patient reach as generic equivalents (in the context of high volume, high value essential medicines) become

available more quickly. Beyond this, governments could enjoy additional economies of scale via pooled procurement which is only possible when the same drug is registered across all participating countries.

iv. Donors/International Organizations (as major funders of medicines to African countries) will also benefit from expanded patient reach and this in turn will contribute to the achievement of the three health-related Millennium Development Goals (Goals 4, 5 and 6).

v. Pharmaceutical manufacturers serving multiple markets will benefit from significant cost savings thanks to common documentation which will permit the submission of dossiers for much needed medicines across multiple countries simultaneously. Moreover, harmonization is likely to lead to more streamlined regulatory approval processes which are faster, more transparent and less burdensome to the industry. Domestic manufacturers in particular will benefit from an expanded regional market as technical barriers to trade are reduced or removed altogether. This, in turn, may attract more producers and/or encourage joint partnerships with international manufacturers leading to technology transfer.

1.2 Workshop Objectives and Expected Outputs

The workshop's focus was to explore possibilities of supporting drug registration harmonization within RECs, as an initial first step to a broader process of regulatory harmonization. The primary aim of drug registration harmonization is to achieve improved public health by increasing rapid access to safe and effective medicines of good quality for the treatment of priority diseases. The workshop therefore provided an important opportunity for Regional Economic Communities, Inter-Governmental Health Forums, Heads of National Drug Regulatory Authorities, the African Union and its NEPAD program, WHO and interested donors to discuss and develop the proposed approach and mutually determine next steps. The specific objectives were to:

i. engage with RECs and member state National Medicines Regulatory Authorities on the proposed approach to drug legislation harmonization, solicit their feedback and agree on the next steps;

ii. promote the public health benefits of improved regulatory harmonization (including standardization, communication and collaboration) with an initial focus on drug registration and regulatory documentation package;

iii. mobilize and structure donor community support for drug registration harmonization within and across African Regional Economic Communities.

The expected outputs of the workshop were to:

i. develop a shared vision of where the process should go and renewed commitment

amongst regulators, countries, RECs and development partners;

ii. initiate a consolidated process leading to the development of project proposals by RECs in a coordinated manner; and

iii. create increased/enhanced awareness of the significance and importance of improving regulation as a means of securing adequate funding from both governments and donor agencies.

1.3 Workshop Process

The workshop consisted of the following: the opening ceremony by the guest of honor, presentations of key theme papers, case studies from Europe, GCC and Africa, and break-up group and plenary discussions. Also, break-up group discussions for each REC were held to:

i. generate dialogue and a sense of shared vision on the way forward;

ii. structure dialogue and clarify objectives and first steps to developing project proposals;

iii. identify future intra-REC processes;

iv. review the status quo (legal and human and financial resources); and

v. involve stakeholders in developing a roadmap and an action plan.

Chapter 2: Summaries of Presentations

2.1 Opening Session Speeches

Hon. Barbara Hogan MP, Minister of Health for South Africa

Hon. Ms Barbara Hogan, Minister of Health for the Republic of South Africa delivered the official opening address of the workshop. Ms Hogan stated that the pharmaceutical landscape has been undergoing significant changes due to multiple factors, including the growth in biomedical science and technological advances, significant market developments, the shrinking research and development pipeline, fragmented and unresponsive regulatory structures and capacity challenges. She further observed that there has been a global debate on access to medical products, increasing investments by various partners in research and development for drugs used to tackle neglected diseases and efforts by countries to individually and collectively address regulatory challenges. Medicine quality problems continue to be a challenge for most countries particularly those with limited technical capacity and resource constraints. This has necessitated the need for a review of the pharmaceutical regulatory environment in some countries. South Africa has recently conducted an evaluation of regulatory processes with the aim of bringing about an improvement in the performance of regulatory agencies. There has been a call for access to essential medicines, the strengthening of health systems and regulatory capacity and the need for innovative products to tackle diseases that particularly affect developing countries. She emphasized that limited access to essential medicines by developing countries hampers their capacity to respond adequately to the needs of their populations. Increasing access to good quality, safe and effective essential medicines is therefore fundamental to providing an effective health service.

Ms Hogan indicated that the SADC health protocol has been a critical step for enhancing regional integration which is essential for the effective control of communicable and non communicable diseases and for addressing common health concerns. This is because SADC Health Ministers have recognized the harmonization of pharmaceutical policies and medicine regulation as an important element. The SADC harmonization process is aimed at improving local capacity through sharing information, the development of standardized guidelines strengthening regulatory control measures that reduce risk and create more certainty in the market, and ensuring that medicines that are available in the region meet standards of quality efficacy and safety.

The Honorable Minister indicated that within the continent, and as part of the African Union pharmaceutical agenda, there is recognition for the appraisal of regulatory systems and for countries within a region to pool their resources and form a harmonized regulatory system. This is consistent with the Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property Rights by the World Health Assembly. This strategy is a follow-up on other global decisions taken such as the Doha Declaration by World Trade Organization members. For countries to safeguard public health and optimize benefits from these processes, certain

regulatory measures need to be put in place.

She highlighted the key challenges which the medicine regulatory authorities face in fulfilling their functions so that the public is protected from substandard unsafe and harmful products. These challenges include:

i. drug regulatory procedures being largely ineffective due to shortages of skilled personnel;
ii. an absence of sound, consistent standards;
iii. inadequate laws, regulations and guidelines;
iv. a limited capacity to regulate medicines; and
v. dwindling financial resources.

In order to address these challenges, regional and sub-regional approaches should be shared and consolidated.

Hon Hogan concluded by saying that African states should ensure that the public has improved access to safe and effective medicines which meet quality standards and are supported by relevant research and development programs. The Honorable Minister welcomed the support of development partners for this important initiative and noted that the pharmaceutical industry has been experiencing change, with drug registration harmonization often featuring on the agenda because it is important for access. She therefore appealed to the workshop participants to come up with recommendations which she would share with fellow council of ministers of health at the African Union.

Mr. Morad Boularaf, Deputy Clerk, Pan-African Parliament (PAP)

The Deputy Clerk made remarks on behalf of the Clerk of the Pan African Parliament (PAP) noting that the workshop on harmonizing drug registration in Africa (jointly organized with the NEPAD Secretariat) was important and timely. He observed that there is a renewed interest in, and, political support for regional economic integration in Africa. The creation of PAP and the establishment of customs unions and trading blocs such as the East African Customs Union, the Common Market for Eastern and Southern Africa (COMESA) and the Economic Community of West African States (ECOWAS) and other RECs is a clear manifestation of the importance that African countries now attach to economic integration. The regulation of drugs and harmonization of technical standards and legislative measures have emerged as important components of the regional economic integration efforts. The degree of progress and approaches to the harmonization of drug regulatory standards and related institutional arrangements may vary from one region to another. The Deputy Clerk further observed that:

i. Africa's regions have similar health and technological challenges. They all have relatively low levels of investment in health research, drug discovery and pharmaceutical development. Countries of these regions are all struggling to procure and make safe and essential drugs available to their populations. This is mainly because of limited

budgets, a lack of adequate infrastructure and human resources and a range of regulatory barriers;

ii. most medicines regulatory authorities (MRAs) in Africa have limited capacities. This has led to the issuing of licenses without carrying out thorough scrutiny of the applications. To make matters worse, some drugs have been approved without competent evaluation for their quality, efficacy and safety. African countries have supported vaccine development initiatives but most MRAs do not have adequate capacity to evaluate vaccines; and

iii. developing and enforcing drug regulatory standards is a complex process. It requires more than the creation of MRAs. There is a wide range of non-health policies, laws and institutions that either directly or indirectly impinge on the regulation of pharmaceuticals. Different ministries of trade and industry, science and technology, environment and justice have administrative and judicial authority in the regulation of pharmaceutical products and processes. Thus, regulatory oversight is a multi-institutional endeavor.

To address these challenges, Africa's RECs are expected to promote the harmonization of regulations and the health of their regions by facilitating the availability of safe and affordable drugs. In addition, their economies are to be liberalized or opened to international pharmaceutical companies. With the support of WHO, some of the RECs have initiatives to harmonize drug regulations and establish regional agencies.

He pointed out that political and legislative bodies such as parliaments play crucial roles in the development and harmonization of the regulations. They set and approve budgets, enact legislation, monitor the enforcement of the regulations, and represent wider public interests in policy-making. Members of parliaments are responsible for passing bills for the protection of public health and ensuring access to essential medicines. They play important roles in developing protocols for regional cooperation in assessing, licensing and approving health products. Thus it is crucial that politicians are persuaded of the importance of harmonizing regulations in the RECs.

He explained that PAP was created to provide oversight of the implementation of policies and programs of the AU. It is also expected to promote the process of African economic integration through legislative actions and advocacy. The PAP's first strategic plan 2006-2010 entitled "One Africa, One Voice" outlines actions that its members will take in order to promote the harmonization and coordination of national legislation and programs of RECs. The Health and Social Affairs Committee of PAP is expected to promote regional and international cooperation in the implementation of health policies and pharmaceutical regulations.

It is for this reason that the PAP and NEPAD Secretariats have joined hands to carry out a program on the promotion of harmonization of drug regulations in order to reduce barriers to research, registration, production of and access to safe essential medicines in Africa. This is

aimed at reducing the disease burden on the continent.

The Deputy Clerk indicated that the PAP was grateful to the leadership of NEPAD for availing the Secretariat for this collaborative program and to the Bill and Melinda Gates Foundation for providing the initial financial support for the program. He assured the workshop participants that PAP awaits working with all the RECs on this important undertaking.

Dr. Vincent Ahonkhai - Bill & Melinda Gates Foundation

Dr Vincent I. Ahonkhai, MD - Global Health Delivery Bill & Melinda Gates Foundation made welcome remarks on behalf of the donor partners. He highlighted that the donor community believes in all lives having equal value and thus their goal is healthy, productive lives for all peoples. To contribute to this global goal, they harness advances and encourage shared responsibility through limited focus, promoting innovative solutions, and strategic partnerships. It is thus not surprising that they are committed to increasing access to essential medicines and innovative health technologies through regulatory harmonization. Dr Ahonkhai shared with the participants BMGF strategy which focuses on drug regulation function and building upon existing regional and country regulatory initiatives, the objective of which is to strengthen, streamline and expedite donor support across and within Regional Economic Communities and countries. He observed that the pre-requisites to success are political will and commitment, technical support, funding and broad stakeholder collaboration. He appealed to participants that initial NEPAD - AU - PAP engagement should be fully supported by a strong and effective REC - Country Member States engagement in order that each REC should have a fundable proposal which would be implemented from 2010. He wished the workshop success and productive engagement for all participants.

Dr. Stella Anyangwe - WHO Representative in South Africa

Dr. Stella Anyangwe, WHO Representative for South Africa delivered an address on behalf of Dr Luis Sambo, WHO Regional Director for Africa. Dr Anyangwe sincerely thanked the South African Government as host country for the workshop and used the opportunity to express her satisfaction with the excellent cooperation that exists between the Republic of South Africa and WHO. She congratulated the Pan African Parliament (PAP) and the New Partnership for Africa's Development (NEPAD), for organizing the workshop, in collaboration with WHO, and thanked the Bill and Melinda Gates Foundation, the Clinton Foundation and the UK Department for International Development (DFID) for financial support. Dr Anyangwe recaptured the theme of the workshop on harmonizing drug registration within African Regional Economic Communities, saying this was an initial step towards broader regulatory harmonization. She also indicated that WHO is determined to make a significant contribution to the efforts.

She observed that essential medicines save lives and improve health when they are available, affordable, of assured quality and properly used. However, lack of access to essential medicines remained one of the most serious global public health problems. Access to affordable

essential drugs was part of the fulfillment of the fundamental right to health. None of the health-related Millennium Development Goals can or will be achieved without essential medicines.

The primary aim of drug registration harmonization is to improve public health by increasing access to safe and effective medicines of good quality for priority diseases. Currently, many low-income countries cannot ensure that the medicines circulating in their markets comply with the above-mentioned characteristics, because of limited or poorly managed regulatory resources, mainly in terms of staffing, expertise, technical requirements, systems and training. This is a global concern that is not limited to individual countries in Africa, given that ineffective medicines regulation has public health implications that stretch way beyond national borders. She indicated that WHO will continue to provide technical support to countries for strengthening national drug regulatory capacity through networking, training and information sharing. WHO has supported regulatory capacity building, cooperation and harmonization in all six WHO regions, and harmonization will be a leading topic for the 14th International Conference on Drug Regulatory Authorities (ICDRA) to be held in Singapore in 2010.

Countries may differ regarding registration systems since not all can implement a comprehensive medicine evaluation and registration system. Therefore, drug registration harmonization is a desirable goal for many reasons, as it can effectively lead to the following: quicker access to affordable, priority essential medicines of assured quality for patients, resulting in improved public health outcomes; more effective medicines control by the strengthened national drug regulatory authorities; and improved procurement practices for securing priority medicines, and subsequent cost efficiency for governments.

Moreover, common documentation requirements and joint assessments can also contribute to a more transparent and predictable regulatory environment, while streamlining the review and registration process. More demanding registration requirements may also affect the markets, sometimes displacing not only undesirable and sub-standard medicines, but also lower priced alternatives. Therefore, developing medicines registration harmonization should also be considered in the overall context of National Drug Policies and not in isolation from other regulatory activities, such as effective post-marketing surveillance and market control.

The following were highlighted as possible areas during the deliberations:

i. how regulatory harmonization can improve access to safe quality medicines by strengthening the technical and administrative capacity of participating national medicines regulatory authorities;
ii. sharing regional experiences and models of successful regulatory authorities;
iii. sharing regional experiences and models of successful regulatory harmonization efforts from other parts of the world;
iv. setting up a structure that would help regional regulators prepare and implement specific projects on the harmonization of drug registration; and
v. setting up mechanisms capable of translating harmonization initiatives into concrete action. In this regard, WHO will continue to provide support in accordance with its mandate.

Dr Anyangwe concluded by thanking the PAP and NEPAD, the delegates and partners present, especially those experts from national regulatory authority agencies who will share their knowledge and experience including best practices vital for knowledge management.

Dr Hesphina Rukato, Deputy CEO of the New Partnership for Africa's Development (NEPAD)

In her welcome address, Dr Rukato thanked all the dignitaries present for honoring NEPAD's invitation to be part of the opening of the workshop on the critical issue of Medicines Regulation Harmonization. She emphasized that the backing of legislators is crucial to Medicines Regulation Harmonization, and it was apt that the Pan African Parliament was NEPAD's partner in co-hosting the workshop. She also noted that the workshop was taking place in South Africa soon after the signing of the formal hosting agreement (between the African Union Commission and the Republic of South Africa) that allows the NEPAD Secretariat to be officially hosted in the country. Dr Rukato further acknowledged the support of the South African Minister of Health.

The Deputy CEO emphasized that NEPAD strongly supported and endorsed the goal of the initiative for more efficient and effective regulation to make quality medicines more accessible to all Africans. From NEPAD's perspective, the importance of the workshop and the program emanating from it goes beyond this. The African Heads of State have determined the agenda for the continent's development. They have, amongst others called for the building and strengthening of African institutions and to enhance their capacity. The regional economic communities, acting as drivers of development and collaboration between countries which are the envisaged products of the Medicines Regulation Harmonization agenda. The way the initiative was structured also provided for an African determined and driven agenda, another core value of NEPAD. The role of the NEPAD secretariat, as an agency/organ of the African Union, is to facilitate and enable the attainment of these goals.

In conclusion, Dr Rukato thanked the Bill and Melinda Gates Foundation, not only for supporting the workshop, but also for providing funding to the NEPAD Secretariat to fulfill the role set out by African Heads of State. She also thanked DFID, the Clinton Foundation and WHO for their partnership in organizing the workshop. She wished the workshop participants fruitful deliberations and encouraged them to keep the interests of the poor of the African continent in mind.

Letter from Adv Bience Gawanas, Commissioner for Social Affairs, African Union Commission

A letter from the Commissioner for Social Affairs of the African Union Commission was read during the opening session. The Commissioner's communication stated that January 2009 marked the Fourth Ordinary Session of the AU Commission in Abuja, Nigeria. The Commissioner requested the AUC work within the framework of NEPAD to lead the development of a pharmaceutical manufacturing plan for Africa. He pointed out that this was aimed at promoting sustainable access to affordable medicines. He further indicated that the plan was adopted in April 2007 by the third session of the AU Conference of Ministers of health in Johannesburg, South Africa and that the harmonization of drug registration is therefore an important part of the

AU Pharmaceutical Manufacturing Plan.

He concluded by urging member states/RECs to update their national/regional health strategies and plans in line with the Africa Health Strategy (AHS) and the detailed commitments of the African Heads of States and Governments and Ministers of Health. He congratulated NEPAD and PAP for organizing the conference and assured the Commission's support and collaboration in organizing similar events in future.

2.2 Key and Technical Presentations

Mrs. Margareth Ndomondo-Sigonda of the Tanzania Food and Drugs Authority made an overview presentation on Drug Regulation and Public Health. She highlighted the important role of NMRAs in protecting and promoting public health and described the potential benefits of expediting the registration of quality medicines in terms of public health gains. The definition of public health ("the science and art of preventing disease, prolonging life and promoting health through the organized efforts and informed choices of society, organizations, public and private, communities and individuals") was provided (1920, C.E.A. Winslow).

She highlighted the factors influencing access to medicines and other health commodities which include availability of new products especially for neglected diseases, affordability especially in resource poor settings and quality through effective regulations. The lack of access leads to mortality, morbidity and poor quality of life. Specific initiatives that are geared towards improving access to medicines both at global and national level were shared including research into and the development of new medicines for treating neglected diseases such as malaria, HIV and tuberculosis. Important programs for financing drugs (e.g. GFATM, UNITAD) and pharmaceutical regulation scheme such as WHO, PQP, FDA Tentative Approval and the EU Article 58 were given.

Mrs. Ndomondo-Sigonda stressed that in order to achieve the objective of medicines regulation, the following must be undertaken:

i. ensuring quality, safety and efficacy;
ii. appropriate manufacturing, storage distribution and dispensing;
iii. detecting and sanctioning illegal manufacturing and trade; and
iv. fair and balanced promotion and advertising of medicines aimed at rational drug use.

She emphasized that ineffective regulation results in substandard, counterfeit, toxic, ineffective drugs, inappropriate information and irrational use which will lead to increased morbidity and mortality due to ineffective and costly treatment.

She further highlighted that although regulators may be perceived as an obstacle to access to essential medicines, the regulatory approval process is not well understood by the general public because it is based on science and therefore needs considerable scientific and administrative capacity to be done effectively. It may be perceived to lack transparency especially by lay persons and health care professionals. Regulatory approval takes time, from three months to well over two years, depending on regulatory capacity. Expediting the process will undoubtedly

reduce health budgets. However, sub-Saharan NMRAs have varying capacity; some limiting factors include inadequate human resources, poor market control and unsustainable funding mechanisms.

Finally, Mrs. Ndomondo-Sigonda appealed to the workshop participants to consider how best regulators can balance their mandate to protect and promote public health, capacity and the wish to regulate on the one hand, and the public expectation, on the other. She further urged the participants to consider a balance between regulatory approvals and market control and the sharing of regulatory information in order to inform correct and timely decisions for a positive health impact.

Professor Eric Buch, Professor of Health Policy and Management, University of Pretoria and Health Advisor to NEPAD.

Professor Buch presented a situation analysis of Harmonization of Drug Registration in Africa. He reiterated that the broad agreements on the value of harmonization include: pooled training, standardization, fewer dossiers that are easier to prepare, better reviews, joint inspections, faster throughput, economies of resources, capacity building, cheaper drugs and better quality drugs for countries.

He emphasized the need to start with a shared sense of benefits for harmonization and highlighted governance as a critical success factor - the need for countries to maintain their national sovereignty and Ministers to be in charge of the harmonization process.

He presented a SWOT analysis of the harmonization of drug registration in Africa. The analysis revealed that the strengths include the following: that most countries have NMRAs most of which are autonomous legal and institutional frameworks; the NMRAs are functional drug registration systems; they have some level of national, regional expertise and capacity.

The (SWOT analysis) weaknesses include the following: long and burdensome drug registration processes which are, country-specific; inadequate infrastructure, financial and human resources; communication and information systems; and an absence of incentives for staff retention.

Professor Buch isolated the key opportunities which RECs and NMRAs can exploit. These include the existence of political will and a commitment to enhancing access to essential medicines; the availability of WHO guidelines and standards; industry and donor interest; and a commitment to drug harmonization and pooled procurement.

In contrast, the threats include: hesitation about regionalization; membership in multiple RECs; and global purchasing requirements.

In summing up the presentation, he emphasized the need for a focused governance structure at the regional level which would be important for the coordination and sharing of information across RECs and advocacy across Africa and globally.

Dr. Lembit Rägo, Coordinator, Quality Assurance and Safety: Medicines, Essential Medicines and Pharmaceutical Policies, World Health Organization, Geneva, Switzerland.

Dr. Rägo presented a global context of Drug Registration Harmonization. He briefed the

participants on the history of developments in Europe and world-wide, especially during the 1980s when discussions were underway between Europe, Japan and the US on possibilities for harmonization.

He informed the participants that the WHO International Conference of Drug Regulatory Authorities (ICDRA), of 1989, and the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human use of 1990 were aimed at:

i. improving efficiency of new drug development and registration processes;
ii. promoting public health;
iii. preventing the duplication of clinical trials in humans; and
iv. minimizing the use of animal testing without compromising safety and effectiveness.

Dr Rägo shared with the participants the key outcomes from European drug harmonization efforts which include 50 guidelines on various technical requirements. He observed that this successful track record has been due to the following reasons: effective management and administration (through ICH Secretariat and Steering Committee); joint participation of regulators and industry; strong support from research-based industries; science-based and consensus-driven policies; and the commitment of all parties to implement harmonized guidelines.

He emphasized that the workshop could take home the key lessons which show that success is due largely to (i) political support for clear long term objectives and incentives for achieving them (creating a common market, faster market access etc.); (ii) a strong commitment from major concerned stakeholders (regulators and regulated parties) for producing results; (iii) effective governance structure with authority supported by a well resourced effective secretariat; (iv) a clear "business model" - with processes and procedures clearly defined and followed, including updates and implementation; (v) adequate human and financial resources made available; and (vi) transparency and effective communication to and with affected stakeholders (patients, the medical community and academia, special interest groups etc.).

He assured the workshop participants that WHO is committed to building regulatory capacity on the continent with numerous activities and will continue to contributing to the assessment of national MRA, providing higher-level advice and help in policy setting, providing highly technical training courses in real assessments and inspection, assisting national quality control laboratories and setting up pharmacovigilance systems, and facilitating information sharing and networks. Dr Rägo concluded by emphasizing that the future is in regulatory harmonization otherwise the price for failure of regulation will be paid by patients.

Dr. Mohammed Al-Haidari, the Head of Drug Central Registration Department of the Executive Board of the Health Ministers' Council for G.C.C. States.

Dr. Al-Haidari shared with the workshop his experiences in drug harmonization. He informed the participants that the GCC states comprise the United Arab Emirates, the Kingdom of Bahrain, the Kingdom of Saudi Arabia, the Sultanate of Oman, Qatar and Kuwait. The

Executive Board is the technical, administrative and financial body, which supervises and executes the resolutions, directives and recommendations of the Ministerial Council. The Secretariat is very lean consisting of five people (two experts and three secretaries) while the member states provide the focal and implementing agencies. The Executive Board's objectives are to:

i. set and promote strategies and health policies to improve the health services in the GCC States;
ii. work collectively and integrally so as to strengthen cooperative ties in the various health fields in the region;
iii. implement a unified drug policy that would help to supervise the imported medicines; look forward to establishing a drug industry that leads to self-sufficiency for the GCC countries;
iv. participate effectively in "Group Purchasing Program" and "Drug Central Registration" so as to enhance further pool procurement for other medical needs; and
v. exchange experiences in education, medical training, attempting to unify and improve educational systems in the various medical colleges and specialties.

Dr Al-Haidari informed the delegates that the Central Drug Registration Department started in 1976 for establishing a unified Gulf Drug Registration System that ensures the effectiveness, safety and quality of medications as well as good manufacturing practices (GMP) according to international standards, and post marketing surveillance after registration and use.

The Gulf Central Committee for Drug Registration (GCC DR) has made several achievements including organizing 41 meetings, the registration of 204 pharmaceutical companies and 1528 products and the development of technical guidelines for GMP standard, bioequivalence guidelines, stability guidelines, GLP guidelines and PMS guidelines. Dr. Al-Haidari also remarked that the DR embarked on Post Marketing Surveillance System in Gulf Countries. The aim of this program is to monitor, register and to follow up on adverse drug reactions. The GCC has already registered 204 pharmaceutical companies, and has carried out GMP inspections. He emphasized that these successes have been due to deliberate political commitment and investment by the member states in the region.

Lenita Lindström-Rossi of the European Unit Pharmaceuticals, Directorate-General Enterprise and Industry, presented a paper on Drug Registration Harmonization in the EU. She highlighted the functions of the directorate which include improving the process leading to the availability of safe medicines to patients, completing the single (internal) market in pharmaceuticals, ensuring a competitive environment which induces growth and creates jobs, developing legislation to realize the benefits of technological innovations and promoting the dialogue on medicinal products with international partners

The European Medicines Evaluation Agency (EMEA) - a key unit within the European Commission - works with the national competent authority responsible for human and veterinary medicine products. EMEA activities include the evaluation and supervision of activities, centralized

procedure, scientific committees (and working groups), the management and coordination of the EU Network, and Scientific advice to companies for the development of new products, and publishing guidelines on quality, safety and efficacy

The European Medicines Evaluation Agency (EMEA) uses three main processes for granting authorizations:

i. centralized system: applications made directly to the EMEA leading to an EU-wide marketing authorization issued by the Commission. Evaluation is carried out by the various scientific committees which adopt an opinion and then transmit it to the Commission for a decision;
ii. mutual recognition: a product is first authorized in one member state under the national procedure. Further applications can be made in other member states in a procedure where the latter agrees to recognize the validity of the original, national authorization; possible community arbitration procedure; and
iii. Decentralized procedure: applications may be simultaneously submitted to different member states selected by the applicant and the procedure is based on the evaluation carried out by one MS acting as reference Member State; possible community arbitration procedure.

Mrs Lindström-Rossi explained that medicinal products may only be placed on the market in the EU when a marketing authorization has been issued by the competent authority of a Member State for its own territory (a national authorization) or a marketing authorization has been obtained for the entire EU (a community authorization). She further emphasized that the EU regulatory network is a consequence of gradual process (increasing harmonization step by step and having a network built on sharing and confidence building).

Dr Hans V. Hogerzeil - Director, Essential Medicines and Pharmaceutical Policies, WHO, Geneva, presented a proposed approach to mobilize support for drug registration harmonization projects within African regional groupings. He explained the meaning of harmonization, provided the reasons for focusing on the concept and outlined the benefits of harmonization across various stakeholders. The WHO program is aimed at supporting African regional groups to work together, to realize their own unique visions for drug registration harmonization through efforts to mobilize financial and technical resources where there is a clear commitment from regulators and their regional groups to harmonize. This is achieved through (i) the use of the current workshop to discuss the potential value of harmonizing drug registration within African regional groups and the possible need for continental coordination; (ii) if these ideas are supported, then interested RECs could move to develop Summary Project Proposals; (iii) these could then be used to attract additional donor support for projects as well as mobilizing resources to launch an organizational structure that would support regional groups and facilitate continental coordination; (iv) donors that express an interest could then move to invite Full Project Proposals where they believe that there are good prospects for success; (v) regional groups that receive funding could then begin implementing their visions.

The objectives for the initiative will lead to sustained capacity to implement and update common technical requirements, share and utilize relevant information, and establish effective and sustainable frameworks for joint evaluations and inspections. He posed three questions: how will countries within a regional group work together? (ii) who will coordinate/lead the initiative? and (iii) how will the group work with other RECs? The answers to such questions should be premised on some key principles to ensure the success of the project. These are:

i. work together as member states and with other RECs by establishing intra- and inter-REC collaborative forums;
ii. share expertise and use risk based approaches to minimize duplication of effort and allocate resources efficiently;
iii. implement the "Regulatory Documentation Package"; and
iv. sustain project activities after initial (financial) support has been withdrawn such that the project acts as a catalyst for processes that are sustainable.

He reiterated the role of WHO towards the ongoing regulatory support to countries and would specifically contribute to the development of REC proposals for this initiative, promote consistency with global norms/standards, facilitate contacts with and linkages to full regulatory and public health agenda, promote technical consistency between and among RECs, catalyze and promote consistency with other RECs (Asia, Latin America).

He concluded by indicating that the proposed approach is an attempt to offer a framework within which regional groups can pursue their drug registration harmonization objectives to the benefit of national governments, regulators and, more importantly, patients. It focuses on mobilizing sufficient technical and financial resources to implement well developed project proposals which can demonstrate multi- stakeholder commitment and give good prospects for success.

Dr Charles Clift of the UK Department for International Development provided a donor's view to Drug Harmonization, explained the importance of regulation in facilitating access to medicines and outlined the expectations for the workshop. He informed the workshop that donors wanted to generate a shared sense of direction that countries and RECs wanted to take; set in train a process which will lead to the development of project proposals by RECs in a coordinated manner and raise the profile and importance of securing adequate funding from both governments and donor agencies.

He requested participants to agree on the objectives, key milestones and activities during the workshop using the planning documents. Thereafter key actions should include:

i. the launch of a coordinating mechanism to provide support to the RECs in project preparation and execution;
ii. actively seeking funding from donor agencies to help finance the project;
iii. continued development of project proposals which can be shared with financing agencies to generate resources;

iv. the circulation of the final document (template) for summary Project proposals by NEPAD organizers;
v. the development of summary project proposals within each REC with assistance from the NEPAD/WHO and others as required; and
vi. resource mobilization for the projects by NEPAD/Organizers in collaboration with other donors/financing agencies.

Finally, he outlined further support expected from DFID which includes proposed support to SADC on access to medicines including a large component on improving harmonization, consideration being given to support a central project coordinating entity and engaging with other donors to seek their support.

Dr Emer Cooke (of the European Medicines Evaluation Agency (EMEA)) presented a paper on CH Common Technical Document (CTD), explaining its background and objectives. She explained that it is a common format acceptable for submission in ICH regions, and is seen as a logical follow-up to the first phase of ICH (40 harmonized guidelines in 1997); and facilitates the exchange of information between regulators, review and electronic solutions. The CTD constitutes an organization of information in the dossier, provides for regional specific administrative information, was originally intended for New Active substance applications (human only), and is applicable to other types of applications (generics, herbal, veterinary etc.) at the discretion of the region and de facto industry standard. It has several modules:

i. Module 1 (not part of CTD) - comments are determined by EU, Japan and US Authorities. They include administrative and prescribing information, application forms, some specific local requirements (e.g. for EU justification that the product meets generic definition)
ii. Module 2 - summaries and overviews of Quality, non-clinical and Clinical
iii. Module 3 - Quality Data
iv. Module 4 - Non-clinical data study reports
v. Module 5 - Clinical data study reports

Dr Cooke highlighted the fact that legislation on regulation of pharmaceuticals in the EU started a long time back with the objective of having a single market for pharmaceuticals. It was in view of EU realization that the basis for harmonization and cooperation was a common format that in 1975 legislation was passed outlining a common format. A Regulatory Guidance Document was therefore developed to that effect.

Dr Cooke highlighted the following advantages of CTD as a de facto industry standard with seven years of application: (i) common format for applications, to be used in the three regions (and beyond); (ii) resource saving for industry due to being a single dossier; (iii) possible simultaneous submissions; (iv) implementation of electronic CTD (e-CTD), more consistent assessment; and (v) easier sharing between regulators and accelerate availability of medicines.

Evidently, the CTD is a common application format and is thus the cornerstone of a harmonized regulatory system and is very logical "standard" to adopt. She appealed to RECs and NDRAs to exploit this facility for better results.

Dr Samvel Azatyan of WHO made a presentation on Regulatory Documentation Package: a WHO standpoint. He initially reviewed the four dimensions of the regulation of pharmaceuticals and presented the principles of medicines regulation which are (i) must be attuned to available resources (financial, technical, human, etc.); (ii) provisions that are developed and successfully implemented in one country may not be equally successful in another country, due to their complexity and lack of adequate resources; and (iii) public health implications of application of guidelines of greater technical complexity should be considered. In addition, marketing authorization applications be broadly classified into three categories which comprise application for: (i) products containing new chemical or biological active pharmaceutical ingredients (APIs), new routes of administration, new strengths, new indications and new fixed-dose combination; (ii) multi-source pharmaceutical products (generic products) that is, new marketing authorization holders, formulations, or sources of well established drugs and (iii) variations to existing marketing authorizations.

He described the minimum necessary activities for the pre-market evaluation of products which include:

i. ensuring that a complete data-set on quality is available;
ii. evaluating, as appropriate, either data on quality or relying on a WHO-type certificate;
iii. ensuring that newly authorized products containing well established medicines are interchangeable with the original products, and that the approved product information is accurate and locally useful; and
iv. issuing a written marketing authorization on completion of the assessment process.

Dr Azatyan also shared with the workshop participants the approaches for evaluating well established products and new regulatory pathways. He emphasized the information required to apply for marketing authorization of generic products and the identification of technical documents for harmonization. It was further shared that three types of the guidelines and other normative documents are available for regulators: national, regional and international and WHO guidelines are available on most of the technical requirements for generic products. Important examples include WHO guidelines in the area of quality assurance of pharmaceutical products, the International Pharmacopoeia (Ph. Int.) Current: 4th edition and WHO Prequalification of Medicines Program.

Dr Azatyan also informed the participants that there is a WHO Project on Registration Summary for Pharmaceutical Products, which was initiated in 2006 in order to: (i) increase the capacity of the national MRAs by the provision of administrative and technical instruments for the establishment of their own decision-making processes on the marketing authorization of medicines; and (ii) ensure that registration summary is a compilation of scientific information,

discussions and conclusions on the quality, safety and efficacy of a particular pharmaceutical product, reached at the end of the process of evaluation of marketing authorization application. The technical part of document is mainly based on known and internationally recognized standards on the content and format of an application for marketing authorization and includes various modules.

To increase regional capacity and capability, WHO has a study involving seven pilot countries, namely Ghana, Kenya, Nigeria, South Africa, Uganda, United Republic of Tanzania and Zimbabwe. These countries have been selected based on their comparable levels of "maturity" to perform main regulatory functions. These countries are testing the model registration package and a consolidated assessment report is being finalized. The registration summary as a part of a "documentation package" is used as a tool for facilitating exchanges of regulatory information on marketing authorizations given by national MRAs and member states are encouraged to adopt this package in their settings and to implement it in their common practices and can be used as a tool for the exchange of regulatory information between MRAs.

He concluded his presentation by highlighting that:

i. RECs and national MRAs should support the harmonization process;
ii. RECs and individual countries need to decide by themselves how fast and how far they want to go with its implementation;
iii. RECs and individual countries have to agree on the range of guidelines and other guidance documents they want to adapt and adopt, based on their public health needs;
iv. common technical requirements, if agreed, could facilitate the development and adoption of a common format for the submission of the applications; and
v. WHO, in cooperation with other partners, is committed to continue providing technical support and advice to the RECs and individual countries in the implementation, maintenance and revision of harmonized regulatory guidelines.

2.3 Summary of REC Presentations

All the Regional Economic Communities (RECs) except CEN-SAD attended the workshop. In addition, several representatives participated from the Economic and Monetary Union of the Francophone West Africa as well as the East, Central and Southern African Health Community. A list of the RECs member states is provided in Table 1 below. Evidently, some countries belong to more than one REC. During the RECs presentations and subsequent discussions multiple membership was viewed as an opportunity rather than a weakness as far as drug registration harmonization is concerned. The next section of the report looks at the presentations made by the different RECs on their activities regarding drug registration harmonization processes and their efforts towards enhancing access to essential medicines.

2.3.1 SADC

Mr. Joseph Mthetwa, Senior Program Manager for Health and Pharmaceuticals presented an outline of the harmonization process for medicines regulation in the Southern African Development Community (SADC) region. He informed the workshop that SADC was formally launched on 17th August 2002 under a Treaty and consists of 15 Member States. The objective of SADC is to "build a region in which there will be a high degree of harmonization and rationalization to enable the pooling of resources to achieve collective self-reliance in order to improve the living standards of the people of the region". The SADC region appreciates the fact that essential medicines play a crucial role in health, are critical in the fight against diseases, but are costly. Consequently, in 1999, the region embarked upon a bulk purchasing initiative, involving five medicines used to treat tuberculosis - an initiative that was initially considered to be suitable for piloting under the project of the SADC Tuberculosis Control Initiative (SATCI), and supported by German Technical Development Agency (GTZ). This entailed the need to harmonize the relevant legal requirements with regard to the registration as well as control before any joint/ pooled procurement initiative could be undertaken. Mr Mthetwa shared with the workshop participants that the SADC region experiences several constraints including lack of established mechanisms for procurement and quality assurance; lack of consumption data, inadequate estimation of needs and forecasting of medicine requirements; lack of information on prices and use of medicines; changing clinical needs and lack of effective management information systems to aid evidence-based decision making.

SADC therefore has a Pharmaceutical Program consistent with the SADC Health Protocol and the SADC Health Policy. Its purpose is to enhance the capacities of Member States to effectively treat diseases that are of major concern to public health in the Region such as HIV and AIDS, TB, Malaria and other communicable diseases. To this end, he highlighted some successes of harmonization which include Pharmaceutical Business Plan, 16 Guidelines for the Registration and Control of Medicines, Medicines Regulatory Forum and a pharmaceutical Task Team. Mr. Mthetwa informed the participants that SADC will very soon (i) bring together the Medicines Regulators, Legal Experts, Procurement Experts, Clinicians, Traditional Healers and other stakeholders to develop a regional legal framework to enhance the implementation of the Guidelines; (ii) develop a training program to share best practices; and (iii) generate an assessment program that will assist in identifying centers of excellence within the region.

2.3.2 COMESA

Mr. Samuel Mwambazi (a member of the Secretariat of COMESA) presented a summary of the activities in COMESA related to harmonization of drug registration. He informed members that COMESA was established in 1994 as successor to the Preferential Trade Area for Eastern and Southern Africa established in 1981. COMESA comprised nineteen member states, seven of

Table 1: Summary of Regional Economic Communities and Forum

AMU	CEEAC	CEN-SAD	COMESA	EAC	ECOWAS
Algeria	Cameroon	Benin	Burundi	Burundi	Benin
Libya	Central Africa	Burkina Faso	Comoros	Kenya	Burkina Faso
Mauritania	Republic	Central Africa Rep	Congo DR	Rwanda	Cape Verde
Morocco	Congo Brazzaville	Cote D'Ivoire	Djibouti	Tanzania	Cote D'Ivoire
Tunisia	Equatorial Guinea	Djibouti	Egypt	Uganda	Gambia
	Gabon	Egypt	Eritrea		Ghana
	Chad	Eritrea	Ethiopia		Guinea
	Congo Kishansa	Gambia	Kenya		Guinea-Bissau
	Angola	Ghana	Libya		Liberia
	Burundi	Guinea- Bissau	Madagascar		Mali
	SaoTome Principe	Liberia	Malawi		Niger
		Libya	Mauritius		Nigeria
		Mali	Rwanda		Senegal
		Morocco	Seychelles		Sierra Leone
		Niger	Sudan		
		Nigeria	Swaziland		
		Senegal	Uganda		
		Sierra Leone	Zambia		
		Somalia	Zimbabwe		
		Sudan			
		Tchad			
		Togo			
		Tunisia			
5	10	23	19	5	15

IGAD	SADC	UEMOA	OCEAC	ECCAS	ECSA-HC
Djibouti	Angola	Benin	Cameroon	Angola	Kenya
Eritrea	Botswana	Burkina Faso	Central Africa	Burundi	Lesotho
Ethiopia	Congo DR	Cote D'Ivoire	Republic	Cameroon	Malawi
Kenya	Lesotho	Guinea-Bissau	Chad	Central Africa	Mauritius
Somalia	Madagascar	Mali	Congo	Republic	Seychelles
Sudan	Malawi	Niger	Equatorial Guinea	Chad	Swaziland
Tunisia	Mauritius	Senegal	Gabon	Congo	Uganda
	Mozambique	Togo		Equatorial Guinea	Tanzania
	Namibia			Gabon	Zambia
	Seychelles				Zimbabwe
	South Africa				
	Swaziland				
	Tanzania				
	Zambia				
	Zimbabwe				
7	15	8	6	11	10

which are in SADC and four in EAC (see Table 1 above) and aims to become a full integrated and competitive regional economic community. Mr Mwambazi informed the participants that the treaty provisions on cooperation in health matters are:

i. Chapter 14: Co-operation on Health Matters provided for co-operation in the Pharmaceutical area;
ii. Article 110 (b) provides for "the facilitation of movement of pharmaceuticals within the Common Market and the control of their quality"; and
iii. Article 110(d) "the training of manpower to deliver effective health care" is the basis of the program on the improvement of the pharmaceutical sector.

He reported that in March 2003, the Council of Ministers met in Khartoum, Sudan. They observed variations in legislation and regulations in DRAs and emphasized the need for the harmonization of the regulatory environment. Consequently, COMESA established a Pharmaceutical Desk within its Secretariat. The COMESA Secretariat constituted a COMESA Regulatory Affairs Conference (CMRAC), a multi-disciplinary technical group, to provide advice on the implementation of the pharmaceutical program in the region. Two years later, the regional body, with assistance from the Commonwealth Secretariat, developed and came up with (i) an Evaluation Tool for Self-evaluation (NMRA Evaluation Process and Procedure Guideline) for MRAs; (ii) Guidelines for Drugs & Substances under International Control (iii) a Manual for Minimum Technical Standards of Harmonization; (iv) fifteen documents as Minimum Technical Standards of Harmonization as well as a MRA tool for self evaluation; and (v) established a steering committee of a Technical Working Group (TWG) with Kenya, Uganda, Zambia and Zimbabwe as members to oversee the implementation prior to the establishment of a pharmaceutical desk. The TWG has been very active since its formation such that several member states are actively involved in drug registration harmonization. Mr Mwambazi assured the workshop organizers that COMESA is very supportive of the initiative and pledged its cooperation with the partners in the harmonization of Pharmaceutical Regulations.

2.3.3 ECSA-HC

Dr Steven Shongwe presented a summary of activities on the harmonization of Drug Regulation in Eastern, Central and Southern African Health Community (ECSA). He informed the participants that ECSA HC is an intergovernmental organization which was established in 1974 to foster cooperation in health and has member states in both Eastern and Southern African regions. The mission of the ECSA Health Community is to promote the attainment of the highest standard of individuals, families and communities in the ECSA region through advocacy, facilitation, cooperation, coordination, brokerage and harmonization of health programs. He highlighted that the administrative structure comprises Conference of Health Ministers (CHM), Advisory Committee, Directors Joint Consultative Committee (DJCC), Expert Committees and Secretariat based in Arusha, Tanzania. ECSA established RPF in 2003 with responsibilities to give technical support to ECSA Program and link Secretariat activities to Member States. In order to function effectively,

its Technical Working Groups (TWGs) have since initiated information sharing on the procurement of pharmaceutical supplies through the establishment of a Coordinated Informed Buying (CIB) website. The RPF has drafted a Strategic Plan, which runs up to 2012 and forms the basis for policy, legal framework and management support, rational use of pharmaceuticals, strengthening procurement and supplies chain management, medicine regulation and quality assurance. Dr Shongwe shared with the participants that in September 2007 ECSA organized a workshop of Chief Pharmacists and NMRA to kick-start harmonization, the recommendations of which were submitted to DJCC. ECSA Secretariat was urged to coordinate the harmonization of drug registration in member states. Jointly with Clinton Foundation, ECSA spearheaded a consultancy on harmonization led by Mrs. Margareth Ndomondo-Sigonda. The key recommendations from this consultancy were (i) the adoption of a Common Technical Document - resulting in shorter lead time to dossier submission; (ii) process streamlining to reduce registration timelines - this entails empowering Technical Committees to make final decisions, implementing parallel processing, developing fast track policy; and (iii) training in medicine evaluation.

Consistent with IECSA Minister's resolution in February 2008 to support harmonization of drug registration, he assured the workshop participants and organizers that ECSA HC will (i) facilitate harmonization of drug registration across RECs (e.g. EAC and SADC); (ii) play a leading role in documenting and disseminating best practices; and (iii) continue to support and strengthen individual NMRAs.

2.3.4 EAST AFRICAN COMMUNITY

Mr. Apollo Muhairwe, the Executive Secretary of Uganda National Drug Authority, presented a summary of EAC activities related to the harmonization of drug registration, on behalf of Dr. Stanley Sonoiya, Health Coordinator of the East African Community (EAC). He informed the workshop that the EAC (which comprises Kenya, Tanzania, Rwanda, Burundi and Uganda) has developed the harmonization of medicines policies and regulatory and pooled bulk procurement framework for 2006 - 2009. This is consistent with EAC treaty - Chapter Twenty One: health, social and cultural activities - article 118: Health - (1). The Health Sector - 3rd EAC Development Strategy the 2006 - 2010 has superseded the previous strategy and has strategic interventions. These include harmonizing national health policies (including drug policies) and regulations and promote the exchange of information on health issues in order to achieve quality health within the Community.

Mr. Muhairwe reported that in 2006, the EAC proposed Harmonized Standards for Pharmaceuticals and Medical Devices which provide for GM, GCP, GLP, Good Distribution Practices, the Classification of Medicines and Guidelines for registration of Medicines/issuing marketing authorization. Mr. Muhairwe further informed the workshop that EAC/WHO/Heads of NMRAs established technical working groups in August 2006 and as a result EAC has developed Guidelines Life Cycle B, Guidelines tracking System and several EAC medicines and food safety commission, health professions authority, EACMFSC Protocol and Bill as well as EACHPA

Protocol and Bill. The workshop also learnt that EAC is receiving technical support from WHO and GTZ and will get a WHO Regional medicines policy adviser from April 2009. Also a senior health officer (medicines & food safety) will be appointed by July 2009, while the GTZ will provide a Regional pharmaceutical adviser (trips & pharmaceuticals manufacturing) from May, 2009.

2.3.5 ECOWAS

Dr Kofi Busia of WAHO briefed the workshop that the Economic Community of West African States (ECOWAS) was created in 1975 and comprises fifteen member states (see Table 1 above). The ECOWAS Commission has formulated Vision 2020 which is to transform it from ECOWAS of States to ECOWAS of the people. It has developed the ECOWAS Health Policy for 2009-2010, which addresses the pharmaceutical component including issues on harmonization to ensure the effective implementation of the policy. To consolidate this development, ECOWAS has established the West African Health Organisation (WAHO) which constitutes the ECOWAS Specialized Agency for Health following a Protocol signed in 1987 (through the fusion of the Francophone Organisation de Coordination et de Cooperation pour la Lutte Contre les Grandes Endemies (OCCGE) and the Anglophone West African Health Community -WAHC), and fully established 2000. WAHO is based in Burkina Faso.

He informed the participants that drug regulation harmonization processes in the ECOWAS region started in 2006, with a number of key activities under the West African Regional Program for Health (PRSAO) - an initiative of the European Commission and ECOWAS. For instance, a meeting was held to develop a framework for harmonization in Côte d'Ivoire in 2007 while in 2008 a Task Force Meeting was held in Cotonou to develop a road map to facilitate harmonization and to capitalize on the UEMOA initiatives. Also, a regional meeting for the Institutional Framework for Harmonization took place in Ouagadougou in 2008, and included representatives from WAHO, UEMOA, WHO and PRSAO. In addition, there have been several visits to member states during which two MRAs teams were constituted to allow Anglophones countries to visit Senegal and Francophone countries to visit Ghana.

Finally, Dr Busia also shared with the workshop participants the fact that a Secretariat for Coordinating the Activities on harmonization will be established to facilitate the implementation of WAHO's Strategic Plan of Action for 2009-2013. The priority areas identified for harmonization include the institutional and legal framework, registration, inspection, local production, including illicit traditional medicines and counterfeit drugs, quality control and pharmacovigilance.

2.3.6 UEMOA

Dr Safiatou Ouedraogo Ouattara (Head of Drug Regulation Harmonization & Cooperation Office (CHRCP) of the Economic and Monetary Union of West Africa (UEMOA)) shared the organization's experience on harmonizing drug regulation in West Africa and the steps for harmonization processes. She indicated that the development of the harmonization project by UEMOA (as recommended in the memorandum of understanding (MOU) signed between the WHO and

UEMOA) started in 2003.

She advised that UEMOA NMRAs held a meeting in March 2004 to debate and discuss the adoption of policy project, leading to the establishment of the CHRCP. On 4 July 2005, the policy on the creation of the CHRCP was adopted, and a pharmacist was appointed to lead the CHRCP Secretariat in December 2007. These efforts resulted in the CHRCP program and an implementation plan was launched in 2008 with three main bodies: the Steering Committee, the Technical Task Team and the Secretariat.

The purpose of the CHRCP is to promote and monitor progressively the drug regulation harmonization in the Union's Member States in order to improve the quality of the population's lives through access to medicines that are safe and of good quality. Its project goals include the promotion of technical cooperation and the exchange of information among NMRAs as well as drug regulation capacities building.

Dr Ouattara enumerated some of the achievements of UEMOA which include:

i. a Common Technical Document;
ii. the CHRCP strategic plan for 2008-2012; and
iii. the Drug Regulation Guidelines Document.

Dr Ouattara informed the participants that in May 2009 UEMOA will hold a workshop on developing drug regulation and inspection projects and the possible adoption by the Health Ministers in September 2009. In conclusion, she emphasized that the strength of the UEMOA drug registration process lies in the policies applicable in all the member states.

2.3.7 CEMAC/ ECCAS

Ms Emilienne Pola Yissibi, Public Health Pharmacist Coordinator: Drug Regulation Harmonization in Central Africa Program HPPN/OCEAC, made a presentation on Harmonizing National Pharmaceutical Policies in Central Africa. She indicated that the Economic and Monetary Community of Central Africa (CEMAC/OCEAC) has six member states following the signing of the CEMAC treaty in March 1994. She further reported that OCEAC was established to coordinate health policies, and lead the process of drug harmonization. This process resulted in a common pharmaceutical policy in Central Africa under the National Drug Policies Harmonization Process (HPPN) with the establishment of a functional task team (Steering Committee) in May 2005.

Ms Yissibi shared some achievements of CEAC which include:

i. Common Drug Policy (CDP) document adopted in August 2007;
ii. an Implementation Plan 2007-2011
iii. guidelines for drug regulation harmonization;
iv. drug inspection handbook;
v. guidelines for drug safety; and
vi. procurement guidelines.

She informed the workshop of CEMAC planned steps towards greater drug harmonization.

2.4 Summary of Project Development

2.4.1 Feedback on the Proposed Approach

The RECs met and reviewed the proposed approach. Participants identified the following key elements for the successful harmonization of registration of medicines in each REC:

i. improved coordination mechanism;
ii. the exchange of information and technical expertise;
iii. database on manufacturing, marketing and the regulation of pharmaceutical products must be available on website where feasible;
iv. well-defined action plans with clear time frames;
v. technical facilities to support the work of NMRAs; and
vi. training human resources.

2.4.2 Resolutions of REC/Organizing Group Meetings

The following is a summary of the discussions held:

1. Agreement on Common Technical Templates across RECs and the Scope of Work

- The organizing group confirmed that there is donor and technical interest in supporting regulatory harmonization to improve medicines access and that this in turn necessitates some kind of prioritization. The group is recommending, as part of the proposed approach, that RECs/regulators start with medicines registration and focus on generic applications therein in order to implement common documentation, share and utilize information and establish processes for joint assessments/inspections.
- That said, donors should be willing to look at any serious proposal and RECs/ regulators could use this opportunity to raise objectives/activities outside of the core scope/focus, that they believe are really essential to, and would complement their proposal for harmonizing drug registration. A justification for including objectives/activities outside of the core should be included as part of the Summary Project Proposal as a basis for subsequent discussions and negotiations once the proposals have been received and reviewed.
- At the same time, and given that the organizing groups do not have a monopoly on proposals, they would encourage RECs/regulators to develop a master plan and sell various aspects to different donors (recognizing, for example, that market control is also a key issue and does not fall under the proposed scope).

2. Mobilizing Political and Policy Processes in RECs and Continentally

- As part of their political advocacy work to raise the profile of, and garner support for, drug registration harmonization, NEPAD will try to engage the five African Union Bureau Chairs on Health as project champions. They plan to meet with the Ministers

chairing these committees, alongside WHO-AFRO, to solicit their support.

- RECs should also report back to their Ministers of Health on the output from the workshop, and their recommendations for the way forward, in order to secure their buy-in and to convince policy makers to make additional funds available.
- It was noted that donors would be looking at how much of the REC budget was committed to regulatory harmonization as part of project proposals as one indication of the requisite political commitment.
- The WHO recommended that this platform be used to advocate autonomous drug regulatory agencies that would help put the drug registration harmonization agenda on a more sustainable path. It was agreed that regulatory autonomy could be encouraged as part of this initiative, and that Dr. Alain Pratt (WHO) will make background documents available on the issues surrounding the governance structure of regulatory authorities to help countries consider their options in this regard.
- NEPAD, through Professor Ambali (NEPAD - Science & Technology) would further consult with RECs to develop a NEPAD strategy for political outreach and advocacy.

3. Confirmation of Timelines and Criteria for Proposal Selection

- The emphasis is on RECs to develop fundable project proposals. NEPAD and WHO can advocate making the pot bigger but the funding decision will ultimately be a donor one, this to avoid any conflicts of interest.
- The following timelines were agreed:

March - May 2009: RECs are invited to submit a summary of project proposals in support of regional medicine registration harmonization by 31st May 2009.

June 2009: the project consortium will review the summary of the project proposals and identify those it wishes to recommend for development into full project proposals. RECs will be informed of the outcome by 30th June 2009.

July-October 2009: selected RECs will be invited to develop their summary proposals into full project proposals, for submission by 31st October 2009.

November-December 2009: the project consortium, will review the full proposals and those which are judged sound and promising will be recommended to interested donors both within and outside the consortium.

January - June 2010 (depending on funding): the start of the first approved projects, with relevant run-in period, if needed.

- It was reiterated that the organizing group's goal was to support the development of good project proposals and that this process should be finished by the end of the year so that any funding could be drawn from 2010 donor budgets.
- The Summary Project Proposals would be reviewed by the project consortium (comprising the organizing group and any additional collaborating partners) against certain criteria (e.g. measurable impact on public health, adherence to the project's

principles, concrete and specific objectives with milestones to track project progress) to identify those that the consortium will recommend for development into full project proposals.

4. Support Requirements for Technical and Proposal Development

- The emphasis is on the RECs to take this initiative forward by developing first drafts of their Summary Project Proposals. NEPAD and WHO would then mobilize limited support in response to any subsequent requests to provide comments on the drafts in order to aid the refinement process.
- RECs should also approach NEPAD and WHO as and when they encounter any particular needs/challenges in terms of proposal development.
- The organizing group confirmed that they would try to make additional support available to guide those groups whose proposals are not selected for further development, with a view to their potential inclusion at a later stage. Although the process is competitive to the extent that financial resources are uncertain and would be limited, the aim is one of expanding participation over time.

5. Handling of Multiple REC Memberships

- There are a number of options, as follows, and RECs/regulators must decide on how best to handle the issue of multiple membership in their respective regions.

CTD & Guidelines: the membership of multiple RECs could be seen as a benefit, both at country-level (through participation in multiple projects) and in terms of promoting broader continental coordination and harmonization. However, different common documents across RECs could be a limiting factor if it pulls countries with multiple memberships in different directions. If RECs/regulators are able to agree to a single CTD & Guidelines (e.g. based on the ICH format and WHO-PQ technical requirements) then this would facilitate and enable country participation in multiple REC projects.

Joint Proposals: RECs have the option to submit a joint proposal if they so choose. Alternatively, one REC could submit a proposal which extends to countries beyond its membership base or RECs could chose to build on their strengths and specialize, with different RECs taking the lead on different objectives/activities.

Country Preferences: countries could decide which REC project they would like to participate in for the purposes of harmonizing drug registration.

- Difficulties in convening regulator meetings within a short time-span was also raised as a potential challenge related to multiple REC membership and as a consequence the timeframe for submitting Summary Project Proposals was subsequently increased from two to three months. Groups could also consider hosting joint meetings to save resources and determine the best approach for cooperation and collaboration across those RECs with a common membership base. Note that in the COMESA/EAC/SADC

region there may be an option to use the 'Troika' system.

6. Funding Processes to RECs/Countries and the Potential Duration of Funding

- A rough guide of five years was suggested (by the organizing group) as a reasonable running time for funding support that should enable RECs/regulators to establish sustainable systems and structures. However, the timeframe may differ across RECs and the continuation of funding would depend on performance against project milestones and targets. Note that the organizing group is recommending a full mid-term review in addition to regular monitoring and evaluation.
- It was suggested that funds could flow through either the WHO or NEPAD to RECs and then onto countries (as appropriate) as this would allow donors to deal with a single entity rather than multiple RECs and/or countries. There was some concern, however, that such a system could cause bottlenecks and that due diligence must be undertaken by the RECs and the organizing group to propose a funding process that would remove/manage this risk and facilitate an efficient and effective project implementation.

7. NEPAD / REC / WHO Follow-up Meeting - Clarify Need, Purpose and Timing

- It was agreed that follow-up meetings are important to consolidate cooperation, but opinions differed on the suitable timing for such a meeting. Note that such a meeting would be much smaller in scope than the current Drug Registration Harmonization Workshop which also included member states' regulators.
- Some REC representatives supported a meeting in mid/end April to share ideas and ensure the complementarities of Summary Project Proposals. Others felt that later in the year would be more appropriate to allow sufficient time to canvass the opinions of member states and adequately reflect their views.
- NEPAD will proceed with their REC consultations to determine the most suitable time for a follow-up meeting.

8. Coordinating Entity and Governance Structure (including the ICH-GCG and a Discussion of Reporting Requirements)

- The organizing group clarified that they envisaged that donors would establish some kind of committee, but that a coordinating entity would also be required to coordinate the initiative across the RECs. There was support for NEPAD - through its health desk led by Professor Buch - to take on this role and to work hand in glove with the RECs. The health desk has funding available for, and plan to appoint, a specific person to focus on this initiative within the coming months.
- NEPAD - through the office of Science and Technology (led by Professor Ambali) - would continue to play an important role in terms of political advocacy, shaped by

ongoing REC consultation.

- Reporting requirements in terms of REC progress in proposal development would take the form of low burden, informal check-ins rather than any formal requirements.
- On the subject of the ICH - Global Cooperation Group (GCG), the WHO advised that there are certain criteria to include regional harmonization initiatives within this group. SADC is already a member, but other African groups would have to be considered on a case-by-case basis. And, although the door is open for other groups to approach the ICH, they may only be accepted on a self-funded basis.

Chapter 3: Recommendations and Conclusions

3.1 Recommendations

The workshop participants agreed on and recommended the following:

i. To launch a coordinating mechanism to provide support to RECs in project preparation and execution.
ii. To actively seek funding from donor agencies to help finance the project
iii. To continue to develop project proposals which can be shared with financing agencies to generate resources for the project.
iv. NEPAD/Organizers will circulate a final document (template) for Summary Project Proposals.
v. RECs/countries should work on and develop Summary Project Proposals in each REC with assistance from NEPAD/WHO and others.
vi. NEPAD/Organisation shall work with other donors/financing agencies to generate resources for the project.
vii. The Pan African Parliament should initiate dialogue with its member states. The PAP needs to engage legislators on this matter so that whatever is discussed is referred to the respective national assemblies. The views and recommendations should then be shared with the African Union.
viii. Governments should be encouraged to have legislative frameworks for the creation of NDRA, where this does not exist.
ix. Member states must honor agreements reached at various regional and continental meetings with respect to drug harmonization.
x. Specific targets and timelines should be set with strict adherence, to fast-track harmonization (see 2.4.3 (3)).
xi. Respective governments should make the NMRAs autonomous with budget commitment to enable it recruit, train and retain staff.
xii. The regional African political groups should provide sufficient resources to strengthen the RECs so as to advance the process of harmonization.
xiii. The RECs should have functional offices and be able to liaise with the NMRAs in their regions.
xiv. Inter REC cooperation should be encouraged through meetings in order to advance continental harmonization.

3.2 Conclusions

The workshop participants unanimously welcomed the initiative and RECs committed themselves to full participation, the realization of drug regulation harmonization in Africa, as well as the development and implementation of projects at the beginning of 2010.

Chapter 4: Closing Remarks

Professor Aggrey Ambali, Advisor, NEPAD Science and Technology closed the conference on 26 February, 2009, on behalf of NEPAD and the PAP. He reminded the participants that the workshop had been convened to build on countries' existing efforts to harmonize medicines regulations as a contribution to improving affordable access to safe and effective medicines of assured quality in Africa. Professor Ambali indicated that he was very pleased with outcomes of the workshop/conference and emphasized following major ones:

i. It is clear that African governments need to strengthen legislative systems that support drug registration harmonization and provide adequate human and financial resources.
ii. There is the need for the involvement of NEPAD and its partners to work with RECs in developing fundable project proposals.
iii. This is a clear signal for NEPAD, WHO and RECs to engage with partners such as DFID, BMGF, GTZ and other development partners on matters of adequate resources for both project development and subsequent implementation.
iv. There is a clear need for RECs and National Drug Regulatory Agencies to aggressively lobby policy and decision makers in the various RECs and member states for optimum support.
v. Good practices from elsewhere (such as Europe, the Gulf Cooperation Community as well as within the continent of Africa) do exist and should be adapted to Africa's needs.

The NEPAD Science Advisor thanked (i) all the participants for coming to Johannesburg, Republic of South Africa, to attend the workshop, and for such a great contribution to this process; (ii) their first round of partners who have supported this workshop - the Bill and Melinda Gates Foundation, and the United Kingdom Department for International Development and indeed for continued support that is earmarked for Africa for this noble assignment of harmonizing medicine registration in the RECs; (iii) the organizing committee of the workshop drawn from the above two funding agencies and other partners, including the William J. Clinton Foundation, WHO and NEPAD. The team had used very sound principles which had guided preparations for the workshop; (iv) members of the Secretariat (William J. Clinton Foundation: Kate Griffith; Bill and Melinda Gates Foundation: Lorna Chang and Courtney Strand and NEPAD Secretariat: Nthabiseng Legodi, Lukovi Seke, Nancy Ngum and Anesu Makina); (v) the Minister of Health of the Government of the Republic of South Africa for opening the workshop, and the people of South Africa for hosting the conference/workshop; (vi) the staff of the Birchwood Conference Centrex who were involved in the smooth running of the workshop; and (vii) the team of interpreters for efficient simultaneous translation.

He declared the workshop closed at 4.00 pm and wished everyone safe journeys to their respective destinations.

Annexes

Annex A: List of participants

Country	First Name	Last Name	Organization
Algeria	Mohamed Benslimane	MANSOURI	Laboratoire national de controle des produits pharmaceutiques, ministere de la santé Algerie
Algeria	Diana Amel	HAMOUCHE	Laboratoire national de controle des produits pharmaceutiques Algerie
Angola	Ana Ferreira de	AGUIAR NSIKALANGU	Direcção Nacional de Medicamentos e Equipamentos/Secção de Registo e Homologação
Angola	Maria de Lourdes	SANTOS	Direcção Nacional de Medicamentos e Equipamentos/Secção de Registo e Homologação
Benin	Kédji Carmelle Nadège	HOUNNOU	DPM/MS
Benin	Kocou Charlemagne	YEMOA	DPM/MS
Botswana	Sinah Matlhodi	SELELO	Drugs Regulatory Unit, Ministry of Health
Burkina Faso	Mahamadou	COMPAORE	Ministère de la Santé
Burkina Faso	Rasmané	SEMDE	DGPML (Direction Générale de la Pharmacie, du médicament et des Laboratoires)
Burundi	Déogratias	NIYONZIMA	Ministère de la Santé Publique
Burundi	Léonard	NDAHATEMBA	Ministère de la Santé Publique
Cape Verde	Edith	DOS SANTOS	D.G. PHARMACY
Cape Verde	Marcelina	ROSARIO	DGF
Chad	Tilna Ingsala	POUMNE	Ministère de la Santé Publique
Chad	Alsadick Haroun	ABDALLAH	Ministère de la Santé Publique
Comoros	Ahamada El Badaoui	MOHAMED	PNAC/VP
Comoros	Ahamada Said	FAZUL	Ministere de lo Sante
Cote D'Ivoire	Dominique Emma	AKE MICHELE	Direction de La Pharmacie Et Du Medicament
Cote D'Ivoire	Amin Aguie Renee Yolande	ANON EPOUSE	Direction de La Pharmacie Et Du Medicament
Congo Republic	Jean-Marie	TRAPSIDA	Organisation Mondiale de la Santé Bureau régional pour l'Afrique
Democratic Republic of Congo	Kindenge	BINZE JUSTIN	Ministry of Health
Democratic Republic of Congo	Bitibiri	BITILON JEAN-PIERRE	Ministry of Health
Egypt	Mona	GHOBASHI	CAPA
Egypt	Caroline	MAMDOUH	CAPA
Ethiopia	Teferi	LEMMA BEDANE	Drug Administration and Control Authority
France	Valerie Constance Denise	ABONDO	

Country	First Name	Last Name	Organization
Gabon	Sophie	BIPOLO	Directeion du Médicament et de la Pharmacie, Ministètere de la Santé et de l'Hygiène Publique
Gabon	Viviane Christiane	ALENE NDONG	Direction du Medicament et de la Pharmacie
Gambia	Janneh Kaira	MARKIEU	National Pharmaceutical Services
Gambia	Jah Sowe	FATOUMATTA	National Pharmaceutical Services, Department of state for Health and Social Welfare
Ghana	Mercy	ACQUAYE	Food and Drugs Board, Ghana
Ghana	Emmanuel	AGYARKO	Food and Drugs Board, Ghana
Ghana	Delese	DARKO	Food and Drugs Board, Ghana
Guinea	Binta	BAH	Ministere Sante et de L'hygiene Publique; Dierction Nationale de la Pharmacie et du Laboratoire
Guinea	Cece Vieux	KOLIE	Ministere Sante et de L'hygiene Publique; Dierction Nationale de la Pharmacie et du Laboratoire
Guinea-Bissau	Zeferina	GOMES DA COSTA	Ministere de la Sante
Guinea-Bissau	Pepas Vicente	NATAK	Ministerio de Saude Publica
Kenya	Elizabeth	OMINDE-OGAJA	Ministry of Medical Services
Kenya	Dominic	MUTIE	Pharmacy and Poisons Board (Kenya)
Lesotho	Piet Johannes	MCPHERSON	Health and Social Welfare Lesotho
Lesotho	Germina Mamoeti	MPHOSO	Pharmaceuticals
Liberia	Tijli Tarty	TYEE SR.	Ministry of Health and Social Welfare
Liberia	Joseph N. B.	JIMMY	Liberia Medicine Regulatory Committee (LMRC)
Madagascar	Jean René	RANDRIASAMIMANANA	Agence du Médicament du Madagascar
Madagascar	Solofomboahangy Harisoa	RABENANDRIANINA	Agency of Médicamen
Malawi	Aaron	SOSOLA	Pharmacy, Medicines and Poisons Board
Malawi	Mtwalo Duncan	JERE	Pharmacy Medicines and Poisons Board
Malawi	Leonard	KAMWANJA	NEPAD Consultant
Malawi	John	SAKA	NEPAD Consultant
Mali	Ousmane	DOUMBIA	Direction Pharmacie/Médicament
Mali	Fanta	SANGHO	Direction de la Pharmacie et du Médicament
Mauritania	Hamoud	FADEL	Ministere Sante
Mozambique	Tânia	VUYEYA SITOIE	Ministry of Health

Country	First Name	Last Name	Organization
Mozambique	Lígia Vanessa Pascoal	TEMBE	Pharmaceutical Department of Mozambique
Namibia	Johannes	GAESEB	Ministry of Health and Social Services
Namibia	Lazarus Mwashekele	INDONGO	Ministry of Health & Social Services (MoHSS)
Niger	Elhadj Maman	MATY	Ministère de la Santé Publique
Niger	Tini	INOUSSA	Ministère de la Santé Publique
Nigeria	Doris	AMLAI	NAFDAC (Nigeria)
Nigeria	Comfort	MAKANJUOLA	NAFDAC (Nigeria)
Nigeria	Princess	FRANK-CHUKWUANI	NEPAD Nigeria
Nigeria	Victor	ORDU	NEPAD Nigeria
Senegal	Papa Amadou	DIOP	Direction Pharmacie et Laboratoires. Ministere de la Sante
Senegal	Néné Atta	DRAME FAYE	Direction de la Pharmacie et des Laboratoires
Senegal	Madické	DIAGNE	Direction de la Pharmacie et des Laboratoires
Seychelles	Lucile	DE COMARMOND	Ministry of Health & Social Development
Sierra Leone	Michael	LANSANA	Pharmacy Board of Sierra Leone
Sierra Leone	Musa Justin	SEPPEH	Pharmacy Board of Sierra Leone
South Africa	Mandisa	HELA	Department of Health
South Africa	Johanna Catharina	GOUWS	National Department of Health
South Africa	Ushma	MEHTA	Medicines Control Council
South Africa	Liesbeth	MANGATE	National Department of Health
South Africa	Portia	NKAMBULE	MRA (SA)
South Africa	Gavin	STEEL	MCC
South Africa	Estelle	TAUTE	NDoH
South Africa	Falaza Frank	HLANGWANE	Medicines Control Council
South Africa	Theo	DEKKER	World Health Organization
South Africa	Vincent	AHONKHAI	Bill & Melinda Gates foundation
South Africa	Abolade	AWOTEDU	NEPAD Consultant
South Africa	Eric	BUCH	NEPAD
South Africa	Nthabiseng	LEGODI	NEPAD
South Africa	Anesu	MAKINA	NEPAD
South Africa	Nancy	NGUM	NEPAD
South Africa	Lukovi Hylde-Mbuta	SEKE	NEPAD
South Africa	Frank	TENG-ZENG	NEPAD Consultant
South Africa	Hesphina	RUKATO	NEPAD
South Africa	Aggrey	AMBALI	NEPAD Science & Technology
South Africa	Stella	ANYANGWE	World Health Organization
Sudan (South)	Manyang	AGOTH	Ministry of Health, Government of Southern Sudan

Country	First Name	Last Name	Organization
Switzerland	Hans	HOGERZEIL	World Health Organization
Switzerland	Thomas	LAPNET-MOUSTAPHA	World Health Organization
Switzerland	Deusdedit	MUBANGIZI	World Health Organization
Switzerland	Lembit	RÄGO	World Health Organization
Switzerland	David	WOOD	World Health Organization
Switzerland	Alain	PRAT	World Health Organization
Switzerland	Samvel	AZATYAN	World Health Organization
Tanzania (Mainland)	Margareth	NDOMONDO SIGONDA	Tanzania Food & Drugs Authority
Tanzania (Mainland)	Hiiti Baran	SILLO	Tanzania Food & Drugs Authority
Tanzania (Zanzibar)	Burhani Othman	SIMAI	Zanzibar Food and Drugs Board
Tanzania (Zanzibar)	Shija Joseph	SHIJA	Ministry of Health and Social Welfare
Togo	Folly Mawuéna	KLIKO	Ministère de la santé
Togo	Atany Bernardin	NYANSA	Ministère de la Santé
Uganda	Apollo	MUHAIRWE	National Drug Authority
Uganda	Apollo	ANGOLE	National Drug Authority
UK	Yahya	IPUGE	Clinton Foundation
UK	David	ELLIS	Clinton Foundation HIV/AIDS Initiative
UK	Katherine	GRIFFITH	Clinton Foundation HIV/AIDS Initiative
UK	Charles	CLIFT	DFID
UK	Robin	GORNA	DFID
USA	Lorna	CHANG	Bill & Melinda Gates foundation
USA	Courtney	STRAND	Bill & Melinda Gates Foundation
Zambia	Esnat	MWAPE	Pharmaceutical Regulatory Authority
Zambia	Maria de Sales	RAMON	Pharmaceutical Regulatory Authority
Zimbabwe	Mafios	DAURAMANZI	Medicines Control Authority of Zimbabwe
Zimbabwe	William	WEKWETE	Medicines Control Authority of Zimbabwe
Zimbabwe	Gugu Nolwandle	MAHLANGU	Medicines Control Authority of Zimbabwe

Annex B: Workshop Program

TUESDAY, 24th FEBRUARY 2009

Opening Ceremony (8.30am - 10.00am) ***Chair:*** *NEPAD - Professor Eric Buch*	
08.30am	**Welcome remarks** *NEPAD Health Advisor - Professor Eric Buch*
08.40am	**New Partnership for Africa's Development (NEPAD)** *NEPAD Deputy CEO - Dr. Hesphina Rukato*
08:50am	**WHO-AFRO** *WHO Representative in South Africa - Dr. Stella Anyangwe*
09:00am	**Representative of the Donors** *Bill & Melinda Gates Foundation - Dr. Vincent Ahonkhai*
09.10am	**Pan-African Parliament (PAP)** *PAP Deputy Clerk - Mr. Morad Boularaf*
09:20am	**Minister of Health for South Africa** *Hon. Barbara Hogan*
Session 1 (10.00am - 12.45pm) ***Chair:*** *South Africa MCC - Ms. Mandisa Hela*	
10.00am	**Drug Regulation and Public Health** *Tanzania Food & Drug Authority (TFDA)* *- Mrs. Margareth Ndomondo-Sigonda* Purpose: Highlight the important role of NDRAs in protecting and promoting public health and describe the potential benefits of expediting the registration of quality medicines in terms of public health gains
10.30am	**Coffee Break**
11.00am	**Situational Analysis of Drug Regulation Harmonization in Africa** *NEPAD - Professor Eric Buch* Purpose: Provide an overview of regulatory harmonization in Africa (with an emphasis on drug registration) as well as some of the challenges faced by African NDRAs when it comes to harmonizing

TUESDAY, 24th FEBRUARY 2009

11.45am	**Drug Registration Harmonization - The Global Context** *WHO - Dr. Lembit Rägo* Purpose: Provide a global overview of medicines regulation including trends towards increased harmonization and describe how regulators in other regions have attempted to deal with some of the challenges faced by African regulators
12:45pm	**Lunch**
Session 2 (1.45pm - 5.30pm) ***Chair:*** *SADC*	
01.45pm	**Drug Registration Harmonization - EU Case Study** *European Commission - Mrs. Lenita Lindström-Rossi* Purpose: Explain the harmonization model implemented in the EU, how they got there and lessons learnt
02.45pm	**Drug Registration Harmonization - GCC Case Study** *GCC - Dr Mohammed Alhaidari* Purpose: Explain the harmonization model implemented in the GCC, how they got there and lessons learnt
03.30pm	**Coffee Break**
04.00pm	**A Proposed Approach for Supporting Drug Registration Harmonization in Africa** *WHO - Dr. Hans Hogerzeil and DFID - Mr Charles Clift* Purpose: Introduce the proposed approach as detailed in the Concept Paper
04.45pm	**Expert Panel to host a Q&A session on the proposed approach** ***Chair:*** *WHO - Dr. Hans Hogerzeil* Purpose: An opportunity for potential participants to ask questions, explore the issues and deepen their understanding of the rationale behind the proposed approach as a backdrop to the work of the next day
05.30pm	**Close**
06.30pm	**Welcome Dinner**

WEDNESDAY, 25th FEBRUARY 2009

Session 3 (8.30am - 1.15pm) ***Chair:*** *ECOWAS / WAHO, Dr Mariane Ngoula*	
08:30am	**RECs reports on Harmonization of Drug Registration** UEMOA - Nati Outtara nee Ouedroogo OCEAC - Yissibi Emilienne UMA - Dine Attallah COMESA - Samuel Mwambazi ECSA-HC - Steven Shongwe SADC - Joseph Mtetwa EAC - Apollo Muhairwe
09.30	**Intra-REC Regulator Meetings - Guidance and Briefing** *WHO-AFRO - Dr. Jean-Marie Trapsida* Purpose: Suggest discussion points to help guide the subsequent break-away sessions
08.45am	**Intra-REC Regulator Meetings** **(Breakaways into 8 REC groups)** Purpose: An opportunity for member state regulators to meet with their REC representatives to discuss the proposed approach and how it might support their vision for drug registration harmonization
10:45am	**Coffee Break**
11.15pm	**Intra-REC Regulator Meetings - Feedback** Purpose: An opportunity for inter-REC sharing of progress made on drug registration harmonization and for each of the groups to report back with feedback on the proposed approach, initial ideas for how to overcome challenges and early insights for how they envisage moving forwards
1:15pm	**Lunch**
Session 4 (2.15pm - 5.30pm) ***Chair:*** *ECCAS/OCEAC, Mrs. Yissibi Emilienne*	
2.15pm	**Regulatory Documentation Package** WHO - Dr. Samvel Azatyan Purpose: Introduce suggestions, questions and options for how the Regulatory Documentation Package could work in practice inc. the methodology for updates to ensure that common technical requirements are maintained and remain up-to-date

WEDNESDAY, 25th FEBRUARY 2009

03:00pm		**International Conference on Harmonization - Common Technical Document** *European Medicines Agency (EMEA) - Ms. Emer Cooke* Purpose: Explain the format of the CTD that is being recommended as part of the Regulatory Documentation Package
03.30pm		**Coffee Break**
04:00pm	**Facilitators Meeting** ***Chair:*** NEPAD - Professor Ambali Purpose: An opportunity for REC representatives (as facilitators in creating an enabling environment) to meet with the organizing group and other interested donors to discuss the proposed approach including ideas for creating effective summary project proposals and managing continental coordination. Interested regulators are also welcome to attend.	**Expert Panel to host a Q&A session on the Regulatory Documentation Package** ***Chair:*** *WHO - Dr. Lembit Rägo* Purpose: Provide regulators with an opportunity to deepen their understanding of the questions and issues surrounding the Regulatory Document Package and to share ideas for how this could work in practice.
05:30pm		**Close**
07:00pm		**Dinner**

THURSDAY, 26th FEBRUARY 2009

Session 5 (8.30am - 12.30pm) ***Chair:*** *EAC/Tanzania, Mr Edward Kataika*	
08.30am	**Feedback Session** *Elected Rapporteurs* Purpose: An opportunity to report back with ideas from the previous days Facilitator and Regulatory Documentation Package sessions (10-15 mins each)
09:00am	**Intra-REC Regulator Meetings - Guidance and Briefing** *NEPAD - Professor Eric Buch* Purpose: Suggest discussion points to help guide the subsequent break-away sessions
09.15am	**Intra-REC Regulators Meetings (Breakaways into 8 REC groups)** Purpose: An opportunity for REC representatives to consult with member state regulators to develop a plan of action for creating summary project proposals for harmonizing drug registration
10:30am	**Coffee Break**
11.00pm	**Intra-REC Regulators Meetings (continued)**
12:30pm	**Lunch**
Session 6 (1.30pm - 4.00pm) ***Chair:*** *WHO - Dr. Hans Hogerzeil*	
01.30pm	**Intra-REC Regulator Meetings - Feedback and Discussion** Purpose: Provide an opportunity for inter-REC sharing with each of the groups reporting back with their respective plans (10 minutes each) followed by a group discussion
3.30pm	**Concluding Remarks** *NEPAD/PAP - Professor Aggrey Ambali* **Evening**
07.00pm	**Dinner**

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