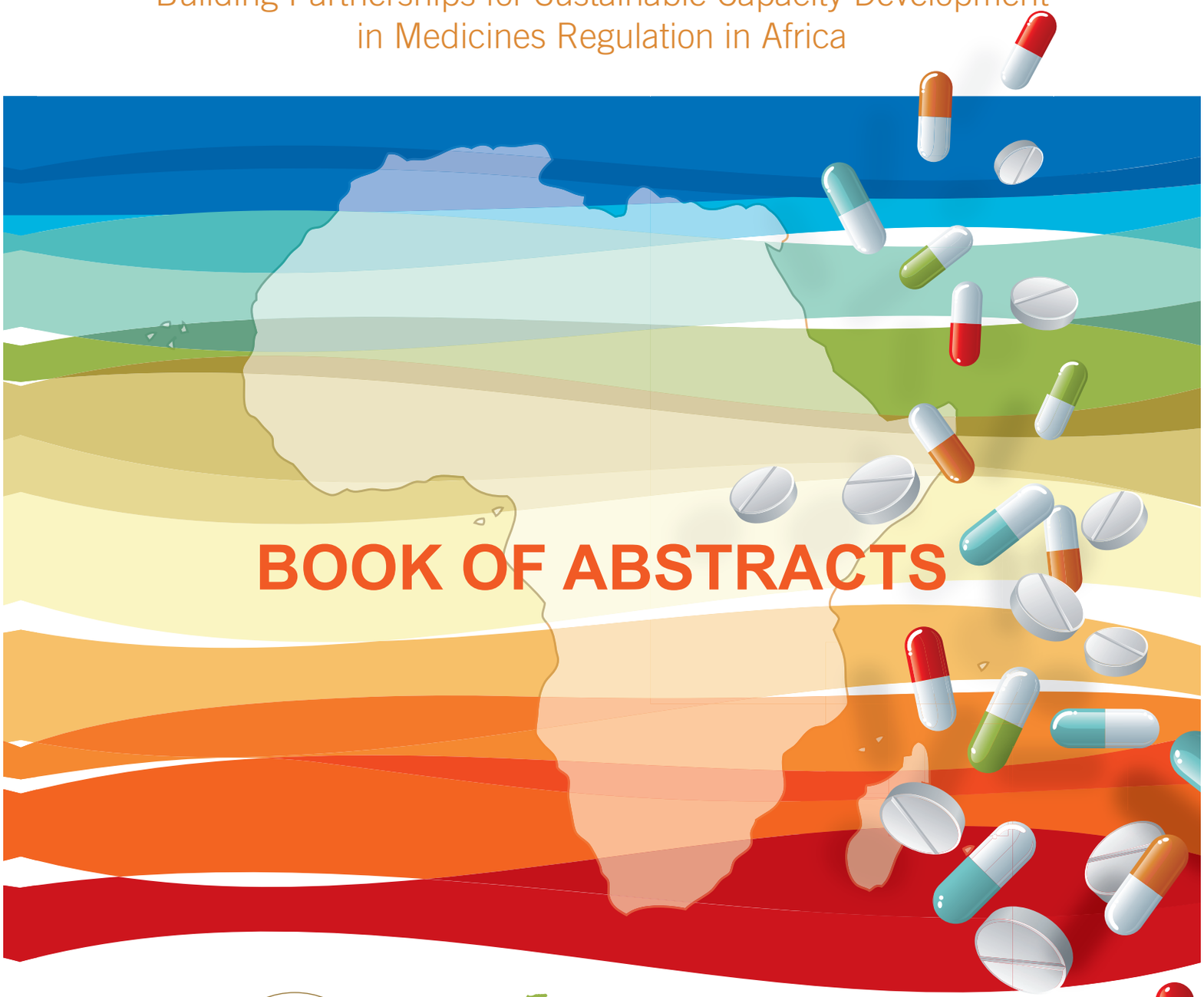
FIRST BIENNIAL SCIENTIFIC CONFERENCE ON MEDICINES REGULATION IN AFRICA

Birchwood Hotel I Johannesburg – South Africa I 2-3 December, 2013

Conference Theme:

Building Partnerships for Sustainable Capacity Development in Medicines Regulation in Africa



BOOK OF ABSTRACTS

NEPAD
TRANSFORMING AFRICA

Book of Abstracts

for the First Biennial Scientific Conference on Medicines Regulation in Africa

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

Birchwood Hotel
Johannesburg, South Africa
2–3 December, 2013

World Health Organization

DNDi

Drugs for Neglected Diseases *initiative*

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

African Medicines Regulatory Harmonization
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QUICK OVERVIEW

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MESSAGE FROM THE CEO: NEPAD AGENCY

It is a great pleasure to welcome you to Johannesburg South Africa and to the 1st Biennial Scientific Conference on Medicines Regulation in Africa that is being held in Birchwood Hotel, Johannesburg South Africa 2–3 December 2013. This Conference is co-organised by the NEPAD Agency African Medicines Regulatory Harmonisation (AMRH) Programme and the Department of Health, Republic of South Africa; in collaboration the World Health Organization (WHO), US Food and Drugs Administration (US-FDA); and Drugs for neglected Tropical Diseases (DNDi) with financial contributions from the World Bank, United States Pharmacopoeia (USP) and AERAS. The Scientific Conference will be followed by the 3rd African Medicines Regulators Conference organised by WHO in collaboration with NEPAD Agency at the same venue on 4–6 December 2013.

The 1st Biennial Scientific Conference on Medicines Regulation in Africa is being held at an appropriate time when we are witnessing progress in economic growth in Africa. During the past decade, African countries have increased their planning capacities and their performance in achieving jointly defined benchmarks and policies. Strategic regional frameworks have been developed and are being implemented in areas spanning from health, agriculture and food security to infrastructure. Mutually reinforcing linkages and coordination mechanisms between the national and regional levels are also being strengthened hence reinstating the notions of planning, ownership and leadership.

African countries with leadership from the African Union, are demonstrating strong political commitment by embracing transformative reforms to address health, especially the epidemics of AIDS, tuberculosis (TB) and malaria, and by building efficient health systems. The African Union has framed a compelling vision for the future of the continent and has developed powerful policy frameworks including the 2006 Abuja Call for Accelerated Action towards Universal Access to HIV/AIDS, Tuberculosis and Malaria Services in Africa; the Pharmaceutical Manufacturing Plan for Africa (2005) and the Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa (2012), just to mention a few.

Critical to all these is the realization of the need for; i) Diversified, balanced and sustainable financing models; ii) Access to medicines through local production and regulatory harmonization; and iii) Leadership, governance and oversight for sustainability.

It is also important to note that African governments are cognisant of the fact that delivery of quality health care in the majority of African countries is hampered by lack of health care workforce, weak infrastructure and unsustainable health care financing mechanisms among others. In the endeavour to meet these challenges, global partnerships of stakeholders play a crucial role.

One of the key mandate of the NEPAD Planning and Coordinating Agency (NPCA) as a technical body of the African Union (AU) is to conduct and coordinate research and knowledge management, and to mobilise the resources and partnerships needed to address continental, regional and national priority programmes. The organization of this conference fulfils this mandate. I hope therefore that through this conference there will be increased understanding of the current global regulatory environment; increased understanding of current trends, tools, technologies and practices deployed in the field of regulatory science; increased collaboration and information sharing amongst policy makers, NMRAs, industry, academia, and research institutions in Africa; acceleration of Regional Economic Community (REC) and country driven medicines regulatory harmonisation initiatives in Africa and that through this 1st Biennial Scientific Conference Africa begins to contribute to global knowledge on regulatory science.

It is equally my hope that this conference will help shape regulatory policy options and approaches that will be beneficial to public health.

The success of this conference cannot only be judged by the quality of scientific papers presented, but more by its ability to stimulate broad support for medicines regulation specifically and public health generally. There is need therefore to assess the various regulatory initiatives and models with a view to identify best practices at country and regional levels. This will facilitate effective utilization of the limited resources available and promote sharing of best practice that will promote regulatory standards and practice in Africa. While Africa continues to make incremental strides in various sectors, this conference provides a platform for Africa's contribution to the on-going global dialogue on medicine regulation.

I would like to assure you that NEPAD, as a widely accepted continental framework for sustainable development, provides a strategic platform for spearheading the African socio-economic development agenda. While African countries are striving to achieve the Millennium Development Goals (MDGs), new ambitions have emerged to go beyond mitigating poverty and its effects towards building a prosperous future with a common rallying call of **'Transforming Africa'**. It is my hope that this conference reflects on some of the challenges facing African governments with a view to provide pragmatic solutions to address them.

In this regard, I wish to thank all the organizers who have made this conference a success. I also wish to applaud the presence of high ranking South African National Department of Health officials and other African government representatives, NMRA representatives as well as representatives of RECs and representatives of the AMRH Partner organizations. To all authors, speakers, presenters and to those who have worked behind the scenes, thank you for your hard work and professionalism.

Thank you

Dr. Ibrahim Assane Mayaki

MESSAGE FROM THE CHAIRPERSONS OF THE CONFERENCE ORGANISING COMMITTEE

It is with great pleasure that we invite you to actively participate in the 1st Biennial Scientific Conference on Medicines Regulation in Africa being held in Birchwood Hotel Johannesburg South Africa. Being the first, we hope it will be a milestone in highlighting the work and research efforts spent in different regulatory science fields in Africa. This will be the first of several biennial scientific conferences that will be organised by the NEPAD Agency African Medicines Regulatory Harmonization (AMRH) Programme Partners and other collaborating organizations and agencies.

The overall goal of the conference is to enable policy makers, regulators, industry, academia, research organizations and scientists to network and exchange information on innovative approaches for pharmaceutical sector development in Africa. Thus it is hoped that the conference will provide a forum to share scientific advances and current best practices in regulatory science disciplines amongst policy makers, regulators, industry and scientists; review current global developments in the regulatory environment and assess their impact on the commercialization of health research products as part of implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA); contribute to global knowledge on regulatory science; and provide inputs to the third African Medicines Regulators Conference (AMRC) that is being held from 4 to 6 December 2013.

The 1st Biennial Scientific Conference on Medicines Regulation in Africa is structured to promote discussion and exchange of ideas so that all participants actively take part in generating the main conference outcomes. The format of the conference will include oral presentations, poster presentations and panel discussions to maximise contributions around the key topics. We hope that the conference will create plenty of opportunities for enriching and stimulating interactions in the medicines regulation field.

We would like to thank the entire Organizing Committee of the conference for its intensive work and contributing their time and intellectual resources to ensure that the conference succeeds. Special thanks are also due to all the individuals and organizations that have supported the organization of this conference financially; namely, The Department of Health – Republic of South Africa, Bill and Melinda Gates Foundation (BMGF), The World Bank (WB); United States Pharmacopoeia (USP); AERAS.

We also thank all the presenters and abstract reviewers who spent considerable periods of time to review the abstracts and provide constructive feedback. We would also like to thank those who have agreed to lead structured plenary and parallel sessions as chairpersons and rapporteurs.

Finally, our thanks are due to all the authors for preparing their papers in the required format and meeting deadlines for revisions.

Thank you

Margareth Ndomondo-Sigonda – Pharmaceutical Coordinator, NEPAD Agency

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

Co-Chairpersons Conference Organizing Committee

ABSTRACTS

1 GLOBAL REGULATORY ENVIRONMENT: WHERE IS AFRICA?

1.1 Oral Presentations

1.1.1 Harmonization of Medicines Regulation Requirements within the East African Community (EAC)

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ABSTRACT

Disparate drug regulatory requirements within the EAC Partner States, has led to low access to essential medicines for the management of diseases of public health importance, and hence their high costs. Harmonization of regulations seeks to adjust these differences by standardization of regulatory requirements, establishing communication and collaboration mechanisms leading to similar approaches to drug registration and ultimately to mutual recognition of the decisions by any of the NMRAs in the Partner States. For this to be achieved a situation analysis was conducted in each of the EAC Partner states NMRA, to assess the pharmaceutical policies, legislation and regulation, to identify =opportunities for harmonization and make recommendation on the best approaches.

The situation in the 6 NMRAs namely Burundi, Rwanda, Kenya, Tanzania, Uganda and Zanzibar is that, human resources are limited both in numbers and skills, physical facilities are inadequate and there are only three drug quality control laboratories. At present all six NMRAs have different requirements for the format and content of application for registration of pharmaceutical products and with inadequate guidelines to comprehensively cover all the key regulatory functions and requirements. In view of this, medicines registration cannot be efficiently harmonized in the absence of harmonized requirements and mechanism for sharing regulatory information.

With such a challenge at hand, the EAC NMRAs, with support from a consortium of development partners including; Bill and Melinda Gates Foundation, and the World Bank (WB), are embarking on harmonization of medicines regulation requirements in the region. This abstract therefore intends to provide a summary of what is taking place in this special area of medicines regulation harmonization.

Keywords: Harmonization, registration requirements, situation analysis

1.1.2 Impact of Regional Regulatory Interventions in ECOWAS Region

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ABSTRACT

Since its establishment, the West African Health organisation (WAHO) has been providing support to ECOWAS Member States to support their pharmaceutical management systems. In 2009, a new impetus was given to the process with the drawing up of a five year strategic plan. Interventions that were strengthened in this process include but not limited to regulatory management, registration harmonization, quality control of medicines, pharmaceutical production and capacity development, good manufacturing practices, pharmacovigilance and TRIPs flexibilities support. Activities centred on provision of direct support based on need for the procurement of laboratory and information technology equipment and medicines and training. This paper seeks to review these interventions, taking into consideration the objectives of each intervention, number of countries that benefited, number of training programmes in the specific areas, and the direct financial and material support provided. Sources of the resources used in implementation of these activities including ECOWAS Commission, experts and financial partners are also evaluated in the paper. In depth discussion on the impact that these interventions have made on the beneficiary countries and institutions as well as the Regional Economic Community (REC) as a whole has been provided. In conclusion, a way forward for the next five years to consolidate the achievements made so far and address challenges faced are provided.

Keywords: Quality Control, Medicines Registration Harmonization, Pharmacovigilance management, enabling environment for pharmaceutical production, Counterfeit and Illicit Trade in Medicines

1.1.3 Position on the process of harmonizing pharmaceutical policies and regulations in Central Africa: Progress, issues and challenges

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ABSTRACT

Since 2005, a programme for the harmonisation of policies and drug regulation in Central Africa is being driven by the Organisation for Coordination of Endemic Diseases in Central Africa (OCEAC). Central Africa consists of two entities: the Economic Community of Central African States (ECCAS) and the Economic and Monetary Community of Central Africa (CEMAC). The programme began with CEMAC member countries and culminated in June 2013 with the adoption of the following texts:

1. Additional Act adopting the Common Medicines Policy;
2. Framework law adopting guidelines on the supply of essential drugs;
3. Regulation on the adoption of a manual of procedures for Pharmaceutical Inspection;
4. Regulation adopting Guidelines on Pharmacovigilance;
5. Regulation framework to harmonise procedures for approving medicines for human use in CEMAC.

This process, which is conducted in a participatory manner, involves pharmaceutical leaders, multidisciplinary experts and partners, and aims to harmonise policies and efforts to:

- establish effective regulatory systems to better control the pharmaceutical industry and therefore medicine;
- use resources available in the Community more effectively;
- facilitate the circulation of pharmaceutical products within the Community;
- improve access to quality medicines and better cost for local use and export.

The extension to other ECCAS countries which are not members of CEMAC is necessary, in order to avoid dual policy structures in the same subregion.

Keywords: harmonisation; pharmaceutical policy; pharmaceutical regulation; Central Africa; approval.

1.2 Poster Presentations

1.2.1 Policy for monitoring the quality of medicines in Cote D'Ivoire

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ABSTRACT

The presence of poor quality drugs in the distribution channels has been noted in several countries. It is a factor in treatment failure and resistance to certain drugs. Monitoring the quality of drugs is a necessary means to ensure the effectiveness of active substances.

Presenting strategies implemented from 1994 to 2013 for monitoring the quality of medicines in Côte d'Ivoire.

Pre-marketing strategy of the medication: it entails reviewing the registration dossier in its different sections (1994), inspecting drug production units (1994) and analytical expertise in laboratory medicine (2008).

Post-marketing strategy of the drug: it oversees the monitoring of possible side effects (pharmacovigilance) (1994, 2008), the inspection of approved institutions for pharmaceutical distribution, the advertisement of medicines to medical and pharmaceutical bodies (1994, 2010), and post-marketing quality control throughout the life of the medicine (2010).

The analysis of drug quality assurance system in Côte d'Ivoire highlights the positive developments in recent years. However, post-marketing deserves to be sufficiently implemented despite the lack of funding.

Keywords: Drugs, Quality assurance, Quality control, Drug approval

2 NATIONAL AND REGIONAL INITIATIVES FOR STRENGTHENING REGULATORY SYSTEMS

2.1 Oral Presentations

2.1.1 Providing a conducive regulatory environment: The NAFDAC Perspective

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ABSTRACT

Within Africa, regulators face a myriad ofchallenges. These include weak regulatory systems, lack of regulatory capacity, inadequate regulatory framework, poor funding, weak or absent legislation as well as the menace of counterfeit medicines.

One of the major challenges being faced by regulatory agencies, especially in developing countries, is the counterfeiting of regulated products.Counterfeiting has become a global problem that presents an enormous public health challenge.According to the World Health Organisation (WHO), over 270 million people in Africa lack access to the most essential medicines. Drug counterfeiters target medicines that are used in high volume for managing diseases of public health interest such as, Anti-malarials, Antibiotics, Anti-hypertensives and Anti-diabetic agents.

The public health implications and consequences are very dire. Patients are denied access to quality medicines leading to, treatment failures, increased hospital admissions, prolonged hospital admissions with the resultant increased burden on the health system.

Counterfeiting can also increase the risk of the development of drug resistance.

In an effort to reduce the negative public health impact and to execute its mandate, NAFDAC has devised several strategies to improve access to safe and efficacious medicines.

These strategies include public enlightenment, national and international collaboration, capacity building, Law review and the use of Cutting-Edge Technologies to secure the supply chain. The Agency is spearheading global efforts, and has gained international recognition in the use of Cutting-Edge Technologies to fight counterfeiting.

The functioning of the Agency, its recent restructuring to support service delivery as well as the different strategies being employed will be elaborated upon in the presentation.

Keywords: NAFDAC, Technologies, Regulatory Capacity, Strategies

2.1.2 Perspectives on harmonized clinical research governance regulatory framework for Africa.

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ABSTRACT

Human experimentation and medicinal products regulators in the global environment are facing rapid changes including technological advancements, cultural issues, demographics, emerging diseases, globalization, and traditionally accepted doctrines for human subject protection that are becoming outmoded. A number of African countries barely have clinical trials regulatory framework whilst others have none. This variability has created gaps in African medical research oversight and puts trials participants at risk.

This presentation aims to serve as a bridge for narrowing the gaps by suggesting strategic initiatives for the development and implementation of a harmonized clinical governance regulatory framework for Africa. Harmonization will lead to concerted clinical trials oversight and bring about transparency.

Recently, the Trovanpediatrics clinical trials in Kano, Nigeria, has highlighted the need for a referendum that demands international clinical trials regulatory oversight in Africa. The Declaration of Helsinki emphasizes that the clinical research protocol "must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards…" Despite these principles, concerns over clinical trials still abound. Most African countries depend mostly on ICH GCP 6 guidelines which are not tailored to the laws and regulations of African countries.

Recommendations for such a framework include, (a) partnerships with African Regulatory Agencies to form a PAN-AFRICAN REGULATORY TASK-FORCE, (b) partnerships with non-African regulatory bodies, academic and commercial clinical research entities, (c) local African community leaders involvement, and (d) Pan-African Regulatory Governance Database. Telemedicine guidelines and regulations for clinical research must be developed. Language issues would need to be addressed to facilitate recruitment and retention of trial participants. Translations from English to French, Arabic and Portuguese could enhance a common understanding whilst accelerating capacity building.

Keywords: Declaration of Helsinki, Clinical Research, Governance, Regulatory Framework, ICH GCP E6

2.1.3 Industry and its impact on patient access to medicines (aspirations/ challenges)

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ABSTRACT

African Regulatory Network (ARN) serving as a key stakeholder/industry voice (ARN through IFPMA represents 24 large research-based Pharma companies), plans to share its view on the AMRH initiative. We recognize the opportunity for the region to demystify the complexities of registering medicines in Africa and foresee this as a very positive initiative that aims to flagship Africa as a single market in the future.

Our current industry challenge is the earlier access to good quality medicines in Africa - the turnaround time of bringing medicines to patients in Africa from major markets approvals is taking approximately up to 5 years (end to end to product being available to the patients).

We would like to bring our thoughts on defining the problem statement on AMRH harmonization into short/medium/long term aspirations, challenges and deliverables. This with the view to allow for tangible and measurable steps forward on the vision from an industry perspective (research-based).

We would also like to discuss situational issues such as CTD format & content alignment, harmonised and clear ancillary requirements/guidelines, fees appropriate to review type, joint/ shared reviews (reduce resources for industry and regulatory authorities), decrease review turnaround timelines (measurable and transparent), stress the importance of lead countries/ centres of excellence, reliance on accredited country inspections.

We believe the industry experience will help authorities drive for efficiency in the harmonised approach, improve speed of review/handovers within the review process and shorten the timings for medicines access to patients from major market approval.

ARN believes strongly that our involvement and active participation supporting the AMRH initiative will bring value to understanding the practical approaches/challenges faced by the industry (research-based). We believe we can also serve to provide an early feedback forum on new/draft processes/guidelines prior to large scale industry reaction being sought.

Keywords: opportunities, harmonisation, Industry role, African single market, medicine access to patients

2.1.4 Medicines regulation in Africa – The controversies and way forward

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ABSTRACT

Over the last ten years, medicines regulatory management, systems and structures have undergone modifications in terms of legislation, placing of the regulatory systems in the national governance structures, the scope of products to be regulated and indeed infrastructural and human capacity development. It is acknowledged that the extent of these developments vary from country to country.

Having been in medicines regulatory practice for almost a quarter of a century, particularly in sub Saharan Africa, this paper seeks to share experiences gathered. It discusses policy reforms that have led to the passing of new or reviewed legislation and the impact this has or potentially have to affect overall medicines regulatory practices in countries and for that matter in Regional Economic Communities (RECs) and the African continent at large. The paper shares the situational analysis based on both the internal and environmental scan of many country systems, the governance structures that have tended to either inhibit or promote effective medicines regulation, the 'Board-Management Dichotomy', appointments and recruitment of staff, adoption, adaption, revision of guidelines, prioritization of regulatory scope and activities based on existing human resource capacity and other infrastructure among others. On the regional level, the paper discusses the controversies surrounding issues like poor regulatory capacity in Africa, what regulators understand as common technical documents, separate and individual country guidelines for GMP, regulation of food alongside medicines, multiplicity and non-coordination of technical and financial assistance to NMRAs and colonial heritage and language barrier to effective medicines regulatory harmonization in Africa. It concludes by suggesting the way forward for improved medicines regulation and harmonization for the next decade.

Keywords: Medicines, Regulatory Authorities, management, Technical Assistance, Harmonization

2.1.5 Medicines harmonization in West Africa: Realities and prospects

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ABSTRACT

In order to improve their populations' access to medicines, West African countries have begun a process of harmonizing pharmaceutical regulations in the countries of the sub region, based on two main sub-regional economic bodies: the West African Economic and Monetary Union (UEMO) and the Economic Community of West African States (ECOWAS).

The objective of this work is to describe the main advances in the harmonisation process, to anticipate challenges to achieving public health goals, and to deal with them in an intelligent way

The methodology used was to trace the main stages in the process of harmonising pharmaceutical regulations in West Africa, to describe the main results and to critically analyse them and to formulate proposals aimed at promoting the health goals and objectives.

It appears from this study that these two regional economic organisations have been successful in harmonising pharmaceutical legislation in West Africa. For example, even though ECOWAS has succeeded in establishing binding legal norms on member States (Regulations, directives) - such as Regulation No 06/2010/CM/UEMOA on registration procedures for medicines in UEMOA member states - ECOWAS remains particularly concerned about harmonising training curricula for pharmacists and harmonising codes of ethics for the practice of pharmacy in ECOWAS. It should be noted that there has been a certain delay by member States in implementing decisions, even though these were consensual, agreed upon by member States themselves on the harmonisation of their pharmaceutical regulations.

Efforts should be made to achieve greater symbiosis between these two sub-regional organisations in order to optimise expected results.

Keywords: Medicines, regulatory harmonization, West Africa

3 LEVERAGING GLOBAL REGULATORY INTERVENTIONS

3.1 Oral Presentations

3.1.1 Registering medicines for low income countries: How suitable are the stringent review procedures of the World Health Organization, the US Food and Drug Administration, and the European Medicines Agency?

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ABSTRACT

New medicines are registered after a resource demanding process. Unfortunately, in low income countries (LICs), demands outweigh the resources. To facilitate registration in LICs stringent review procedures were established by the European Medicines Agency (EMA Article-58), the Food and Drug Administration (FDA PEPFAR-linked Review) and WHO (WHO-Prequalification). Of these only PEPFAR-linked Review gives approval while the others give approval recommendations. This study assessed the performance and discussed the challenges of these stringent review procedures.

Data from WHO, FDA, EMA, Medline, and Internet was analysed. Over 60% of medicines reviewed by the stringent review procedures are manufactured in India. Until 2012 WHO prequalified 400 medicines (211 vaccines, 130 antiretrovirals, 29 tuberculostatics, 15 antimalarials and 15 others). On the other hand PEPFAR-linked Review approved 156 antiretrovirals while Article-58 recommended approval for 3 antiretrovirals, 1 vaccine and 1 antimalarial. WHO-Prequalification and PEPFAR-linked Review are free of charge and as a result have accelerated access to antiretrovirals and built capacity in Sub-Saharan Africa (SSA). Though WHO issues prequalification it relies technically on stringent regulatory authorities and financially on donors. Whereas, Article-58 offers the largest disease coverage and strongest technical capacities it is costly and involves less LICs. Overall, the stringent review procedures may be challenged by the scant pharmacovigilance infrastructure in Africa and by the Western orphan medicines of public health impact for LICs.

In order to meet the high demand for quality medicines in LICs there is still need for these stringent review procedures to enlarge their disease coverage, increase collaboration, and build regulatory capacity in SSA. Importantly, to avoid that SSA medicine regulatory activities fully resign to external regulatory expertise and to facilitate implementation of approval recommendations stringent review procedures should actively involve user LICs. In this regards stringent review procedures should serve as transition towards development of regional agencies in Africa.

Keywords: Medicines, drug approval, developing countries, stringent evaluation procedure, developed countries

3.1.2 Intersection of public policy and regulatory science: US and EU efforts to address unmet medical needs from serious bacterial and neglected tropical diseases

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ABSTRACT

Despite great scientific advancements and improved investments in global public health, a large segment of the world continues to experience significant unmet medical needs from serious bacterial infections and neglected tropical diseases. This undesirable situation is not simply due to the increasing bacterial resistance to available antibacterial drugs, but mostly results from the dwindling antibacterial drug pipeline from lack of commercial viability of new drugs that could stay ahead of the resistance challenge. In addition, given that the bulk of neglected tropical diseases occur in resource-scarce countries, the limited health expenditure in those countries may be neither attractive to multinational drug companies nor able to sustain a viable local research and development enterprise. Fortunately, policy makers, regulators, and funders have recognized these challenges and have redoubled their efforts to address them through legislative and other public policy initiatives. These partners are also promoting advances in regulatory science. The presentation will examine recent initiatives in the US and EU aimed at promoting product development targeting serious bacterial infections and neglected tropical diseases. In addition, the presentation will share some legislative and policy instruments for driving further advances in regulatory science. The presentation will also highlight potential stakeholder engagement opportunities within these initiatives since such engagement may be relevant to the implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA).

3.1.3 Improving the efficiency and effectiveness of drug approval for Low Income Countries (LIC): should sovereignty matter for the approval procedures of the World Health Organisation (WHO), the European Medicines Agency (EMA), and the Food and Drug Administration (FDA)? What to expect if the sovereignty question is made obsolete?

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ABSTRACT

Access to quality drugs for malaria, HIV/AIDS, tuberculosis and other poverty-related diseases are essential to achieve the UN millennium development goals (Sachs et al. 2005). The quality of a drug is assessed by a drug regulatory authority based on data that are provided by drug manufacturers. However, many African LIC-countries do not have the infrastructure to guarantee a stringent assessment of drug quality, by a national drug regulatory authority.

Upon recommendation of the International Conference of Drug Regulatory Authorities (ICDRA), three assessment procedures were created as rigorous mechanisms for drug approval exclusively for LIC: the WHO's prequalification of medicines; article 58 of Regulation No 726/2004 of the European Union ; and the US PEPFAR-linked approval. All three are procedures foreign to the LIC, even though their results aim at the LIC drug market.

The WHO prequalification assesses data of the drugs and emits a "prequalification", an approval opinion. Under article 58 of Regulation 726/2004, the European Union also delivers an approval opinion, meaning that it is the LIC that take the final approval decision. On the other hand the FDA provides an approval decision through the PEPFAR-linked Procedure.

However, the implementation of a drug approval decision by a foreign drug authority without an active involvement of the user countries may be challenging. Furthermore, by substituting the LIC in assessing the drug application dossier, putting these countries in mere implementation role, foreign drug authorities may be interfering with the countries' sovereignty, as well as local social and religious norms. What are the expected consequences?

Keywords: Sovereignty, drug approval procedures, low-income countries

3.1.4 Harmonisation and beyond: The case of Medicines Regulatory Systems in Africa

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ABSTRACT

The quest for harmonised approaches in various aspects of health systems has been an area of huge academic, policy and practice interest in Africa and globally. The World Health Organisation has been active in this area through their work with drug regulatory authorities (medicines control systems), while in Africa the African Union, the New Partnership for Africa's Development with technical and financial support from the Gates Foundation, World Bank and others and working through regional economic communities (RECs) have sought to facilitate the establishment of harmonised drug registration systems as a way of removing some of the bottlenecks in the development of drugs/medicines and their delivery to patients across Africa. Based on a 2 year study conducted in Eastern and Southern Africa (2010 to 2012), this presentation systematically analyses past, on-going and planned harmonisation initiatives for medicines regulatory systems in Africa, drawing lessons that can be used for a more structured, predictable and impactful approach to harmonisation at various geographical, product and process scales. The presentation will also analyse some of the regulatory and health system realities that are making harmonisation both desirable and feasible, in addition to some of the 'usual or common' factors militating against harmonisation and examples of sustained progress made in addressing them. The cost of harmonisation and the need for holistic approaches and 'fall back' positions will also be discussed. Finally, the presentation will reflect on the policy and practice impact of the harmonisation agenda in Africa, and how some of this impact will be measured and sustained.

Keywords: Africa, harmonisation, health systems, medicines control

4 CASE STUDIES AND COUNTRY EXPERIENCES IN STRENGTHENING REGULATORY SYSTEMS

4.1 Oral Presentations

4.1.1 NAFDAC E-Registration Process

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ABSTRACT

The National Agency for Food and Drug Administration and Control (NAFDAC) was established by Decree 15 of 1993, as amended by Decree 19 of 1999, and now the NAFDAC Act Cap N1 Laws of the Federation of Nigeria, 2004 to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, medical devices, chemicals, detergents, and packaged water (NAFDAC regulated products).

The Registration and Regulatory Affairs (R&R) Directorate is one of the thirteen Directorates that of the Agency. The Directorate is charged with the responsibility of registering all NAFDAC regulated products and ensuring that they meet set standards of quality.

To make the system of registration more efficient, the Agency recently introduced the NAFDAC Automated Products Administration and Monitoring System (NAPAMS). This is a web-based application that allows for electronic submission and commencement of the registration process by applicants.

In September 2012, a pilot deployment of the e-Registration platform for drugs, cosmetics and herbal products manufactured in Nigeria commenced.

Hitherto, applications for marketing authorization of food, drugs and other regulated products had only been paper based.

The platform offers many benefits. It allows for the remote submission and follow-up of applications by applicants. This makes for faster processing, efficient communication with applicants and makes the process more transparent. Applicants are able to track submissions and receive e-mail notifications throughout the process.

Regulatory officers have access at different levels and are able to progress applications through the different steps involved.

This Poster Presentation will highlight the capabilities of this customized system

Keywords: NAFDAC; NAPAMS, e-Registration; R&R; Authorization

4.1.2 Medicines registration in Zimbabwe

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ABSTRACT

Introduction: Limited human, technical and financial resources within the regulatory authorities in resource-limited settings affect access to quality assured medicines. Furthermore, the greatest public health threat in such settings is due to HIV/AIDS, TB and malaria.

Objective: The objective of this study was to evaluate the trend in medicine registration from January 2003 to July 2013.

Methods: This was a descriptive study conducted by analyzing the register of received and approved products over the ten-year period. The products were categorized according to pharmacological classification.

Results: Between January 2003 and July 2013, a total of 697 products were approved. During the same period, 1,485 new applications were received of which, 1,226 were reviewed. The highest number (135) of products approved in a given year was in 2003. Thereafter, there was a steady decline with the lowest number (32) of approvals in 2009 corresponding to the economic decline in Zimbabwe during the same period. HIV and AIDS, tuberculosis and malaria accounted for 24.3% of approved products during this period. The top five classes of products approved in corresponding order, were anti-HIV medicines including other antivirals (20.4%), anti-infectives (19.5%), cardiovascular medicines (9.1%), anti-neoplastic and immunosuppressive medicines (5.1%) and dermatological and topical preparations (3.9%). The median time to registration was higher, 687 days (range 19 to 4,401 days) compared to well-resourced settings. For example the median time for approval of new cancer drugs in Europe is 418 days, 595 days in 2011 for WHO prequalification for generic medicines and 576 days in Japan in 2009.

Conclusion: Anti-HIV medicines accounted for the highest number of approvals within this period. The median time to registration is higher compared to well-resourced regulatory authorities. Strategies such as partial reviews based on approvals in other countries can improve access to quality assured medicines by reducing the regulatory burden.

Keywords: Access to medicines, registration of medicines, medicines regulatory authorities

4.1.3 A unique regulatory perspective developing an NCE SOLEY for the prevention of HIV-1 in African women

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ABSTRACT

Dapivirine is a NCE (New Chemical Entity) administered via a silicone matrix vaginal ring providing monthly sustained drug release, for the prevention of HIV-1 in women at high risk. It is a non-nucleoside reverse transcriptase inhibitor (NNRTI) that has potent anti-viral activity against HIV-1. The dapivirine vaginal ring Phase 3 clinical programme, with two pivotal safety and efficacy trials involving over 5000 women, is currently underway in Africa. The ultimate goal is to gain regulatory marketing approval of the product in African countries with a high burden of HIV. One the unique regulatory challenges in developing dapivirine ring is that this NCE product has not been approved anywhere in the world and therefore clinical and safety data are limited. Generic drugs with known safety and efficacy profiles comprise many of the registered medicines in African countries. On the other hand, an NCE brings further challenges to the regulatory approval process in that additional resources are required such as expert reviewers and increased dialogue with the sponsor during the review period. Dialogue, meetings and guidance from African Regulatory agencies were sought on region-specific requirements for a NCE regulatory submission to determine resource and planning needs. The sponsor also plans on involving African Regulatory Agency participation in discussions with the EMA and WHO (pre-qualification) review process.

To further the development of a regulatory strategy, an understanding of access programmes and country specific collaboration with international organisations was necessary. The sponsor's regulatory strategy is based heavily on EMA, FDA and ICH regulatory guidance's and the WHO pre-qualification procedure. These mechanisms provide stringent drug development guidelines that are respected by many African regulatory agencies. Continual involvement and advice from African regulatory agencies is paramount to assure that all regulatory requirements are met in an expeditious manner.

Keywords: NCE, Africa, Regulatory, HIV prevention

4.1.4 Assessment of the policy and legal frameworks of the Ethiopian pharmaceutical supply chain

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ABSTRACT

Background: The national drug policy of Ethiopia and legislations enacted thereof govern the pharmaceutical supply chain of the country. The policy is 20 years old since its official declaration in November 1993. This long aged policy document has never been revised but there are a number of problems in the Ethiopian pharmaceutical supply chain system. This study has been conducted to assess the policy and legal environment of the Ethiopian pharmaceutical supply chain.

Methods: The study was designed to gather both primary and secondary data. The primary data was collected from interviewing 42 policy makers, legislators, company managers and technical advisors in the pharmaceutical sector based on judgmental sampling technique. The secondary data was collected from the medicines policy documents of Ethiopia, Ghana, South Africa, India and Australia. Each policy document was reviewed against the building blocks of a national drug policy recommended by World Health Organisation and World Bank. In addition, the national drug policy of Ethiopia was reviewed in comparison with the above mentioned countries' policy documents.

Results: Based on review of policies and legislations, the national drug policy of Ethiopia has included the major building blocks of such a policy for developing countries. The basic regulatory frameworks for manufacturing, importation, distribution and use of medicines are also addressed in the country's legislations. However, only the minority of stakeholders (45%) said that the national drug policy enables the establishment of competitive pharmaceutical supply chains in Ethiopia. Overall, 81% of them said that implementation of the national drug policy is not properly managed to achieve the policy objectives.

Conclusion: The policy document is formulated with clear strategic objectives but lacks direction for implementation especially in addressing key areas of legislation, relevant institutional set ups and development of strategic plans.

Keywords: National Drug Policy, Legislation, Building Blocks, Supply Chain

5 IMPROVING EFFICIENCY OF CLINICAL TRIAL APPLICATIONS REVIEW

5.1 Oral Presentations

5.1.1 Clinical trials in Africa: impediments and opportunities

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ABSTRACT

The pattern of disease is fast changing in Africa with non-communicable diseases like hypertension and diabetes mellitus competing with infectious diseases like malaria, TB and HIV/AIDS. The medications used in the treatment of these conditions are produced and supplied mainly from other continents. While many of these medications have gone through clinical trials in other non-African countries before registration, very few of them are tested on indigenous African population. It is a known fact that populations have variable genetic composition hence may respond differently to the same medication. This highlights the need for clinical trials to be conducted in African countries among the potential users of these drugs. Records from the clinical trial registration website (Clinicaltrial.gov) shows that out of about 147,867 trials that had been registered worldwide, only 3342 are carried out in Africa [1]. Poor infrastructure in many African countries, lack of qualified clinical research personnel, cultural issues, lack of or inefficient regulatory authorities and lack of trust to deliver credible results are some reasons for this lopsidedness. While some of the drawbacks mentioned above are true, we believe that the opportunities for the African people and pharmaceutical companies are enormous. Promoting clinical trials would go a long way in improving access to health care for the teeming population of Africa. These can occur in some of the following ways: through extended post-trial benefits, improved healthcare infrastructure and equipment and capacity building for healthcare personnel. One of the opportunities is the availability of a good number of qualified medical and paramedical personnel who could form the backbone of the clinical research industry. Presently in Nigeria, there are about 129 universities with over 100 of them with Faculties of Science and 36 of them with Colleges of Medicine [2, 3]. The population of the region with its diverse types of diseases is another advantage to be explored. The relatively low cost of conducting clinical trials in Africa when compared to developed countries is another major advantage [4]. Despite these numerous opportunities, African governments need to put in robust mechanisms that would ensure that ethical, regulatory and business standards are adhered to.

Keywords: Clinical trials, ethical issues, challenges, capacity building, regulatory agencies

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5.1.2 Timelines for ethical and regulatory review of clinical trial applications in low- and middle-income countries: Challenges and opportunities

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ABSTRACT

As research and development of new products targeting priority diseases like HIV/AIDS, malaria, tuberculosis, and neglected tropical diseases advances, more clinical trials are being conducted in low- and middle-income countries where these diseases are endemic. Ethics committees (ECs) and national regulatory authorities (NRAs) in these countries play a crucial role in ensuring that clinical trials are conducted safely and ethically. However, they often have insufficient resources and expertise to evaluate clinical investigations.

Lengthy and uncertain timelines for approval of clinical trial applications and amendments delay the initiation and conduct of clinical trials, sometimes substantially. Uncoordinated, often sequential (rather than parallel) reviews by ECs and NRAs within and across countries often further prolong the process. In turn, these delays lengthen the time it takes for new interventions to reach patients and communities that need them most. Further, delays may increase the cost of developing products significantly, as sponsors must maintain physical infrastructure and human capacity during gaps in clinical trial conduct. Such gaps also can lead to attrition of trial subjects, resulting in incomplete data and further delaying market approval and access to new products.

The Global Health Regulatory Team, comprised of regulatory professionals working for non-profit product developers, collected and analysed data on EC and NRA review timelines for clinical trials members conduct in various therapeutic fields. The resulting data set represents nearly 60 Phase I through III trials of drugs, vaccines, and diagnostics conducted in 25 endemic countries over a 10-year period. This abstract presents key findings from that analysis, focusing on challenges such as delays resulting from sequential review and inefficiencies associated with the lack of harmonized reviews across and within countries. The team expects sharing these findings to stimulate discussion with EC members, regulators, and other stakeholders about how to address these critical obstacles to product development.

Keywords: Ethics review, clinical trials, regulatory, product development, timelines

5.1.3 Research for Health and Innovation Organiser (RHINNO): Striving for quality and efficient review of clinical trial protocols

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ABSTRACT

The conduct of biomedical research and in particular clinical trials is vital to speeding up development of and access to affordable essential health interventions for African populations. Clinical trials build evidence, support innovations, and create new solutions, technologies and drugs. However, their conduct must be controlled by medicines regulatory authorities (MRAs) and research ethics committees (RECs) in order to protect the rights, safety and welfare of human participant populations. Currently majority of African countries have some form of provision in place to control the conduct of clinical trials, but there is still lack of capacity to enable quality and efficient review of clinical trial protocols. The urgent need for development of new medicinal products, new technologies and health care techniques has resulted in an increase in volume and complexity of clinical trial protocols. This poses a heavy demand on MRAs resulting in an inability for them to respond adequately. Common problems include reliance on manual systems for the review due to lack of electronic information management systems, various 'unlinked' databases and unreliable local servers. In response to these challenges, the Council for Health Research and Development (COHRED)-Web for Development (Web4Dev), created software called "Research for Health and Innovation Organiser for Ethics (RHInnO Ethics 1.0)". RHInnO is a customized web-based platform designed to manage the entire life cycle of a clinical trial protocol review process providing quick and reliable 'near real-time data, monitor and evaluate the review process and enable communication among research regulatory bodies.In conclusion, this software can speed up the review process, therefore is timely because it comes at a time when Africa has embarked on the Medicines Regulatory Harmonization (AMRH) Programme.

Keywords: Research for Health and Innovation organizer (RHInnO),Medicines Regulatory Authorities, Research ethics Committees, Clinical Trial Protocols Review

5.1.4 Regulation of vaccines for tuberculosis in Africa

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ABSTRACT

Challenge: Vaccines are often licensed in industrialized nations prior to their registration and introduction into developing regions like Africa. However, tuberculosis (TB) vaccines may be licensed first in a country endemic for TB. Production of TB vaccines can be complex, requiring a stringent review of the product and manufacturing as well as the clinical development program. These issues present both an additional challenge to TB vaccine sponsors conducting clinical studies in Africa and an opportunity to work with African National Regulatory Authorities (NRAs) to find creative solutions to regulatory challenges. Since regional clinical research sites are active partners in TB vaccine development, it also beneficial for African researchers to be engaged in the regulatory approval process.

Solutions: African regulators are aware of the important role they play in facilitating the introduction of products for diseases like TB that are prevalent in their countries. National efforts to strengthen individual NRAs and activities to harmonize regulatory requirements and policies have been initiated within Africa. The South African Medicines Control Council (MCC) is in the process of implementing IND-like procedures intended to streamline review of new products and reduce the time required for approval of clinical trials. Many African nations participate in the AVAREF initiative that promotes the sharing of information among African regulators to improve the efficiency of ethical review and regulatory oversight of clinical trials in Africa. The NEPAD Agency AMRH Programme and other partners are promoting sustainable institutionalized regulatory capacity building through African academic institutions and in close collaboration with NRAs.

Conclusions: There is a need to improve capacity and create novel mechanisms that strengthen the competency of NRAs and promote the convergence of regulatory policies across Africa in order to streamline the regulatory evaluation and approval of new vaccines for diseases like TB that will significantly improve the health of thousands of Africans.

Keywords: AVAREF, AMRH, Vaccines, NRAs, tuberculosis

6 REGULATORY CAPACITY DEVELOPMENT AND PARTNERSHIPS

6.1 Oral Presentations

6.1.1 Establishing Regional Centres of Regulatory Excellence (RCORES) in Africa

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ABSTRACT

As part of its mandate to strengthen regulatory capacity development, the AMRH Programme is in the process of establishing Regional Centres of Regulatory Excellence (RCOREs). The RCORE will be an institution or partnership of institutions with specific regulatory science expertise as well as training capabilities. RCOREs will have the mission to produce regulatory workforce in Africa through: provision of academic and technical training in regulatory science applicable to different regulatory functions and managerial aspects; skills enhancement through hands-on training, twinning and exchange programmes among NMRAs and practical training through placement in pharmaceutical industry. An RCORE shall thus be an institution or partnerships between institutions such as National Medicines Regulatory Authorities (NMRAs); university faculty; national or regional training centre or scientific and/or research institutions; industry, Quality Control Laboratory; Pharmacovigilance Centre; and/or Drug Information Centre.

RCOREs will be categorized according to their areas of expertise and strength in training and/or service delivery in at least one of the following regulatory functions: assessing the safety, efficacy and quality of medicines, and issuing marketing authorization; clinical trials oversight; licensing of the manufacture, import, export, distribution, promotion and advertising of medicines; pharmacovigilance and pharmacoepidemiology; inspecting and surveillance of manufacturers, importers, wholesalers and dispensers of medicines; providing independent information on medicines to professionals and the public; and Quality Assurance and Quality Control of medicines and medical devices.

In addition, institutions providing training in medicines laws and policies, Regulatory Systems, NMRA Quality Management Systems (QMS) and Regulatory Information Management Systems (IMS), Good Regulatory Practices (GRPs), Regulatory Performance Monitoring, Pharmacoeconomics and Health Technology Assessment and medicines pricing regulation will also be considered.

RCOREs will therefore constitute a centre of excellence with proven capacity and capabilities in training and/or delivery of service in at least one of the categories of regulatory and managerial functions identified. The eligibility criteria for consideration of RCOREs shall include: regulatory capability; training capacity; existing governance & management systems; and supporting infrastructure.

Keywords: RCORE, regulatory science, training, skills enhancement

6.1.2 The IFPMA-African Regulatory Network (ARN) view on the African harmonization process, burden on the role of academia in medicine regulation: Center for Drug Discovery Development and Production (CDDDP) as a case study

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ABSTRACT:

Access to essential medicines in Africa is currently limited by importation. About 90% of available drugs in Sub-Saharan Africa are imported mainly from Asia. On the alarming rate, is the circulation of substandard and counterfeit pharmaceutical products in developing countries especially Sub-Saharan Africa due to chaotic medicine distribution.

A lack of pharmaceutical innovation and critical mass of trained pharmaceutical scientists and professionals with the technical know-how within Africa is severely hampering the continent's ability to discover, develop and regulate medicines that meet local needs.

The role of academia in the regulation of medicinal products cannot be overemphasized and this includes: training of adequate personnel via short and long term courses, research and development, evaluation of claims, quality assurance, pharmacovigilance, bioequivalence, pre-clinical and clinical trials, and current good manufacturing practices (cGMP).

To contribute to drug development and medicine regulation, the Faculty of Pharmacy, University of Ibadan, Nigeria through a MacArthur Foundation grant set up a Centre for Drug Discovery, Development and Production (CDDDP) with the following objectives:

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

In addition to other activities, CDDDP recently in conjunction with Reckitt Benckiser organized a historic and novel international conference in University of Ibadan tagged 'Medicine Regulation of Claims: From Concept to Launch". It brought together regulators, industry, community pharmacists and consumers with academia as the bridge.

Keywords: Drug Development, Academia, Regulatory, Training, bridging gap

6.1.3 Creating a regulatory profession in LMICS via a global regulatory curriculum framework

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ABSTRACT

In 2012, the Institute of Medicine (IOM) released a report, "Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad," which identified lack of high quality and consistent training for food and drug regulatory staff as a major challenge in ensuring food and drug safety across the globe, particularly in low and middle income countries (LMICs).

A multi-stakeholder group comprised of non-profits, government, industry and standard setting organisations is now working to create a competency based, modular curriculum to educate regulatory staff in LMICs. This will include defining the minimal competencies needed by regulatory professionals in LMICs.

There will be opportunities for global stakeholders, including the community in Africa, to actively participate in this project to assure relevant issues are included in the competency/curricula maps. This will be followed by an expert group that will develop global curricula plans, based on required competencies.

Results of this project will include definitions of minimal competencies necessary for a competent regulatory workforce and the creation of a modular curriculum available for implementation by any interested party, and the development of a gap assessment tool that can be used by a country to assess its regulatory training needs. The resulting competency/curricula could also be effectively integrated into strategies for education and training with various centres of excellence. Its dissemination could be enhanced by housing it within a global, public institution.

The global curriculum will ultimately create a global regulatory professional identity and a core-competency based training, all of which will help to protect and promote global public health by ensuring drug and food safety.

Keywords: Global Regulatory Curriculum Framework

7 PARTNERSHIPS IN REGULATORY CAPACITY DEVELOPMENT

7.1 Oral Presentations:

7.1.1 Health Canada's regulatory capacity building activities in support of developing National Regulatory Authorities

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ABSTRACT

Introduction: Health Canada's regulatory capacity building program is aimed at strengthening the capacity of national regulatory authorities (NRAs) in Africa, Asia and Latin America. This program is supported under the Canadian HIV Vaccine Initiative (CHVI) – a Government of Canada and Bill and Melinda Gates Foundation partnership. Health Canada's regulatory capacity building activities are performed in collaboration with the World Health Organisation (WHO), and are one of the key activities under Health Canada's WHO Collaborating Centre for Standardization and Evaluation of Biologics.

Methodology: The regulatory needs of developing NRAs were identified using surveys, face-to face meetings and teleconferences, in consultation with the WHO and Pan American Health Organisation (PAHO). Health Canada experts developed and administered training, using case studies and interactive group discussions. Training sessions included clinical trial application review, clinical and quality review of vaccines and vaccine lot release.

Results: Since 2010, Health Canada has trained of over 100 participants from more than 40 countries. This includes the establishment and continued mentorship with regulatory agencies in Nigeria and Malawi, regional training in Southern and Eastern Africa, and the provision of regulatory and technical expertise at the African Vaccines Regulatory Forum. Health Canada has prepared and delivered regulatory training sessions via vaccine and clinical trial forums, and sponsored NRAs to attend these forums to provide learning opportunities and encourage the exchange of best regulatory practices. In addition, Health Canada has increased their regulatory capacity building efforts in Latin America in collaboration with PAHO and the Pan American Network for Drug Regulatory Harmonization.

Conclusion: Health Canada has successfully implemented capacity building initiatives in countries with developing NRAs, helping to strengthen their capacity in the regulation of vaccines. Moving forward, the focus of capacity building efforts will take a regional approach in order to maximize training opportunities for countries with similar regulatory challenges.

Keywords: Regulatory capacity building

7.1.2 Role of a Regional Economic Community in the harmonisation of pharmaceutical regulations at national level: The experience of the Economic and Monetary Community of Central Africa (CEMAC)

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ABSTRACT

In keeping with its mission of implementing the coordination of development programmes, the Commission of the Economic and Monetary Community of Central Africa (CEMAC) in 2007 created a sub-regional programme for the Harmonisation of National Pharmaceutical Policies (HPPN). This programme was coordinated and directed by OCEAC, the CEMAC agency responsible for the implementation of health policies. In terms of this programme's development strategy, OCEAC, under cover of the Commission, initiated a process leading to the signing of legislation binding on states, as a prerequisite for the implementation of technical support projects. Thus, in June 2013 an additional Act to the Treaty establishing a Common Pharmaceutical Policy was adopted, with three community-wide regulations and one framework regulation. This choice opens the way for OCEAC to implement projects aimed at improving the population's access to medicines that are safe, effective and quality controlled in the six member countries. Indeed, the project activities could be based on a comprehensive body of law, facilitating coordination at sub-regional level and visibility at international level, for both market operators as well as development partners working in the pharmaceutical field in the sub-region.

In terms of PPC objectives, the process was long and performance indicators will only be measurable in the medium term. However, the choice to offer a set of binding texts and achieve a solid legal structure improves the accountability of the HPPN programme vis-à-vis CEMAC states, but also vis-à-vis technical and financial partners who have a mandate to contribute to the sector in order to improve access to quality medicines.

Keywords: CEMAC, OCEAC, Medicines, Harmonization, Pharmaceutical Regulation, Accountability

7.1.3 Strengthening regulatory and partnership regulation

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ABSTRACT

Drug regulation incorporates several complementary activities that are mutually reinforcing and that all aim to promote and protect public health. Their implementation differs from one country to another, but they are common in sharing the relevant standards to ensure public health: quality, safety, efficiency and performance. The Main objective is to strengthen medicines regulation, namely:

- Approve the manufacture, import, export and distribution of medicines.
- Assess the safety, efficacy and quality of drugs and deliver Market Authorizations.
- Inspect and monitor manufacturers, importers and wholesalers.
- Control and monitor the quality of medicines on the market.
- Control the promotion and advertisement of drugs.
- Monitor adverse drug reactions.
- Provide information on medicines to professionals and to the public.

Factors contributing to the effectiveness of medicines deregulation in general:

- Political will and commitment of the public authorities in favor of regulation.
- Solid application of the principle of drug regulation.
- Effective cooperation between the national regulatory authority and other law enforcement agencies.
- Qualified and experienced professionals in the pharmaceutical field.
- Systematic checks after registration.
- Pharmaceutical legislation and regulation.
- Appropriate structures and systems according to set standards.
- Cooperation and effective collaboration between national regulatory authorities and other partners.

Keywords: Quality, security, efficiency, regulatory performance and business.

7.1.4 Building capacity in African research institutions through facilitated partnerships and scientist exchange

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ABSTRACT

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

Keywords: Hosting, partnerships, NTDs, neglected diseases

8 INITIATIVES, COUNTRY EXPERIENCES AND PERSPECTIVES IN REGULATORY CAPACITY DEVELOPMENT

8.1 Oral Presentations:

8.1.1 Increasing access to quality essential medicines and services by drug shops in Uganda through accreditation

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ABSTRACT

Problem Statement: Most people in rural areas of Uganda often first visit local drug shops for their medicines and health care needs. These shops may not be licensed, have unqualified personnel and sell medicines that may be of uncertain quality.

Objectives: To transform existing Class C drug shops into well regulated Accredited Drug Shops (ADS), so that people living in rural communities have access to quality medicines.

Design: A quantitative and qualitative pre and post intervention design in Kibaale district, with Mpigi district as control. Baseline (2008) and endline data (2010) was collected using surveys and interviews.

Setting and Study Population: 45 ADS in Kibaale district; 43 Class C drug shops in Mpigi district.

Intervention: Transformation of drug shops into ADS included setting standards for operations and the facility. Drug shop operators were trained in drug management and support supervision was provided from district level. Advocacy campaigns were used to raise consumer awareness of the need to buy medicines from licensed sources.

Outcome Measures: Percentage indicators of medicines availability, affordability and service quality.

Results: From Kibaale, injection services in ADS dropped from 74 to 2%, compared to 17% increase in the control district; availability of essential medicines increased from 16 to 40% availability of essential antibiotics compared to the control district where there was a 3 to 8% reduction in availability.

Conclusions: Results indicate that accreditation of Class C drug shops into ADS improved access to quality products and services in retail drug shops that serve populations living in rural areas

Keywords: Access, Essential Medicines, Quality, Drug shops, Accreditation

8.1.2 Comparative dissolution profiling as a basic requirement for product licensing in the West African sub-region

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ABSTRACT

In vitro bioequivalence studies ought to be undertaken for product licensing and post-production by regulatory authorities and researchers in order to protect public health from substandard medicines. In vitro dissolution profiling is a more accurate approach than single point assay for bioequivalence studies. The provisions of the USFDA on biowaivers for bioequivalence studies were applied to three (3) brands of an antiretroviral, twelve (12) sulfadoxin-pyrimethamine and six (6) ciprofloxacin solid dosage forms available in Nigerian market. Dissolution apparatus II was employed for the antiretrovirals (ARVs) and sulfadoxin-pyrimethamine (SP) dosage forms while dissolution apparatus I was employed for the ciprofloxacin tablets/caplets using dissolution media (0.1 N hydrochloricacid and phosphate buffers at pH 4.5 and 6.8) at 37oC and 50rpm. Samples were withdrawn at pre-determined intervals and assayed using liquid chromatography for ARVs and Ultra-Violet spectrophotometry for SPs and ciprofloxacin tablets/caplets. Similarity factor f2 and difference factor f2 were utilized to compare the dissolution profiles for bioequivalence and ascertain if the different brands can be used interchangeably. Two ARVs were considered rapidly dissolving and bioequivalent; while both were bio-inequivalent to the reference product. The reference, prequalified by WHO did not exhibit greater than 85% in 15min and so was not considered a rapidly dissolving product. Furthermore, 5 out of 12 products of SPs compared favourably with the reference product. Three SPs brands released less than 30% of the active ingredient after 60min, while 3 of ciprofloxacin brands may not be used interchangeably with the innovator product. Dissolution profiling is a practical substitute for in vivo bioequivalence studies that African countries can utilize for product licensing and post monitoring of medicines. Consequently, it is suggested that regulatory authorities in Africa should implement the provisions of regulations or enact where they do not exist already.

Keywords: Dissolution, bioequivalence, product licensing, regulatory authorities, dosage forms

8.1.3 Swaziland Ministry of Health and SIAPS partnering in strengthening regulatory capacity

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ABSTRACT:

Introduction: Swaziland is one of three remaining countries in the SADC Region that do not have adequate regulatory and legislative frameworks to control the use, importation, manufacturing and exportation of medicines. The country is currently governed by the Pharmacy Act of 1929, which does not provide for the effective regulation and control of medicines.

Method: To address the gaps in the control of medicines, Management Sciences for Health, through the USAID funded Systems for Improved Access to Pharmaceuticals and Systems (SIAPS) program, supported the Ministry of Health in the following activities towards the establishment of the Swaziland Medicines Regulatory Authority (MRA):

i. Legislation review to develop the Medicines and Related Substances Control Bill (to establish the MRA) and Pharmacy Bill (to establish the pharmacy council).

ii. Establishment of an interim MRA working desk to undertake some functions of the MRA and prepare for the establishment of the MRA upon the enactment of the Medicines Bill.

iii. Building capacity of MRA desk through benchmarking consultative visits to more established SADC regulatory authorities.

iv. Development of a Pharmaceutical Services Strategic Plan 2012-2016.

v. Development of an MRA establishment plan.

Results:

a. The Medicines Bill was passed by the House of Assembly in July 2013 and is currently awaiting discussion by the House of Senate.

b. The MRA establishment implementation plan was developed to guide the formation of the MRA.

c. Draft regulations have been developed to facilitate the prompt implementation of the Medicines and Related Substances Control Act.

d. A medicines listing/registration database is under development to register all medicines imported, sold and used in Swaziland.

Conclusion: There is political will to establish the MRA in Swaziland and with Partner support, the Ministry has made commendable progress in its preparation for the establishment of the Authority.

Keywords: Medicines regulatory authority, legislation, medicines database, SIAPS governance, implementation plan

8.1.4 Regulatory capacity building efforts in NAFDAC, Nigeria

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ABSTRACT

In a bid to strengthen regulatory capacity, the Agency has made human capacity development in all areas a top priority. We have engaged several partners in this effort in order to leverage on existing initiatives. This will allow judicious use of existing resources in the light of funding constraints. We have continued to participate at international fora to expose staff to best practices such as those organized by the USFDA, Centre for Drug Evaluation and Research (CDER) and Health Canada.

NAFDAC has recently entered into a mentorship program with Health Canada under the Canadian HIV Vaccine Initiative(CHVI) Regulatory Capacity Mentorship Program to build capacity in the six critical functions of vaccine regulation. In-house capacity building has become entrenched allowing for continuous sharing of information and knowledge dissemination.

NAFDAC is participating in the trainings offered by the United States Pharmacopoeia (USP) at the Centre for Pharmaceutical Advancement and Training (CePAT), Ghana. Regulatory officers will be trained in relevant areas which include Dossier Assessment; current Good Manufacturing Practices (cGMP); Laboratory Quality Management Systems and Good Laboratory Practices (GLP).

Within the West African Sub-region, NAFDAC is involved in the harmonization efforts being coordinated by the West African Health Organisation (WAHO).

We are involved in WHO programs such as the Paediatric Medicines Regulatory Network (PmRN), Collaborative procedure for registration of WHO pre-qualified medicines, and the Expedited procedure for registration of WHO pre-qualified vaccines. We are also involved in the United Nations Commission Program for Life Saving Commodities for Women and Children.

This presentation will provide clarity on these, and other initiatives, undertaken to boost regulatory capacity within the Agency, as well as provide further insight on partnerships and collaborative initiatives entered into, in furtherance of the work of the Agency.

Keywords: NAFDAC, Capacity, Health Canada, USP, CePAT

9 STRENGTHENING PHARMACOVIGILANCE SYSTEMS IN AFRICA

9.1 Oral Presentations

9.1.1 Kenya Pharmacovigilance: Online Reporting System

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ABSTRACT

Background: The disease burden in Africa is not only pronounced due to lack of drugs but also presence of substandard drugs. The exact extent of the substandard, spurious or falsified medicines is at times not known. Monitoring both the quality and safety of the medicines after registration is important as most poor patients usually opt for over-the-counter medications since they can rarely afford to visit well-equipped hospitals which at times are far between.

The ultimate goal of PV is to ensure appropriate and safe use of medicines through assessment and communication of their risks and benefits. Initially, a paper-based reporting system was successfully implemented, and then over time the need to develop a more efficient electronic mechanism for submitting reports became apparent. Consequently, PPB with support from donors has developed the Pharmacovigilance Electronic Reporting System (PvERS). This is a suite of four software applications enabling anyone to report suspected ADRs and poor quality medicinal products through online and offline access via mobile and fixed devices

Methodology: Working together with developers, the Board came up with applications that allow both healthcare workers and consumers to report any suspected adverse drug reactions and poor quality medicines. A client can report any suspected ADR or poor quality medicine using a computer or even the mobile phone. This report is then received immediately at the National Pharmacovigilance Centre which will then trigger action from PPB to prevent any more patients from being harmed.

Conclusion: The PvERS will therefore add to the monitoring system for the quality of medicines already circulating in the Kenyan market. Development and implementation of the PvERS is expected to boost reporting and tracking of ADRs and suspected poor quality medicinal products. This should ultimately improve assessment and communication of quality and safety information on medicines in the market.

Keywords: Pharmacovigilance online reporting system Kenya

9.1.2 Setting up pharmacovigilance systems: Experiences from Ghana

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ABSTRACT

Ghana became the 65th country to join the World Health Organisation Programme for International Drug Monitoring in November 2001 and the first country in West Africa to become a full member of the WHO Programme.

The backbone of the pharmacovigilance system in Ghana is spontaneous reporting. This system is however challenged by under reporting by healthcare professionals. Common reasons for this are unawareness of the reporting system, not having enough time to complete reporting forms and difficulty in diagnosing adverse drug reactions.

Ghana's system started at a Teaching Hospital with few doctors, the system is at the moment decentralized to all the regions and districts in Ghana. The system operates with a number of stakeholders whose roles and responsibilities are clearly defined. The stakeholders are; Patients/ General Public, Primary Reporters, Public Health Programmes, Institutional Contact Persons in Healthcare Facilities, Safety Monitoring Contact Persons in Industry, Regional Pharmacovigilance Officers and the Technical Advisory Committee for Safety which carry out causality assessment of reports received and makes recommendations to the Food and Drugs Authority regarding safety issues.

The Institutional Contact Person concept adopted by the National Centre involves appointing and training healthcare professionals who serve as a link between their institutions and the Pharmacovigilance Centre on matters relating to drug safety. Although this has worked effectively in contributing to the decentralization promoting pharmacovigilance activities it is also adversely affected by high staff turn-over particularly in the public health facilities.

The National Pharmacovigilance Centre collaborates effectively with Public Health Programmes to carry out safety monitoring of products used in these programmes which has resulted in increase number of reports received.

Safety information is communicated to stakeholders through a biannual Newsletter, Dear Doctor Letters, official website and Press Releases.

9.1.3 Improving ADR signal generation through a Patient-focused Pharmacovigilance Program in South Africa

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ABSTRACT

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

The overall objectives of the decentralized pharmacovigilance programme are several-fold. Among others, they involve the establishment of the designed set-up and processes involved in the decentralization at primary healthcare level, a first of its kind in South Africa. Secondly, they involve efforts to generate ADR signals in HIV/AIDS ART in SA; a platform we envisage will take on other indications in the near future.

This report evaluates the successful implementation of our decentralized targeted spontaneous adverse drug reaction reporting in Mpumalanga's ART programme where 314 reports were received in the first 3 months compared to no reports over a similar period previously. A total of 1,756 ART ADR reports were received from the province between July, 2011 and February, 2013. 495 were males (28.9%), 1,057 female (60.19%) and in 204 (11.6%) reports, gender was not reported. 908 were satisfactorily completed, 445 (49%) reported one ADR, 366 (40.3%) two ADRs, and 97 (10.7%) reported three or more. The most commonly reported ADR was peripheral neuropathy and the most prescribed regimen was d4T/3TC/EFV. d4T-containing regimens were the highest suspect drug combinations. Correlations were observed between d4T and the occurrence of peripheral neuropathy and lipodystrophy, Nevirapine (NVP) and efavirenz (EFV) with rash while zidovudine (AZT) was observed to be associated with anaemia. Tuberculosis was found to be the most clinically significant concomitant medical condition with the highest frequency (32.3%).

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

Keywords: Regulatory, Decentralized Pharmacovigilance, Antiretrovirals, Adverse Drug Reactions

9.2 Poster Presentations:

9.2.1 Presence of impurities in pharmaceutical dosage forms as establishing a pharmacovigilance system in Lesotho

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ABSTRACT

Background: Lesotho is a Kingdom landlocked within South Africa. It does not have a pharmacovigilance (PV) system. Attempts have been made at setting this up, but so far none implemented. This study looks into those previous attempts; reasons for failure, and proposes a framework for setting up the PV system.

Objectives:

- To establish reasons for previous failures;
- To design a system that can be used to identify and manage ADRs;
- To provide the framework for establishing a PV system in Lesotho, starting with Maseru District.

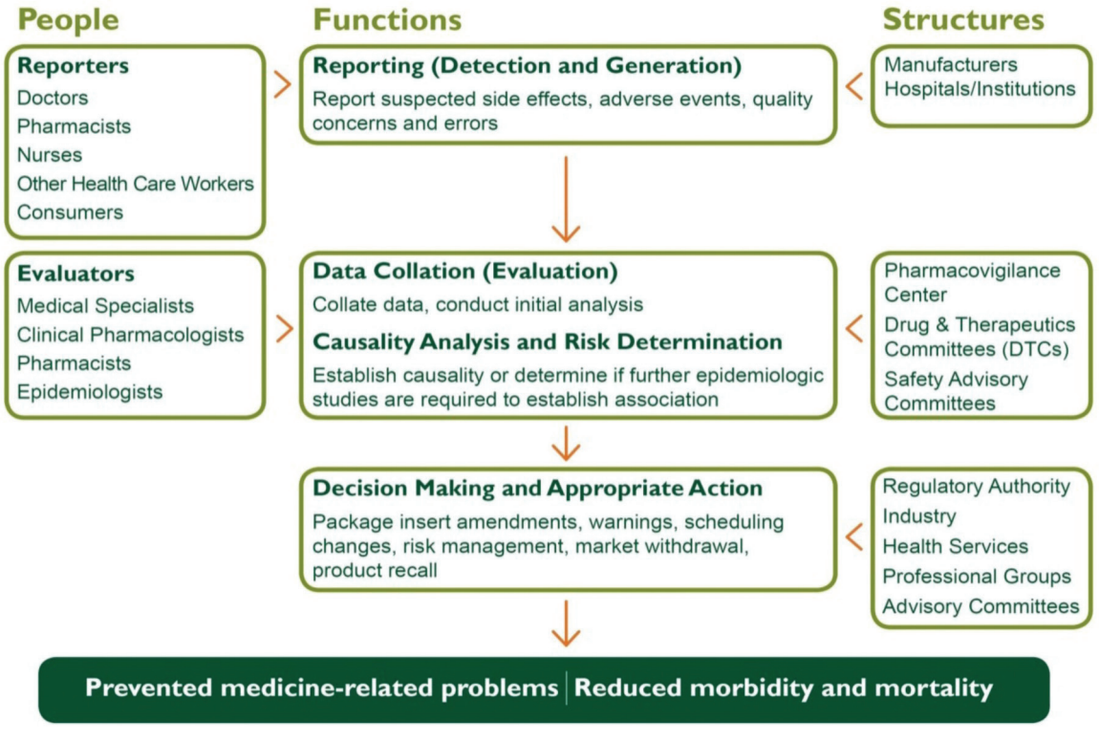
Methodology: Questionnaires were sent to 53 health professionals in Maseru District between April and May 2013: 5 general practitioners, 18 pharmacists, 16 nurses and 8 pharmacy technicians. Interviews were also held with 5 Ministry of Health officials and 1 marketing authorization holder).

Questionnaires were designed to find information about knowledge of ADRs, PV principles and past failures at establishing a PV system.

Results: From the 53 questionnaires, 47 were collected, representing 85% response rate. Results revealed that there are no PV centres in Maseru District. The number of patients who presented with ADRs as a percentage of number of patients seen was 6.5%, with no way of patient follow-up in most health centres. There are no PV laws yet in Lesotho. The Medicines Act in use is the 1973 one which is extremely outdated.

Conclusion: There is no known PV system in Lesotho because of shortage of human resources at health facilities and absence of current medicines regulation. A PV system needs full backing of the law, otherwise it is difficult to establish a PV system in its absence..

Recommendations: We sincerely recommend that the Government of Lesotho sets up a PV system and upgrades its current medicine laws in order to have an enabling environment for pharmacovigilance. Below is a framework that can be used to manage PV system in Maseru Lesotho.



Keywords: Pharmacovigilance, ADRSs, Cost, Regulation, Personnel

9.2.2 The globalisation of the Pharmaceutical Market and Pharmacovigilance Programs: A call for monitoring quality

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ABSTRACT

Pharmacovigilance systems, which were firstly developed almost 50 years ago in Northern countries following the thalidomide disaster, usually focus on the surveillance of the safety profile of pharmaceutical products during the post-marketing phase. As such, product quality is not brought into question.

However, growing evidences show that the globalisation of the pharmaceutical market has created a situation of multiple qualitative standards, and that particularly patients in low- and middle income countries (LMICs) are increasingly exposed to the risk of receiving poor-quality medicines.

Nonetheless, most national pharmacovigilance systems haven't yet been adapted to this new scenario, and only in a few cases the standard notification forms include quality defects among the possible causes to be investigated for explaining side effects or lack of efficacy. Furthermore, an informal search of the medical literature, conducted through PubMed using the keywords « adverse drug reaction OR adverse event OR adverse effect OR drug safety OR drug safety OR pharmacovigilance » AND « substandard OR counterfeit OR fake OR falsified OR drug quality OR medicine quality », shows that the connections between poor-quality medicines and their clinical consequences are poorly investigated, despite several case reports shows the public health impact of the phenomenon.

Based on existing evidences of the size of the problem of poor-quality medicines, we suggest that the scope of pharmacovigilance programs should be broadened, by including "quality defect" in the standard pharmacovigilance notification forms. The first encouraging examples, such as the notification system adopted by the pharmacovigilance program in Rwanda, could be taken as a model for broadening the scope of the National and International Pharmacovigilance Centres, in order to ensure that also quality-related safety and efficacy problems are timely identified and tackled.

Keywords: Drug quality, pharmacovigilance, drug safety, adverse drug reaction

9.2.3 Strengthening Post Marketing Surveillance (PMS) in Africa – The NAFDAC Consumer Safety Club (NCSC) experience

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ABSTRACT

NAFDAC Consumer Safety Club was formed as part of NAFDAC's PMS strategy for eradicating, fake and substandard products from circulation.

It creates a forum for educating secondary school students on the circulation of fake products and promotion of quality products. It also empowers students to disseminate information on NAFDAC regulatory activities to their immediate communities. Membership is drawn from secondary schools in all the 36 states of the federation including Abuja. As at November 2012, over 787 schools nationwide participated in the annual secondary schools competition.

NAFDAC achieves its objective of "catching them young" and training members as vanguards for consumer protection and post marketing surveillance by engaging them through the club's website; annual schools' competition which focus mainly on NAFDAC related activities; dissemination of information on how to identify genuine and fake products; distribution of NAFDAC publications on its regulatory activities to members of the club nationwide through their schools. Additionally, the club strives to instil the culture of quality and positive behavioural change in its members.

Through this platform, we have nurtured a pool of young Nigerians (who are either current members of the club or have passed through the club) who have good understanding of how to avoid fake, substandard regulated products, who know how to read and understand product labels and who are knowledgeable about adverse drug reaction reporting among other benefits.

The club has also been used as a platform for conducting Knowledge, Attitude and Practice Survey on pharmacovigilance/post-marketing surveillance hence availing the Agency information on perception of the public on the impact of its activities and programmes.

NCSC members are considered a part of NAFDAC team and NAFDAC counts on their cooperation in achieving the goal of assuring the quality of all regulated products sold in Nigeria.

Keywords: NCSC, Regulated Products, PMS Strategy, Schools Competition & Educating

9.2.4 Barriers and facilitators to suspected adverse drug reaction reporting among healthcare professionals in Uganda

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ABSTRACT

Background: Pharmacovigilance systems are relatively new in Africa and there is a paucity of published literature on adverse drug reaction (ADR) reporting in these settings. We sought to determine the level of awareness of pharmacovigilance, and the extent and determinants of suspected ADR reporting among healthcare professionals in Uganda.

Methods: We employed a cross-sectional design with both descriptive and analytic components. The survey was conducted in purposively selected, geographically diverse health facilities in Uganda. Healthcare professionals in public, private for-profit and private not-for-profit health facilities in both rural and urban settings were selected.

Results: Of 1,345 respondents evaluated, 14.7% (190/1,296) had reported a suspected ADR in the previous 12 months. Mean age of healthcare professionals was 32.4 (SD = 8.86) years and the majority were nurses (57.9%, 776/1,340).

Significant demographic and professional factors independently associated with a lower likelihood to report ADRs in the final adjusted multivariable model included: older age >30 years (vs. <30 years; Odds Ratio, OR = 0.6, 95% Confidence Interval (CI): 0.39 – 0.91; P < 0.024), private for-profit health facility (vs. public; OR = 0.3, 95% CI: 0.12 – 0.92, P = 0.038), surgery department (vs. Medicine OR = 0.5, 95% CI: 0.32 – 0.64; P = 0.001), and having a lower patient load <30 per day (vs. >30 patients per day; OR = 0.8, 95% CI: 0.60 – 1.00; P = 0.047); while those associated with a higher likelihood to report ADRs included: having ever encountered a fatal ADR (OR = 3.0, 95% CI: 2.29 – 4.04; P < 0.001).

Conclusions: Only one in 7 healthcare professionals had reported an ADR in the previous 12 months supporting data on low rates of ADR reporting throughout sub-Saharan Africa. Priority should be given to more private sector engagement and targeting older healthcare professionals in future interventions to improve ADR reporting.

Keywords: Adverse Drug Reaction Reporting, Pharmacovigilance, Uganda

9.2.5 Strengthening pharmacovigilance systems in the Kingdom of Swaziland

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ABSTRACT

Background: Global health stakeholders increasingly recognize the need to strengthen pharmacovigilance systems as part of health systems strengthening efforts, including assuring effective pharmaceutical services and patient safety to improve treatment outcomes. The Ministry of Health (MoH), Swaziland is implementing interventions to ensure product quality, therapeutic effectiveness, and safety of medicines. A Pharmacovigilance unit has been set up in the Ministry and a regulatory framework to establish a Medicines Regulatory Authority is near finalization. Strengthening of pharmacovigilance activities remains vital for improving patient safety and treatment outcome.

Description: A number of activities were employed in strengthening pharmacovigilance activities. This included;

- Capacity building for the pharmacovigilance unit
- Reviewing, Printing and Dissemination of Adverse Drug Reaction reporting forms and Standard Operation Procedures
- Development of tools (SSASSA & DCAT) for active surveillance of TB and HIV medicines
- Development of medicines safety watch newsletter for risk communication
- Introduction of Active surveillance system at 6 pilot sites

All the interventions are building blocks for a functional pharmacovigilance system.

Lessons learnt: Some adverse drugs have been characterized and quantified to inform patient management and prove information that may inform future changes to guidelines and policies.

An assessment of the different components of a pharmacovigilance system is essential to identify gaps and guide the strengthening of the current practices in the country.

Recommendations: The phased-in and participatory approach used in Swaziland has yielded a country-driven and owned process. This can be replicated in the country in other interventions.

Keywords: Strengthening, Pharmacovigilance, Systems. Adverse Drug Reaction, Active surveillance

9.2.6 Strengthening monitoring of adverse drug reaction in Nigeria

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ABSTRACT:

In an effort to strengthen Adverse Drug Reaction (ADR) reporting, the National Pharmacovigilance Center (NPC) Nigeria introduced a new system of direct consumer alert termed Pharmacovigilance Rapid Alert System for Consumer Reporting (PRASCOR).

This system empowers a consumer who experiences ADR from use of a medicine to send a short text message to a prepaid short code 20543 using designated mobile network services. The network provider converts the message to an email and sends to the NPC where a trained NPC staff contacts the sender to facilitate completion of individual case safety reporting form. The staff inter-phases between consumer and Health Care Provider (HCP) on appropriate next steps. Pharmacovigilance staff at the source location of the alert does a follow up to validate the report following which it is deemed a bona-fide Individual Case Safety Report (ICSR) and assimilated with other ICSRs for further assessment and documentation.

From the commencement of the system in April 2012 to May 2013, the NPC has received 7226 alerts out of which 237 (3.28% of the 7226) were genuine reportable alerts that were further screened to 88 (1.22% of the 7226 alerts) and inputted into the existing database for ADRs. Other alerts that were not convertible are also investigated for other safety and quality issues which have led to regulatory actions such as mop ups and sanctions.

Public enlightenment and education on proper use of PRASCOR system by consumers is done through Information, Education and Communications (IEC) on pharmacovigilance in general and PRASCOR in particular.

The system enables consumers to alert the regulatory authority on incidences of ADRs and other medicine associated problems which hitherto were limited by HCP disinclination.

Keywords: PRASCOR, Pharmacovigilance, ADR, CONSUMER, NPC

9.2.7 Cohort event monitoring of Artemether and Lumefantrine in public facilities in Tanzania

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ABSTRACT

Background: Artemisinin combination therapies such as Artemether/Lumefantrine (ALu) are known to be effective for treatment of malaria and are used as first line treatment of uncomplicated acute falciparum malaria in Tanzania. However, the safety profile of ALu in large populations has not been fully assessed. The main objective was to monitor adverse events associated with the use of ALu in public health facilities in Tanzania.

Methodology: This was a prospective observational study involving a cohort of patients prescribed with Alu during outpatient clinical visits and followed up to establish any event which occurred. Questionnaires (A and B) were used to record events by filling A when Alu was administered and B after 7 days. Study period was from 2009-2012.

Results: A total of 8,040 cohorts were followed up of which 6,147 patients were included in the analysis. Overall, a total 530 adverse events (AEs) were experienced in 383 (6%) patients. Most common AEs at follow up were in alimentary tract system organ (42%) including nausea, vomiting, diarrhoea, abdominal pain, anorexia followed by neurological (25%) and mental health (9%) which was mostly malaise. Causality assessment of the events showed 52.1 % (276/530) were possibly related to ALu. There was a significant difference ($P<0.001$) in occurrence of events among different age categories with increase in AEs with increase in age ($P<0.001$). There was no statistically significant difference in the occurrence of the events between males 246/2924 and females 382/3159 ($p=0.504$).

Conclusions: The events observed were similar to those reported in literature. The safety profile of ALu for treatment of p. falciparum malaria continues to be favourable. Cohort Event Monitoring as a pharmacovigilance tool requires sufficient resources and commitment of all involved stakeholders.

9.3 Poster Presentations

9.3.3 Presence of impurities in pharmaceutical dosage forms as a means of investigative pharmacovigilance

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ABSTRACT

Adverse drug reactions (ADR) reporting, Pharmacovigilance, is vital for a robust health care system that would provide not only effective, efficacious but above all safe medicines to members of the public. However, rarely do pharmacovigilance get sufficient scientific investigations to establish their root causes. Most physiological responses are as a result of exposure to chemical and/or biological moieties from the parent drug compounds and/or their impurities. Reported adversed drug reactions to Artesunate alone and in combination following use had led us to investigate the presence of impurities in ten brands of their solid dosage forms. Also following observed physical changes of a brand of paracetamol tablets on storage, twenty-five different brands of paracetamol were investigated for possible chemical impurities. The methods used for qualitative analysis were Thin Layer Chromatograph (TLC) and Gas Chromatograph-Mass spectroscopy (GC-MS). Extracts of paracetamol and artesunate containing tablets were obtained by Accelerated Gradient Chromatography (AGC). The likely chemical impurities identified were N-phenylglucosamine, N-(ethylphenylether) glucosamine and 4-aminophenol from paracetamol. The sources of the related compounds (impurities) of paracetamol were thought to be as a result of a base-catalysed hydrolysis or due to incomplete reactions and thorough recrystallization to ensure a pure paracetamol end product during its synthesis. For artesunate, succinic acid and dihydroartemisinin were identified as impurities, which may be as a result of hydrolytic degradation. The incomplete conversion of dihydroartemisinin to artesunate is also a possible source of these impurities. The likely physiological effects of the chemical impurities qualitatatively determined are discussed even where limits for some of the impurities could not be obtained from official monographs. It has been suggested that the presence of certain impurities in pharmaceutical preparations such be used as an indicator of the type of side effects that could result from its administration and therefore ought to be investigated following pharmacovigilance reports.

Keywords: Pharmacovigilance, impurities, paracetamol, artesunate, adverse drug reactions

10 INITIATIVES AND COUNTRY EXPERIENCES IN PHARMACOVIGILANCE

10.1 Oral Presentations

10.1.1 Paediatric pharmacovigilance: Use of pharmacovigilance data mining algorithms for signal detection in a paediatric phase IIIB clinical trial safety dataset from 7 African countries

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ABSTRACT:

Background: Pharmacovigilance programmes monitor and help ensure the safe use of medicines which is critical to the success of public health programmes. The commonest method used for discovering previously unknown safety risks during post-marketing is spontaneous notifications. In this study we examine the use of data mining algorithms to identify signals from adverse events reported in a phase IIIb clinical trial that evaluated the efficacy and safety of several artemisinin-based combination treatments (ACTs) in African children.

Methods: We used safety data from a randomized, open-label non-inferiority clinical trial conducted in 12 sites in seven African countries. Each site compared three out of four ACTs, namely amodiaquine-artesunate (ASAQ), dihydroartemisinin-piperaquine (DHAPQ), artemether-lumefantrine (AL) or chlorproguanil/dapsone and artesunate (CD+A). We applied and assessed two pharmacovigilance signal generation methods- proportional reporting ratio and Bayesian Confidence Propagation Neural Network.

Results: A total of 4,116 children 6-59 months old with uncomplicated P. falciparum malaria were treated (1,226 to AL; 1,002 to ASAQ; 413 to CD+A, and 1,475 to DHAPQ), actively followed up until day 28, and passively for the next six months. Patients that received CD+A were excluded from this analysis since the use of this drug was discontinued for safety reasons. A total of 6,238 adverse events were reported, resulting into 346 drug-event combinations. Nine signals were generated both by proportional reporting ratio and Bayesian Confidence Propagation Neural Network. Review using manufacturer package leaflets or a Multi-Drug Symptom/Interaction Checker (DoubleCheckMD) and further by a therapeutic area expert reduced the signals to five.

The ranking of some of the drug-ADRs pairs on the basis of their signal index differed between the two methods.

Conclusions: These two data mining methods worked well in predicting signals. Phase IIIb clinical trial safety data should be analysed in depth to complement spontaneous reporting systems and to validate previously reported ADRs.

Keywords: Paediatric, pharmacovigilance, ACTs, signals, Africa

10.2 Poster Presentations

10.2.1 Medication safety self-assessment at Provincial General Hospital (PGH) Kakamega

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ABSTRACT

Background: An effective health system requires safe and appropriate use of medications. However, It has been shown by different studies that medication errors occur in all health care systems when human and system factors interact to produce an unintended and potentially harmful outcome.

Objective: The objective was to conduct a medication use process assessment using a standardized tool to examine current practices and identify opportunities for improvement

Setting: The assessment was conducted at a Provincial General Hospital, Kakamega between April and June 2013.

Methodology: The Medication Safety Self Assessment (MSSA) is a proactive rapid diagnostic systems approach of examining the entire medication use process using a standardized tool to compare existing practices against established safe medication practices. We adapted to our local context the Institute of Safe Medication Practices (ISMP) tool with self assessment practices that have successfully been applied in the US, Canada, Spain and Australia. The data collection was done by a multidisciplinary team through focused group discussion with selected hospital staff. This involved rating of the current practices against established safe medication practices in the adapted tool. Analysis was done to establish strengths, weakness and opportunities for improvement.

Results: From the assessment it was inferred that potential areas for improvement are in handling of patient information, access to drug information, medication storage practices, labeling of medications, enhancement of the newly implemented computerized system, staff education, patient education and change of culture to learn from medication errors.

Conclusion: The application of the systems approach was an 'eye opener' to understanding the 'medication' journey at the hospital including the interaction between various actors and processes. A number of challenges can be addressed through increased involvement of pharmacy staff within the hospital.

Funded by Management Sciences for Health (MSH)/ Center for Pharmaceutical Management through the Innovation Challenge (INCH) Fund

Keywords: Medication Safety, Self assessment, systems approach

10.2.2 The E-Med mailing list, a community practice on essential medicines, a tool for information, reflection and ethics monitoring

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ABSTRACT

E-med is a discussion list that can make information on the rational use of essential medicine, the supply and management of medication, and national or international drug policies, etc.. by email. This list is intended specifically for pharmacists and healthcare professionals practising in Francophone Africa, and has a growing number of subscribers (1960 subscribers in 2013 to more than 50 countries). It was created in 1998 by Jerome Sclafer, medical doctor of the Journal Prescrire, and Carinne Bruneton, pharmacist and Delegate General of ReMeD (1994-2012), the main moderator of e-med.

E-med is a so-called "moderated" list to prevent the posting of messages that are farfetched or unrelated to the list; this ensures consistency, independence and quality of the pharmaceutical information communicated.

In the early years, an average of 250 messages were posted every year; in 2012, there were more than 1200 posts. All exchanges are archived on the site http://www.essentialdrugs.org/emed/about.php. The debates show to what extent medicines are a central element in national and international health policies, and a warning system in matters of pharmacovigilance. Many posts deal with the rational use of medicines and treatment guidelines.

Other topics are covered: good professional practice, fight against corruption, drug regulations, supply systems, etc.

The E-med list, which is now widely known and accepted, must continue evolving in order to serve its subscribers, while preserving the spirit of transnational solidarity and exchange of knowledge inherited from the Medicines and Development Network (ReMeD).

It is this aspect that will be developed in the context of Communities of Practice supported by the platform Harmonization for Health in Africa (HHA) funded by the French Fund Muskoka through the UNICEF regional office.

Keywords: Communities of practice, rational use, pharmacovigilance

11 PROVIDING AN ENABLING ENVIRONMENT FOR PHARMACEUTICAL PRODUCTION IN AFRICA

11.1 Oral Presentations

11.1.1 Mapping of the pharmaceutical manufacturing capacity in the WHO Eastern Mediterranean (EM) region – A pilot survey including 4 countries in Africa (Morocco, Tunis, Sudan and Somalia)

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ABSTRACT

Introduction: A rapid literature review revealed a wide gap in knowledge about the pharmaceutical industry's manufacturing capacity in the WHO Eastern Mediterranean (EM) Region[1]. The main objective of this study was to map the current situation in the 23 Member States of the WHO EM region

Methods: A data collection tool (questionnaire) was developed with indicators on 1) Manufacturing capacity of pharmaceutical industry; 2) Pharmaceutical Market size; and 3) Regulatory barriers for local pharmaceutical manufacturing. The questionnaire tool was sent to NMRA's from 23 Member States of the WHO EM region.

Results and Discussion: Response rate was 52% with 12 out of the 23 countries responding to the questionnaire tool.[2] The total number of local pharmaceutical manufacturers registered in the 12 responding countries was 714 by the end of 2012. Manufacturers ranged from public and private sectors, including joint ventures, and multinational manufacturers. The highest number of contract manufacturers was in Morocco. In 9 countries there were more than 3 companies in process of licensing and planned to become operational in the period of 2012-2015. Out of the 714 manufacturers, more than 130 manufacturers produce at least one molecule for treatment of non-communicable diseases (NCD). 11 manufacturers in 4 countries produce anticancer medicines[3]. In terms of quality standards and export potential to stringently regulated markets (SRA), Less than 20 manufacturers export to ICH markets[4]. Production of active pharmaceutical ingredients (API) takes place only in 3 countries. The average time for issuance of manufacturing licenses was 5 months. There are efforts ongoing on harmonizing regulatory requirements, particularly among the member countries of the Gulf Cooperation Council.

Conclusion: Further research may be instigated from this work, focusing on deconstructing the different assumptions on local production and its relationship with access to medicines. Relationship between the different variables involved both as challenges and facilitators to local production in low and middle income countries should be studied.

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1 Afghanistan, Bahrain, Djibouti, Egypt, Iran, Iraq, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Pakistan, Palestine, Qatar, Saudi Arabia, South Sudan Somalia, Sudan, Syria, Tunisia, UAE, Yemen

2 Afghanistan, Iran, Jordan, Kuwait, Morocco, Palestine, Oman, Pakistan, Qatar, Somalia, Sudan, Tunisia

3 Iran, Jordan, Pakistan, Oman

4 International conference on harmonization

11.1.2 The pharmaceutical industry as a key stakeholder in the harmonisation process

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ABSTRACT

The African Regulatory environment is very diverse ranging from countries that have strong Regulatory systems, to countries that do not have any systems in place. A similar scenario is also reflected in the Regulatory human capacity, with certain countries having fully fledged and resourced authorities to those that do not have any Regulatory human capacity. This poses challenges when discussing harmonisation across economic zones where this diversity is present and poses challenges to both the Agencies and the Pharmaceutical industry , it trying to determine what pathway to follow for the harmonisation, taking into account the different country strengths an weakness.

The Pharmaceutical Industry as exist in the African region is composed of the Local/Regional Manufacturers and Multinational manufacturers that may also be performing manufacturing activities in Africa.

The later group of industry has been a key stakeholder in the ICH process, and involved in harmonisation initiatives within the European countries, Latin American countries and Most recently in the ASEAN and Gulf states harmonisation initiatives. In particular the ASEAN countries harmonisation is being implemented in an environment that provides similarities with the African situation and learnings gathered from the ASEAN process can be shared and implemented, in the African harmonisation initiative to ensure a more effective process avoiding pitfalls encountered in the other regions.

The African Medicines harmonisation needs to ensure that there is full industry input on the following areas:

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

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

This presentation will aim to highlight some of the key challenges and opportunities from some of harmonisation initiatives, focusing on the areas highlighted above focusing on specific suggestions to ensure a successful implementation of harmonisation, and also highlight industries expectation on the African Medicines Harmonisation Initiative.

11.1.3 What are the common elements of a good quality regulatory review process?

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ABSTRACT

Background: Regulatory agencies in most countries are continuously evolving their process and practices to ensure use of the best tools and techniques. As agencies in developing countries evolve their process, examples of good review practice (GRevP) that underpin a quality review can be identified and adopted from agencies with more experience.

Objective: This CIRS Study sought to identify the key elements of all the processes and procedures undertaken to review a new medicines that are critical and that can be identified as enablers of the review.

Methods: In this survey, global pharmaceutical companies and regulatory agencies were asked to identify attributes that enable regulatory review in terms of timeliness, predictability, transparency, and quality and to rate regulatory agencies for these attributes. Results from the 12 companies and 11 agencies are presented.

Results: The characteristics that agencies and companies felt enable quality reviews differed. The top two characteristics that all 12 companies felt an agency should demonstrate were the ability to have dialogue with assessor for clarification of issues raised in a deficiency letter and the opportunity for pre-submission dialogue. All 11 agencies agreed that decision frameworks and internal training, for example, by experienced internal staff were the most important characteristics on which an agency should focus. However, there was one characteristic indicated by both agencies and companies as an enabler of regulatory review: a detailed description of each stage of the approval process including target times. Having this process in place would allow better transparency and predictability of the review, allowing companies to understand the process better and enabling agencies to adhere to target timelines by managing their workload more efficiently.

Next steps: CIRS plans to use these results to drive discussions with regulatory agencies to identify areas for process development to help enable a streamlined quality review.

Keywords: Regulatory review; transparency; timeliness; quality; predictability

11.2 Poster Presentations

11.2.1 Harmonization of Good Manufacturing Practice audit in Africa, a key to creating an enabling environment for quality medicine

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ABSTRACT

By the year 2020 the population of Africa is expected to reach 1.3 billion and a combined GDP of 2.9 trillion USD. The health care expenditure could increase to 200 billion. By 2016, pharmaceutical spending could grow by 11% and reach 30 billion. Africa therefore shows sign of becoming a favourable market for the pharmaceutical business. However, the prospect for increased pharmaceutical manufacturing in African by African own companies still remains a major challenge. Increasing stringent regulation, lack of specialized skills in the pharmaceutical sciences and related disciplines, and strong downward price pressure in Africa, has made pharmaceutical manufacturing in Africa very difficult. African Pharmaceutical manufacturers consider Good Manufacturing Practice (GMP) compliance in accordance with international standards as the most challenging technical requirement. This mainly owns to the financial burden involve in meeting GMP requirement and maintenance. This financial burden could multiply when the manufacturer is registering more products in several countries which may require several GMP inspections. To improve the quality of pharmaceutical manufacturing in Africa and at the same time enable African pharmaceutical manufacturers meet GMP compliance at a reduced cost, we proposed the harmonization of GMP Audit across Africa as part of the African Union's Pharmaceutical Manufacturing Plan for Africa (PMPA). When GMP Audits harmonization is carefully addressed by proposed African Medicine Regulatory Harmonization (AMRH), audit findings could be shared among member states and the accessibility of audit findings from other Global pharmaceutical watch dogs could be made possible. This will lead to quality Medicine manufacturing and cut down in manufacturers GMP-inspection financial burden. More importantly, the lack of GMP specialists in most African regulatory authorities will be addressed. The Audit finding could be useful in helping both manufacturers and regulators identify gap in the quality manufacturing process.

Keywords: Good Manufacturing Practice, African Medicine Regulatory Harmonization, quality medicine, Pharmaceuticals

11.2.2 Providing an enabling environment for pharmaceutical production in Africa

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ABSTRACT

Local Pharmaceuticals production can be successfully done in the continent. However there is need for the African countries to re-assess the realities, possibilities and the feasibility of the programs so that it moves from being a political slogan to a reality after good ground work.

The **objective** of the study is to provide an enabling environment for pharmaceutical production in Africa which is the hotly contested issue in many African countries. It runs to the heart of key concerns such as Quality, availability, and price of medicines as well as the broader issues of the economic development and Trade.

The research is fact-based summary of the current situation and aims to illustrate the situation and sets out some of the arguments / **guidelines** of the local manufacturer.

Main findings of the research include the Identification of various Challenges and barriers faced by Africa-based manufacturers and methodology, is to address the series of key issues such as an economic analysis however needs to be done to ensure appropriate planning. A detail study has been carried out and number of **recommendations** were made for the African Union Conference of Ministers of Health to mandate a technical body well versed with manufacturing to do a "skill search" and appoint all the relevant expertise (taking care of all the regional groupings i.e. geographical, linguistic) to study the detailed implications and come out with a suggested plan to advise the ministers in this area. African governments were urged to take more action to collaborate regionally, establish and properly resource regional regulatory & enforcement systems, reduce or remove tariffs to promote the flow of products through their regions, and ensure transparency in drug procurement processes. Legal frameworks needed to be assessed, gaps filled, and overlaps removed. A proper industrial policy to promote pharmaceutical manufacture was needed. Technical support from WHO needed to be improved and QA standards better justified, in order to promote Africa-based production.

Keywords: Economic analysis, skill search, Regional regulatory & enforcement systems, Industrial Policy, QA standards.

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