BOOK OF ABSTRACTS

2nd Biennial Scientific Conference on
Medicines Regulation in Africa

“Promoting Research and Development in
advancing local production of medical products for Africa”
# Book of Abstracts

## Parallel Session 1: Innovative Post-Marketing Surveillance Interventions in Resources Limited Settings

1. Detecting product quality problems and protecting public health using pharmacovigilance data: the Ethiopian experience
2. Regulatory assessment of pandemic (A)H1N1 influenza vaccine and narcolepsy safety issue: lessons to learn for resources limited countries
3. Medication error disclosure and attitudes to reporting by healthcare professionals in a sub-Saharan African setting: a survey in Uganda
4. Assessment of Substandard/Counterfeit medicines in the Ethiopian Pharmaceutical Market
5. Surveillance of Medical Devices and In-Vitro Diagnostics (IVDs) In Resource Limited Settings: Tanzania Experience

## Plenary Session I and Parallel Session 2: Medical products regulatory systems in Africa in the advent of regional integration and regulatory harmonization

1. Experience and lessons learnt from the ZAZIBONA Collaborative Medicines Registration Model
2. Registration of Pharmaceutical Products Approved by Stringent Regulatory Authorities*: 1st pilot with Janssen INTELENCE 25 mg HIV pediatric formulation organized by WHO/PQT
3. Setting up a process of regionalization of the function "Registration" of medicinal products in Central Africa
4. WHO Prequalification and market access of an innovator product. An industry experience.
5. The role of regulatory interventions in improving access to quality pharmaceutical services: lessons learned from accredited drug seller initiatives in Tanzania, Uganda, and Liberia

## Plenary Session II: Advancing local production of medical products for Africa – Where are we?

1. Status of pharmaceutical Manufacturing in Africa, PMPA + 10: Where are we?
2. Barriers to pharmaceutical production in Africa
3. The Implementation of 350-2500 nm Reflectance Spectroscopy and High Performance Thin Layer Chromatography to Rapidly Assess Manufacturing Consistency and Quality of Co-trimoxazole Tablets in Tanzania
4. GMP Roadmap for implementation of the AU Pharmaceutical Manufacturing Plan for Africa (PMPA): A Regional Approach
Parallel Session 3: ICT for Advancing regulation of medical products in Africa

4.1. Monitoring Quality of Anti-malarial Medicines in Kenya by use of Minilab Technology, a five year analysis

4.2. The impact of Management Information System in strengthening Regulatory Systems: Experience From Tanzania Food and Drugs Authority

4.3. Deployment of ICT as a Tool in Advancing Medicinal Products Regulation in Nigeria: Development of NAPAMS Version 2.0

4.4. Drugs, Data & Technology- Developing electronic systems for drug registration in Bangladesh, Ethiopia and Mozambique

4.5. Advancing medicine registration through process optimization and automation

4.6. ICT for Advancing Regulation of Medical Products in Africa

Plenary Session: The Future of Medical products regulation in Africa: Post 2015 development Agenda


5.2. The Institute for Regulatory Science; A model for building Regulatory Capacity in Africa

5.3. The Institute for Regulatory Science; A model for building Regulatory Capacity in Africa

POSTER PRESENTATIONS

6.1. Regulatory Resources for Africa

6.2. Regulation Of Medical Devices In Cote D’ivoire: Where Are We?

6.3. Law N°2015-536 Of 20 July 2015 Or The Official Recognition Of Medicine And Traditional Pharmacopoeia In Cote D’ivoire

6.4. Prospects and challenges in pharmaceutical industry development in Africa for universal health coverage- A policy perspective

6.5. STRENGTHENING THE NATIONAL REGULATORY SYSTEM TO PROMOTE LOCAL PRODUCTION OF ANTIMALARIAL MEDICINES IN THE DEMOCRATIQUE REPUBLIQUE OF CONGO (DRC)
Parallel Session 1: Innovative Post-Marketing Surveillance ventilations in Resources Limited Settings

1.1. Post Marketing Surveillance of Antimalarial Medicines in Tanzania

S.A. Mziray\textsuperscript{1}, G. Mng’ong’o – Shimwela\textsuperscript{1}, A. S. Kijo\textsuperscript{1}, A. M. Fimbo\textsuperscript{1}, H. B. Sillo\textsuperscript{1}

\textsuperscript{1}Tanzania Food and Drugs Authority

Background:
Presence of substandard and counterfeit antimalarial medicines on the market is a major public health concern in countries with high prevalence of malaria. Systematic assessment and monitoring of medicines circulating on the markets is critical in ensuring quality of medical products and the fight against the burden of malaria disease in Africa. We are reporting the results of post marketing surveillance of selected antimalarial medicines which were sampled and tested for quality assurance in Tanzania.

Objectives:
This surveillance was conducted by Tanzania Food and Drugs Authority (National Medicines Regulatory Authority) with the aim of monitoring the quality of registered antimalarial medicines circulating on the Tanzanian market.

Methodology:
Samples of selected antimalarial medicines were collected between 2012–2014 from hospitals, dispensaries, health centers and pharmaceutical outlets and subjected to product information review, quality screening using Global Pharma Health Fund (GPHF) Mini-Lab kit method and confirmatory testing by full monograph analysis at TFDA-WHO prequalified laboratory. Sampling was done using an approved sampling plan.

Results:
A total of 358 samples of oral solid formulations were sampled and tested. Out of these, 223 (62.29\%) failed on labelling and package insert requirements and 32 (8.94\%) failed on identity test. Out of 112 samples subjected to laboratory confirmatory testing, 4 (3.37\%) samples failed. One sampled (i.e. Quinine Sulphate 300mg) was confirmed to be counterfeit.

Conclusion:
The results highlights the importance of establishing a robust post marketing surveillance programme as an additional measure of assuring the quality of medicines by Regulators after issuing marketing authorization and a way to detect counterfeit and substandard medicines circulating on the African markets.

Email:
Post marketing surveillance (PMS), antimalarial medicines, substandard and counterfeit medicines
1.2. Detecting product quality problems and protecting public health using pharmacovigilance data: the Ethiopian experience

H. Tadeg¹, E. Woldemariam¹, H. Gerba², E. Ejigu¹ M. Thumm³

¹Management Sciences for Health, SIAPS program
²Food, Medicine and Health Care Administration and Control Authority
³Management Sciences for Health, USAID/SIAPS program

Background:
The limitations of pre-marketing drug safety data are well-recognized; hence, there is a heavy reliance on pharmacovigilance systems, particularly spontaneous reporting of medicine safety and quality issues. However, underreporting of Adverse Drug Events (ADEs) by healthcare professionals remains a problem in many countries. This is compounded by a lack of regular feedback by regulatory authorities. In Ethiopia, a comprehensive ADE reporting system was introduced combined with in-service training and regular feedback as part of an effort to increase ADE reporting and tracing medicines with quality problems.

Methodology:
The ADE reporting guideline and form was revised to incorporate medication error and product defects, in addition to adverse drug reactions. In-service training was provided at 114 health facilities between January 2012 and May 2015 to increase ADE awareness and reporting among health care providers, followed by dissemination of reporting tools. The pharmacovigilance center provides regular feedback on all ADE reports. Reports on suspected product quality problems are reviewed by Pharmacovigilance forum, which include experts from registration, inspection and quality control directorates. Based on recommendations of this forum, regulatory decisions are taken by the authority.

Results:
The yearly number of ADE reports has increased from 79 in 2012 to 411 in 2015. Of the 840 total reports received in four years, 138 were related to suspected product quality issues. Among the products reported as having quality problems, 52.9% had visual/physical changes; 24.6% had negative effects; and 17.4% had packaging problem. Further follow-up and investigation on these products resulted in recall of 14 products, temporary closure of one manufacturing facility, suspension of a market authorization license and permanent cessation of production for one product.

Conclusion:
In contexts where regular post marketing quality surveillance is not currently feasible, incorporating reports on product quality problems into regular ADE reporting systems is an effective solution to detect the circulation of substandard and counterfeit medicines.

Keywords: Pharmacovigilance, Product quality problem, regulatory decision, recall, market authorization
1.3. Regulatory assessment of pandemic (A)H1N1 influenza vaccine and narcolepsy safety issue: lessons to learn for resources limited countries

J. Doua¹

¹Consortium for African Regulatory Expertise Development (CARED)

Background:
Rare but serious adverse events (SAE) may pass clinical trial phases unobserved. To assure that SAEs are captured in post-approval, pharma companies and regulators are required to put pharmacovigilance systems in place. Unfortunately, pharmacovigilance infrastructures are still very weak in resources limited countries. To help raising safety awareness for regulators and society, we reviewed the narcolepsy and pandemic (A)H1N1 influenza vaccine issue by highlighting the strengths and weaknesses of pharmacovigilance.

Methodology:
In August 2010, following widespread vaccination against the (A)H1N1 pandemic, serious cases of narcolepsy were reported in Nordic European countries. After review, the European Medicine Agency required more data to clarify the emerging safety concern. A nation-wide observational study conducted by the Finnish regulatory authority showed a 17-fold increased risk of narcolepsy in children and adolescents few months after vaccination than before. All identified narcolepsy cases had specific HLA-genotypes. The Finnish and Swedish authorities withdrew the vaccine although EMA required additional data before any regulatory action due to potential bias in the association. A larger study conducted by eCDC found strong association between narcolepsy and the vaccines, OR=14.2 (95%CI 2.5–infinity) in Nordic countries reversely to non-Nordic countries OR=2.3 (95%CI 0.9–6.3). As results, EMA excluded persons under 20 years for the use of vaccine.

Conclusion:
In the light of the narcolepsy issue, routine SAE reporting is relevant in generating safety signals but not for robust vaccine pharmacovigilance risk assessment for which additional pharmacovigilance tools such as pharmaco-epidemiology studies are more appropriate. To reliably monitor medicines safety in Africa the hospital records and epidemiological disease surveillance need improvements to gather background incidence for serious conditions. Additionally, pharmaco-epidemiology research abilities should be promoted alongside the current African harmonization and regulatory systems strengthening initiative. Neglecting these measures would impair the regulatory efficiency and thereby adversely affect access to quality-assured medicines for patients.

Keywords: Influenza, vaccine, pharmacovigilance, narcolepsy
1.4. Medication error disclosure and attitudes to reporting by healthcare professionals in a sub-Saharan African setting: a survey in Uganda

H. Ndagije

1Drug Information Department. National Drug Authority

Background:
Medication errors (MEs) are largely underreported, which undermines quality improvement and medication risk management in healthcare.

Objectives
To assess attitudes of Ugandan healthcare professionals (HCPs) towards ME reporting, and identify characteristics of HCPs who endorsed integration of ME and adverse drug reaction (ADR) reporting, valued patient involvement in ME reporting, disclosed having ever made potentially harmful MEs, or observed possibly harmful MEs committed by other HCPs.

Methodology:
Healthcare professionals self-completed a questionnaire on their attitudes towards the occurrence and reporting of MEs in purposively selected Ugandan health facilities (public/private) including the national referral and six regional referral hospitals representative of all regions.

Results:
Response rate was 67 % (1345/2000). Most HCPs (91 %; 1174/1289) approved a national ME reporting system for Uganda and 58 % (734/1261) endorsed integration of ME and ADR reporting. Two-thirds (65 %; 819/1267) of HCPs valued patient involvement in ME reporting, one-fifth (18 %; 235/1310) disclosed that they had ever made potentially harmful MEs, while two-fifths (41 %; 542/1323) had ever identified possibly harmful MEs committed by other HCPs. Endorsing patient involvement in ME reporting was more likely by HCPs who valued root-cause analysis and reporting of both actual and potential MEs, or who conceded inadequate communication and lack of time. Self-disclosure of having ever committed potentially harmful MEs was more likely with the need for confidentiality, working in stressful conditions, and willingness to report ADRs. Identifying possibly harmful MEs committed by other HCPs was more likely by non-nurses and those who reported blame culture, stressful conditions, ever encountered a fatal ADR, or attachment to hospital-level health facility.

Conclusion:
A non-punitive healthcare environment and patient involvement may promote ME disclosure and reporting in Uganda and possibly other African countries.

Keywords: Medication errors, reporting, pharmacovigilance, healthcare professionals
1.5. Assessment of Substandard/Counterfeit medicines in the Ethiopian Pharmaceutical Market

D. Dilbeto

1Ethiopian Food Medicines and Health care Administration and control Authority and UNFPA Ethiopia office

Background:
Medicines quality is increasingly becoming a concern in many parts of the world due to the recent increase in the magnitude of medicines counterfeiting. The threat of counterfeiting appears to be invisible due to its nature as well as the neglect it has suffered over the years from the nature of stakeholders involved in the pharmaceutical supply chain. This problem is particularly important in many developing countries due to inefficient regulatory control mechanisms and weak systems as well as an increased burden of both communicable and chronic diseases among other numerous public health issues.

Objectives:
The present study was undertaken to provide evidence on the existence and patterns of substandard/counterfeit medicines in the Ethiopian market and to propose strategies to combat medicines counterfeiting in Ethiopia.

Methodology:
This was a cross-sectional descriptive study carried out in selected sites located in eight regions of Ethiopia. Data were collected between 10 July and 10 August 2013. Survey questionnaires were used to gather pertinent information on regulatory capacity and representative medicines selected based on defined criteria during sample collection. The samples were then subjected to appropriate qualitative and quantitative tests to determine the identity and amount of active ingredient present in the product. Drug quality was measured by level of active ingredients as percentage of stated content and by compliance with pharmacopeia standards. Association of failure with type of products and source of samples was established using Chi square test.

Results:
Although all regulatory frameworks were in place, there were some setbacks identified in the regulatory system. Presence of unregistered products, few manufacturing plants without fulfilling GMP requirements, lack of pertinent data on proportion of imported drugs by different sectors, and importation of drugs through unauthorized sources were few of them. Three hundred and nineteen samples formulated as generic (38) and brand (281) products, representing nineteen different drugs were collected and subjected to evaluation and analysis. About 90.6% and 9.4% of the products were collected from formal and informal sources. Among the total samples collected during the survey, registration status of 2.5% of the samples could not be known, bringing the number of samples whose status was known to 97.5%. Out of the 311 samples whose status was known, 50 (16.1%) of them were not registered by the national regulatory authority. Twenty five of the samples were either below or above the limit specified by the United States and British pharmacopeia, giving rise to a failure rate of 7.8%. Out of the 25 samples that fell short of complying pharmacopeias specifications, 18 (72%) were collected from formal and 7 (28%) from informal sources. Failure to meet pharmacopeias specifications did not seem to be affected by the type of product (Generic vs. brand), source (formal vs. informal) and by the site of collection.

Conclusion:
The data generated from this study indicate the presence of substandard products among the investigated products in the Ethiopian market. Nevertheless, the prevalence of substandard drugs appeared to be of lower magnitude compared to other developing countries. Capacity of the regulatory system appeared to be not that strong and due attention should be paid so that it could restore public confidence.

Keywords: Regulation, Regulatory authority, counterfeit/substandard medicines, Ethiopia
1.6. Surveillance of Medical Devices and In-Vitro Diagnostics (IVDs) In Resource Limited Settings: Tanzania Experience

A. S. Kijo¹, G.M. Shimwela¹, S. A. Mziray¹, A.M. Fimbo¹, H. B. Sillo¹

¹Tanzania Food and Drugs Authority (TFDA)

Background:
Post-marketing surveillance (PMS) of medical devices and diagnostics was one of the pillars in the WHO Project titled ‘Strengthening Regulation of Diagnostics in Tanzania” which was conducted in Tanzania between 2012 -2014. The aim of the Project was to increase access to affordable diagnostic technologies of assured quality that are appropriate for use in resource limited settings. At the same time, TFDA was implementing its PMS programme on medical devices and henceforth both activities were merged to effectively utilize both human and financial resources. We report the results of PMS programme for medical devices and in-vitro diagnostics (IVDs) conducted in Tanzania between 2012 and 2014.

Objectives:
The main objective of the surveillance was to assess the quality of selected medical devices and IVDs circulating on the Tanzanian market.

Methodology:
Samples were collected from different sampling points according to an approved sampling plan. Other aspects were, training of sample collectors and use of sampling tools including temperature monitoring devices for IVDs. Samples were collected from 10 regions from healthcare facilities. Collected samples were subjected to product information review and laboratory testing. Medical devices were tested for sterility while diagnostics by a gold standard method.

Results:
A total of 2,483 samples were collected as follows; 20 malaria RDTs, 80 HIV RDTs and 2,383 medical devices. Laboratory results indicated compliance rate of 100% for all diagnostics sampled and tested and for medical devices only 2 (0.2%) samples of syringes and IV Cannulas failed on sterility testing.

Conclusion:
Results of the surveillance indicated a relatively high compliance rate for both diagnostics and medical devices. The surveillance also revealed issues that if addressed will improve regulation of medical devices and diagnostics. Regardless of the limited resources, surveillance of medical devices and IVDs is possible with proper planning, coordination and cooperation with key stakeholders.

Keywords: Post marketing surveillance (PMS), medical devices and In-vitro diagnostics (IVDs)
2nd Biennial Scientific Conference on Medicines Regulations in Africa

Plenary Session I and Parallel Session 2: Medical products regulatory systems in Africa in the advent of regional integration and regulatory harmonization

2,1. Experience and lessons learnt from the ZAZIBONA Collaborative Medicines Registration Model

L. Gwaza¹, G. N. Mahlangu¹,

¹Medicines Control Authority of Zimbabwe

To this end, medicines regulatory authorities in Botswana, Namibia, Zambia and Zimbabwe (ZAZIBONA) decided to cooperate and explore a model suitable for work sharing in medicines assessment and inspections in the regional context. The World Health Organization Prequalification Team-Medicines (WHO-PQTM) and other partners provide support in this endeavour. The initiative is practically oriented and focused on achieving results in terms of accelerated approvals for applications for registration while enhancing the quality of approved products. The specific objectives are to reduce regulatory workload, accelerate registrations of selected products, develop mutual confidence in regulatory collaboration, demonstrate a mechanism of technical cooperation among regulatory authorities and provide a platform for trainings, harmonisation of requirements and practices.

ZAZIBONA adopted a work sharing process for assessment of applications for registration, which incorporates SADC and WHO standards. Until October 2015, the involved regulatory authorities had successfully held eight sessions for assessors, and inspected two facilities through joint good manufacturing practice (GMP) inspections. As of October 2015, 92 applications for registration have been considered and 37 of these are waiting responses from manufacturers while the rest have been concluded and recommended for finalisation at national level.

This paper will explore the ZAZIBONA work-sharing model that has been utilised over the last 24 months, identify the critical success factors, challenges, the lessons learnt, sustainability issues and possible options for scaling up to other countries.

Keywords: Work sharing, collaboration, medicines registration, harmonisation
2.2. Registration of Pharmaceutical Products Approved by Stringent Regulatory Authorities”: 1st pilot with Janssen INTELENCE 25 mg HIV pediatric formulation organized by WHO/PQT

M. Caturla\textsuperscript{1}, M. Smid M\textsuperscript{2},

1. Janssen pharmaceutical companies of Johnson & Johnson
2World Health Organization
1International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
2Janssen HIV Access Team
2INTELENCE Compound Development Team, Janssen Infectious Diseases

Background
Currently, it could take up to five years longer to make medicines available for patients in Africa compared to the other parts of the world. To improve access to needed medicines WHO together with IFPMA has put in place a pilot procedure by which regulatory approval in African countries is targeted within 4 months of application. This procedure is applicable to finished pharmaceutical products (FPP) already approved by a Stringent Regulatory Authority (SRA). For the purposes of this pilot the European Medicines Agency (EMA) is the SRA of reference.

Methodology
Full EMA assessment and inspection reports are shared with the National Medicines Regulatory Authorities (NMRAs). NMRAs benefit from EMA regulatory expertise and perform a fast review based on an adapted dossier and strive to provide approval within 4 months. WHO’s role is to facilitate the process between all parties. During the process a F2F meeting takes place between WHO and NMRAs to review the dossier. Participation of EMA experts is possible when necessary. The company receives questions consolidated among participating NMRAs and it is expected to provide answers timely.

Janssen INTELENCE® 25 mg tablets (HIV pediatric formulation) was selected to participate in the first pilot of the “Collaborative Procedure in Assessment and Accelerated National Registration of Pharmaceutical Products Approved by Stringent Regulatory Authorities”.

Conclusion
The pilot has been running in eleven African countries. The first approval was granted within 86 days only. In other countries approvals are expected within 4-7 months. Pilot results are very encouraging and provide a learning for the next pilot phases. Thanks to this collaborative approach and effective information sharing between all involved parties, this procedure may therefore become a useful tool to expedite access to SRA approved medicines for patients in need.

Keywords: SRA-approved drugs, WHO collaborative procedure, accelerated registration, pilot, information sharing
2.3. Setting up a process of regionalization of the function “Registration” of medicinal products in Central Africa

A. De La Volpiliere¹, B.A. Djitafo Fah¹, E. Pola Yissibi¹,

¹Organization for the Coordination of the Fight Against Endemic Disease in Central Africa (OCEAC)

Background:
Establishing the principle of free movement of goods, the Treaty of the Economic and Monetary Community of Central Africa (CEMAC) laid the foundations for the necessary harmonization of national drug policies (HPPN) in order to provide to the population, some quality, safe, effective and affordable medicinal products. To do so, the Registration of Pharmaceuticals is a keystone to fulfill requirements for effective scientific evaluation and rapid access into market.

Methodology:
After a training phase with national actors in July 2015, the objective of the following intervention is to conduct jointly a scientific assessment on a common dossier following technical guideline adopted at regional level in 2013.

The proposed method consists to request marketing authorization applicants for a simultaneous deposition of a medicines marketing authorization (MA) dossier in the 6 countries of the sub region of Central Africa according to technical document of reference. This dossier will be examined together with the head of national medicines regulatory authorities (NMRAs) and will rely on the mobilization of external experts.

Results:
The results should enable:

a. To develop a single assessment report (pooling of capabilities)
b. Harmonize technical documents of MA and reduce delays for obtaining it (access to innovation)
c. To initiate the publication of a list of authorized medicines (transparency, good governance)

Lessons learned:
It is too early to draw lessons from this project is a response to the full implementation of a common technical document by mobilizing regional actors including local scientific expertise. The methodological approach remains transferable to other regions. The results will be subject to a subsequent communication.

Next steps
Two joint reviews per year are scheduled from 2016 to create a habit of working together. This activity is first step of a regional commission of MA which will be able to be incorporated into a future regional Medicines Agency according to guidelines of the African Union.

Keywords: Registration, Harmonization, Joint review, Marketing Authorization, Regional Agency
2.4. WHO Prequalification and market access of an innovator product. An industry experience.

F. Benoist

1Global Brand Regulatory Director. IFPMA African Regulatory Network Novartis Pharma

Background and Methodology:
In collaboration with national medicines regulatory authorities (NMRAs), the WHO Prequalification of Medicines Programme (WHO/PQP) offers an opportunity for countries to make quality priority medicines available for their patients. In addition to its evaluation and inspection activities, WHO/PQP aims to build national capacity for sustainable manufacturing and monitoring of quality medicines. Thus, the collaborative procedure, a procedure for collaboration between the WHO/PQP and interested NMRAs, serves to facilitate and accelerate national registration of products which WHO/PQP has already assessed and prequalified. In the advent of Regional integration and regulatory harmonization, having a product WHO qualified is foreseen as an insurance for faster approval of quality and harmonized products on markets.

Results:
In the case study of Coartem® 80/480mg (an additional dosing strength), we share our experience and challenges met during and after the procedure to obtain an innovator product review in parallel with a Stringent Regulatory Authority (SRA), NMRA, WHO/PQP and ZanZiBoNa collaborative procedure in Southern Africa Development Community. As a result, WHO prequalification for the product occurred months after approvals by the SRA and several African Regulatory Authorities. As a consequence, the WHO Prequalification dossier format was not fully harmonized with the dossier format approved by SRAs leading to complexity in the life cycle management. It has been a good learning experience in the advent of further collaboration with WHO/PQP to strengthen regulatory systems in Africa in view of the expansion of access to quality medicines.

Keywords: WHO prequalification, stringent, harmonisation, timelines
2.5. The role of regulatory interventions in improving access to quality pharmaceutical services: lessons learned from accredited drug seller initiatives in Tanzania, Uganda, and Liberia

E. Mkumbo1, S. Kimatta1, K. Johnson1, E. Shekalaghe2, M. Embrey1, E. Rutta1, R. Lieber1,

1Management Sciences for Health
2Pharmacy Council of Tanzania

Background.
Most people in low-income countries access medicines from retail drug shops—particularly in rural areas lacking pharmacies; however, the quality of products and services is questionable.

Objective of the Intervention.
Increasing access to quality medicines and pharmaceutical services in retail drug shops through a public-private partnership based on accreditation, standards, and regulation.

Methodology.
Using a holistic approach changes the behavior and expectations of those who use, own, regulate, or work in retail drug shops. Regulatory activities include developing accreditation regulations and standards of practice, establishing accreditation process, identifying medicines that accredited shops can legally sell, and establishing inspection protocols. Shop owners and sellers receive management and dispensing training, business incentives, and supervision combined with efforts to increase customer demand for quality products and services.

Results.
Since the launch of Tanzania’s accreditation program in 2003, service improvements have been sustained: Before accreditation, 6% of malaria encounters in drug shops were treated according to treatment guidelines; after the pilot (2004), 24% were treated correctly; in 2010, the rate was 63%—a 950% improvement. In Uganda, the percentage of shops offering injections (which is illegal), fell from 74% to 0 after accreditation in the pilot district. In Liberia, the percentage of expired, damaged, or counterfeit products on the shelves of drug shops went from 28% at baseline to 8% at endline.

Conclusion and Recommendations.
To sustain drug seller initiatives, local stakeholders need to be involved from the beginning to develop and carry out the mix of public- and private-sector responsibilities. For the regulatory structures to function successfully, national and local-level strategies must include increasing regulatory capacity related to human and financial resources, making available and using regulatory tools effectively, incorporating regulatory activities into local plans and budgets, and strengthening coordination and reporting among regulatory entities and retail drug outlets.

Keywords: accredited drug seller initiatives; access to medicines; regulatory oversight of the private sector
Plenary Session II: Advancing local production of medical products for Africa—Where are we?

3.1. Status of pharmaceutical Manufacturing in Africa, PMPA + 10: Where are we?

G. Makateto¹, P. Tanui², M. Ndomondo-Sigonda², C. Chamdimba², I. Chergui ¹, J. Byaruhanga¹,

¹African Union Commission (AUC)  
²New Partnership for Africa’s Development (NEPAD)

Background:
As Africa embarks on the trajectory of economic transformation, the pharmaceutical manufacturing industry is promising creation of jobs, economic benefits, improved social and human outcomes as well as stimulating other economic activities across its complex value chain. A vibrant pharmaceutical manufacturing sector in Africa has the potential to contribute to improved access to medicines, better public health outcomes and economic growth.

Since 2005, when African leaders during a special summit on HIV & AIDS, TB and malaria identified the sector as a priority, there have been various on-going efforts undertaken at national, regional and international level towards strengthening Africa’s capacities for local production of pharmaceutical products, opening up and expanding markets through integration processes, strengthening and harmonizing regulatory systems. In some pockets of the continent, predominantly in North Africa and in South Africa, the status of local manufacturing of pharmaceutical products has gained a sturdy foothold.

It’s estimated that more than 70% of the drugs used in Africa are imported. The African pharmaceutical Manufacturing only accounts for less than 30% which is the reasons for low access to essential drugs in Sub-Saharan Africa. The gap in African pharmaceutical Manufacturing has been identified as a concern in the continent. It is with this hindsight that this paper seeks to review the progress made in the last ten years in the implementation of PMPA.

Methodology:
A desk review of various publications coupled with interviews with selected Member States and Regional Economic Communities (RECs) has been undertaken to gain insight on the status of local production in the continent. Gaps in the level and processes of implementation of the PMPA were identified and recommendations proposed with a view to influence policy decision on the future of PMPA.

Results:
Preliminary results show that; the pharmaceutical market size has increased steadily from US$ 4.2bn in 2000 to US$4.7bn in 2003 to $20.8bn in 2013 and is projected to reach US$ 45 bn. by 2020. Pharmaceutical firms have increased tremendously with over 900 pharmaceutical manufacturers existing in Africa 500 of which are in seven (7) countries namely South Africa, Algeria, Nigeria, Morocco, Egypt, Tunisia and Kenya and the remaining 400 distributed across the rest of the Member States.

The African Union Commission is also currently promoting quality infrastructure in the pharmaceutical sector. This initiatives among others have ensured that pharmaceutical products from South Africa, Algeria and Tunisia are already accessing Europe and Middle East. Africa hosts some of the leading global innovators and generic manufacturers. Starwin in Ghana, Saidal in Algeria, Universal in Kenya, Aspen in South Africa, or Cipla in Nigeria are home grown manufacturers.

The Regional Economic Communities (RECs) namely EAC, SADC and ECOWAS currently have programmes that are promoting the African Pharmaceutical Manufacturing and are at varying levels of implementation. In
addition, RECs are implementing regional medicines regulatory harmonization programmes among which, countries are harmonizing standards for good manufacturing practice (GMP) with a view to improve the quality of products produced locally. For instance, the East African Community Partner States have adopted harmonized GMP in line with WHO standards, which came into force on the 1st January, 2015.

**Conclusion:**
This review has identified progress on local production by the AU Member States, implementation gaps and enumerates recommendations that will improve the rate of implementation of PMPA

*Keywords: PMPA, pharmaceutical manufacturing in Africa, quality, safe and efficacious essential medicines.*
3.2. Barriers to pharmaceutical production in Africa

D. Nahamya1 C. Mark1

1National Drug Authority, Uganda

Background:
Essential drugs are the foundation for nearly every public health programme aimed at reducing morbidity and mortality in the developing world. Pharmaceutical expenditure can account for a high proportion of the total health expenditure of a country.

The lack of essential drugs or vaccines, because of economic reasons raises new human rights issues in a world that remains divided among wealthy countries and the rest of the world. It’s estimated that more than 80% of the drugs used in Uganda are imported. The domestic production only accounts for less than 20%. The low domestic production is one of the reasons for low access to essential drugs in Sub-Saharan Africa. The gap in domestic manufacturing has been identified as a concern in the continent.

One of the policies of the National Drug Policy/Authority Act, Cap 206, laws of Uganda is to support local production of medicines. The National Drug Authority (NDA) has put in place measures to support local production of drugs. These measures include; technical support, waiver of verification fees on imported pharmaceutical raw materials and faster market authorisation of locally produced drugs.

Methodology:
A study was conducted to assess the barriers to local production of medicines, and the methodology involved interviews with the key stakeholders in the industry.

Results:
The study identified several constraints to local medicine production. The barriers to local production include the following among others: small markets within individual countries, weak policy environment and limited government support to local pharmaceutical industry, weak or non-existent capacities for research and development and shortfalls in capital, and skills including scientists and industrial pharmacists. The study recommended measures to overcome the barriers.

Conclusion:
Despite the above mentioned interventions, there has been no significant improvement in local production of drugs.

Keywords: Local production, barriers
3.3. The Implementation of 350-2500 nm Reflectance Spectroscopy and High Performance Thin Layer Chromatography to Rapidly Assess Manufacturing Consistency and Quality of Co-trimoxazole Tablets in Tanzania

**E. Kaale¹, M. Hope², D. Jenkins³, T. Layloff⁴,**

¹Muhimbili University of Health and Allied Sciences, Dar es Salaam, Tanzania;  
²United States Agency for International Development, Washington, DC  
³Product Quality and Compliance, FHI 360, Durham, NC 27713, USA  
⁴Supply Chain Management System, Arlington, VA

**Background:**
In order to improve access to life saving medications under the President’s Emergency Plan for AIDS Relief (PEPFAR), the “Partnership for Supply Chain Management” (PFSCM) has established a program to procure locally manufactured product within the same country as the destination health facilities / clinics. Tanzania has been the prime country for implementation, where PFSCM in support of the “Supply Chain Management System” (SCMS) project purchases on a consignment basis, large amounts of cotrimoxazole tablets produced by a Tanzanian manufacturer. The manufacturer is not prequalified by the World Health Organization (WHO) or approved by a Stringent Regulatory Authority, but is registered in Tanzania and has been qualified through the PFSCM’s internal quality assurance program.

**Methodology:**
In order to assure that the products are consistently produced under good process controls, PFSCM has instituted a reflectance spectroscopy procedure with periodic quality assessment confirmation by assay and dissolution testing using validated HPTLC techniques (including weight variation and disintegration evaluations).

**Results:**
The implementation of this program has demonstrated dramatic improvements of the ongoing product quality from this local manufacturer.

**Conclusions:**
This approach provides a model for rapidly assuring product quality of future procurements of other products that is more cost effective than traditional pharmaceutical testing techniques.

**Keywords:** Manufacturing consistency, High Performance Liquid Chromatography; HPTLC. High Performance Thin Layer Chromatography; Near-infrared; Co-trimoxazole.
3.4. GMP Roadmap for implementation of the AU Pharmaceutical Manufacturing Plan for Africa (PMPA): A Regional Approach

_P. Tanui^1, M. Ndomondo-Sigonda^1_

^1New Partnership for Africa’s Development (NEPAD)_

**Background:**
Rationale for compliance to current Good Manufacturing Practice (cGMP) standards by manufacturers and the need for harmonized standards and regulatory frameworks by AU Member States is predicated by the need for faster, quality, predictable and transparent approval of medical products.

The attainment of cGMP standards of manufacture by pharmaceutical manufacturers will benefit from agreed cGMP roadmaps in the RECs. It is therefore proposed that partners align their support towards assisting regions and countries through the steps listed above. A consultative and stepwise approach is therefore recommended. Ultimately the success of national and regional cGMP roadmaps will require a common understanding and acceptance by all stakeholders.

**Proposed Regional Approach:**
It is proposed that the GMP guidelines endorsed by the EAC Council of Health Ministers which came into force in January 2015 will serve as a standard for the African Union Member States and RECs. The GMP Roadmaps developed by the Republic of Kenya and Ethiopia with support from UNIDO will serve as a reference for implementation at country level. The regional approach under the coordination of NEPAD Agency and AUC will follow the following steps:

a) Baseline survey/assessment on status of GMP compliance by local manufacturers based on an agreed assessment tool
b) Stakeholders meetings to discuss results and agree on a roadmap for compliance to regionally harmonised GMP standards
c) Monitoring and evaluation to assess progress

The attainment of cGMP standards of manufacture by pharmaceutical manufacturers will benefit from agreed GMP roadmaps in the RECs. It is therefore proposed that partners align their support towards assisting regions and countries through the steps listed above. A consultative and stepwise approach is therefore recommended. Ultimately the success of national and regional GMP roadmaps will require a common understanding and acceptance by all stakeholders.

**Objectives:**
The main objective of development of the regional approach is aimed at aligning national GMP Roadmaps with the PMPA and AMRH Frameworks.

The specific objectives are to: i) align efforts of RECs and development partners towards a common approach for attaining acceptable GMP status of manufacture in AU Member States; ii) avoid duplication of efforts by partners in the implementation of the AU PMPA Business Plan; iii) anchor national and regional GMP Roadmaps within the PMPA and AMRH Frameworks; and iv) efficiently utilize resources for optimal impact.

**Expected outcomes:**

a) GMP Regional Roadmaps aligned to PMPA and AMRH Frameworks
b) RECs, Member States and Partners adhere to the Regional Approach to attain acceptable GMP standards for manufacture of pharmaceuticals

**Implementation Plan:**
The implementation plan of the GMP Regional Roadmaps will be developed under the coordination of NEPAD Agency and AUC, with technical guidance from WHO, and in collaboration with RECs and NMRAs as the implementing agencies. It is proposed that the activities for implementation will be stepwise and in three phases as listed in the regional approach described above.
4.1.  Monitoring Quality of Anti-malarial Medicines in Kenya by use of Minilab Technology, a five year analysis

E. Abwao¹, A. Toroitich¹, S. Kimatu¹

¹Pharmacy and Poisons Board, Kenya

Background:
The availability of good quality anti-malarial medicines is important to any malaria-endemic country. Monitoring the quality of medicines circulating in the country is one of the core functions of any National Medicines Regulatory Authority.

Methodology:
Pharmacy and Poisons Board (PPB) is the national medicine regulatory authority in Kenya. PPB has an established robust post marketing surveillance program to assess the prevalence of poor quality medicines in the market.

Objective:
The objective of this paper is to provide a systematic review of the prevalence poor-quality anti-malarial medicines circulating in Kenya market from studies conducted by PPB and USP. There was identification of poor quality anti-malarial medicines in Kenya from 2010 through 2015. The studies are limited to field surveys studies carried out using the Global Pharma Health Fund Minilab ® Kit (GPHF Minilab Testing System). They excluded studies not conducted in collaboration with Pharmacy and Poisons Board.

Results:
The results from studies carried out from 2010 shows an increasing compendial testing pass rate of anti-malarial medicines. Minilab testing offers an affordable and cost effective means for monitoring the quality of medicines in the market in resource constraint countries. The main challenges to effective post market surveillance include choice of medical products to be sampled, location of sampling and testing resources especially financial resources.
A. Mwafula¹, S. S. Ngendabanka¹ H. B. Sillo¹

¹Tanzania Food and Drugs Authority

Background:
The management information system (MIS) is one of the powerful tool for tracking, storing, manipulating and distributing information to internal and external customers. The same can help Regulatory Authorities in decision-making process. Nevertheless, many institutions have not realized the benefits of MIS and still they use non computerized systems for storing, processing and reporting data. ICT solutions in processing data are critical in strengthening regulatory systems. We are reporting the importance of ICT solutions in regulatory decision-making processes as it had been experienced, practiced and helped the Tanzania Food and Drugs Authority (TFDA) over the last three years.

Objectives:
The development including designing of the TFDA - MIS based on the East African Community (EAC) harmonization project is being reported. The system was developed to facilitate the flow and processing of information for decision making using web based technology.

Methodology:
The Software Development Life Cycle (SDLC) was adapted in implementation of TFDA MIS. The requirements were collected from respective departments. This involved collecting registration forms, standard operating procedures (SOPs) and guidelines. Several interviews were conducted to internal and external stakeholders to gather inputs when designing the system.

Results:
The system was developed and tested for user acceptance. The system which is now operational since 2014 has all the functionalities that assist TFDA in processing and managing regulatory data. It caters for the following regulatory functions - registration of medicines, medical devices, cosmetics and food; registration of premises and clinical trials; Good Manufacturing Practices (GMP) inspection and import and export control. To improve customer service delivery, the system has been upgraded to incorporate online application and now applicants can apply online through the TFDA website.

Conclusion:
MIS is a vital tool for helping Regulatory Authorities in processing and managing data. It is also useful in decision making process and improving service delivery to customers.

Keywords: Tanzania Food and Drugs Authority (TFDA), Management Information System (MIS), ICT solutions and decision-making process.
4.3. Deployment of ICT as a Tool in Advancing Medicinal Products Regulation in Nigeria: Development of NAPAMS Version 2.0

B.O. Jayeola¹, P.B. Orhii¹, M.H. Eimunjeze¹
O.O. Sopein-Mann¹

¹NAFDAC

Background:
In September 2012, the National Agency for Food and Drug Administration and Control (NAFDAC) introduced the NAFDAC Automated Products Administration and Monitoring System (NAPAMS). This was a web-based application that allowed for electronic submission and commencement of the registration process of regulated products in Nigeria.

Methodology:
The use of ICT has shown a lot of promises as a viable partner in advancing regulation of medicinal products in Nigeria. This presentation will highlight the deficiencies of the old version, the new processes captured by the new version as well as the capabilities of the upgraded Version 2.0 of NAPAMS.

Results:
This pioneer version was designed as a virtual platform to interphase with applicants for easy processing of new application and renewal of existing marketing authorization for drugs, cosmetics and herbal products manufactured in Nigeria. This version was well received but had some limitations that necessitated a review of the system.

The system has been upgraded to include all NAFDAC regulated products and to cover more regulatory processes that were not included in the first version. Applicants are enabled to follow up their submissions via their social media accounts and thus facilitate transparency and a more encompassing stakeholders’ involvement.

Conclusion:
Deploying Information and Communication Technology (ICT) has enriched our regulatory process whilst supporting a data repository that enables easy retrieval of information. NAPAMS is a system driven portal, with the capacity to reduce human errors and also improve applicants’ response time to raised deficiencies. It has been able to make regulatory processes more transparent and efficient.

Keywords: NAFDAC, NAPAMS, R&R, VERSION 2.0, ICT
4.4 Drugs, Data & Technology- Developing electronic systems for drug registration in Bangladesh, Ethiopia and Mozambique

K. Duarte¹, M. Thumm¹, U. Srivastava¹, E.M. Kim¹

¹Management Sciences for Health

Background:
National Regulatory Authorities (NRAs) are faced with multiple challenges: inadequate human resource capacity; overburdened staff; inefficient manual processes preventing the transparent capture, processing and communication of essential drug registration, licensing, and inspection information. These challenges prevent NRAs from fully adopting international standards in medicines regulation. There is an opportunity for technology solutions to help NRAs address these challenges and accelerate the registration of essential medicines in countries.

Methodology:
The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Project partnered with NRAs in Bangladesh, Ethiopia, and Mozambique to analyze deficiencies in regulatory information. The NRAs, identified and prioritized challenges and gaps. SIAPS followed software development best practices, combining international best practices and local country requirements to design Pharmadex, a web-based regulatory information management platform. SIAPS worked with technical working groups (TWGs) in each of the countries to review and refine existing regulatory guidelines and SOPs, developed NRA’s capacity to review applications, adopt international standards, and manage the application. TWGs were held accountable for project milestones by the NRA, thereby ensuring local leadership and ownership for the entire process.

Results:
Over 70% of registration processes and tools have been optimized; international standards for medicines regulation have been adopted; historical data have been updated; and, IT infrastructure strengthened. NRAs have task-shifted accountability of selected steps of the registration process to the applicants, which helps ease the administrative burden and improve the quality of application submissions.

Conclusion:
Pharmadex has led to improved efficiency and transparency in regulatory processes. In collaborating with the applicants, and task-shifting select steps of the process, the work-load on NRAs is reduced. Additional modules are planned to incorporate other regulatory functions, creating an integrated regulatory information system. By sharing discrete NRA data through broader implementation of Pharmadex, countries can further support regional harmonization of medicines regulation.

Keywords: Pharmadex, ICT for medicines regulation, regulatory system strengthening, electronic registration
4.5. Strengthening Medicine Regulatory System by implementing electronic medicine registration data management system (PharmaDex) in Mozambique

T. Sitoie¹, N. Bay², L. Williams², E. Kim², U. Srivastava²

¹Ministry of Health of Mozambique
²Management Sciences for Health

Background:
Since medical product marketing authorization was instated in Mozambique in 1999, the Pharmaceutical Department (PD) within the Ministry of Health has registered approximately 4,200 pharmaceutical products. However, the PD has faced increasing challenges as inefficiencies in medicine registration processes and a shortage of technical staff have resulted in a backlog of applications for marketing authorization. The PD has struggled to track the status of applications through the various registration process steps and to maintain a record of registered products and related information. In 2012, with support from the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) project, the PD decided to implement an electronic medicine registration system (PharmaDex) to expedite the registration process and improve regulatory information management.

Methodology:
Before implementing an electronic medicine registration system, SIAPS provided technical support to the PD to conduct a thorough review of the medicines registration process, regulatory framework, tools and IT infrastructure. Based on that review, the PD and SIAPS revised key processes and tools, streamlined the system, and then incorporated the final requirements into a tailored software solution and established necessary IT support.

Results:
The revised medicine registration review process uses multiple reviewers per application, rather than a single reviewer, to allow for cross-checking and promote transparency. An embedded, question-based review report template in PharmaDex enables staff to review applications and record justifications for registration decisions in a uniform, structured way and generates a permanent record of regulatory decisions and recommendations to further increase transparency and accountability in the medicines registration process. PharmaDex also established a mechanism for the PD to track registration applications in real time, contributing to reductions in processing times. PharmaDex went live on October 1, 2015.

Conclusion:
PharmaDex implementation and related system improvements have helped the PD to streamline its medicines registration process and increase efficiency and transparency.
4.6. Advancing medicine registration through process optimization and automation

H. Tadeg\(^1\), E. Gebre\(^2\), H. Gerba\(^3\), E. Ejigu\(^1\), M. Thumm\(^2\) K. Duarte\(^2\), A. Mengistu\(^4\)

\(^1\)Management Sciences for Health, SIAPS program  
\(^2\)Management Sciences for Health, USAID/SIAPS program  
\(^3\)Food, Medicine and Health Care Administration and Control Authority  
\(^4\)Management Sciences for Health, SCMS

Background:
Inefficiencies in a national regulatory authority’s medicine registration process can delay entry of essential products into a country, thereby limiting the population’s access to lifesaving medicines. In Ethiopia, the Food, Medicine and Health Care Administration and Control Authority (EFMHACA) identified the need to improve the efficiency of its medicine registration system, the first step of which has been optimizing medicine registration processes with support from USAID/SIAPS. The improved processes and tools are being incorporated into software that will, during the next phase of implementation, introduce an electronic information system.

Methodology:
An analysis of existing tools and processes was conducted between July and October 2014. This was followed by optimization of processes and tools according to international standards, which are contributing to the development of an electronic information system. All improvements to processes and tools have been adopted through technical working groups and then approved by a steering committee to promote institutionalization and accountability.

Results:
Eight types of applications were identified, for which the processes and associated tools were reviewed. Out of the 46 tools, including guidelines, SOPs, checklists, and forms, 28 (74%) were modified as part of the optimization process. 8 new tools were developed and introduced based on international best practices. Web-based software has been developed to reflect the optimized processes and requirements. An organizational change management plan was developed and is being implemented to guide the transition from a manual to an electronic system.

Conclusion:
Systematically reviewing and optimizing product registration processes and tools is an essential step towards improving the efficiency of the system and preparing it for automation. Improved processes and tools will increase the potential impact of an electronic regulatory information management tool by streamlining procedures, institutionalizing international standards, and using resources more effectively. The resulting increase in data visibility and access to information can help facilitate efforts in regulatory harmonization.

Keywords: Medicine registration, process optimization, process mapping, automation
Plenary Session: The Future of Medical products regulation in Africa: Post 2015 development Agenda

5.1. Strengthening health R&D and regulatory harmonization in the Sustainable Development Agenda

C. Wingfield¹, P. Bahati², C. Chamdimba,³ M. Ndomondo-Sigonda,³

¹PATH
²International AIDS Vaccine Initiative
³New Partnership for Africa’s Development

Background:
The Sustainable Development Goals (SDGs) set out an ambitious agenda to achieve economic prosperity for all. However, research and development (R&D) and regulatory strengthening has been left out of the SDG measurement and evaluation (M&E) framework.

Objective:
R&D and regulatory strengthening targets are included but no indicators have been proposed that will measure progress and impact in the SDG framework.

Methodology:
This presentation sets out the rationale for the inclusion of R&D for health and regulatory strengthening in the SDG framework. An in-depth analysis and cross-sector consultation was conducted to identify indicators that could be used to monitor progress toward R&D and regulatory strengthening, their rationales, and data collection approaches. Building on this, the African Union Commission, NEPAD Agency and the African Peer Review Mechanism (APRM) have embarked on a process to develop a measurement and evaluation framework for health research and regulatory strengthening in Africa.

Results:
The proposed indicators provide a measurement of research and regulatory capacity. Eight global and national indicators were identified. Global indicators tracking R&D investments and number of new health technologies will be monitored by all countries. The remaining five indicators monitor national priorities. Two of them measure impact of regulatory strengthening efforts and harmonization processes. While the remaining three measure domestic capacity and quality of research and coordination platforms. This analysis used criteria aligned to proposals by the UN Statistical Commission and Member States. Cross-cutting indicators were favored as a way to limit the number of indicators required.

As a way of domesticating the indicators in alignment with the African Union (AU) Agenda 2063 and policy frameworks on health, five indicators have been selected to measure investment in technological innovation for health, regulatory capacity strengthening and local production.

Conclusion:
Appropriate measurements are needed to ensure resources and accountability to R&D and regulatory strengthening are prioritized in the SDG and the AU Agenda 2063. African countries and regional blocs should advocate and ensure inclusion of the proposed indicators in the SDG and the AU Agenda 2063 M&E framework.

Keywords: Post-2015, indicators, regulatory, research and development (R&D), SDGs

B.B Kwame\textsuperscript{1}, E. Yissibi Pola\textsuperscript{2} J.B. Nikiema\textsuperscript{3}  
Kasilo Ossy\textsuperscript{3}

\textsuperscript{1Medicines Regulatory and Quality Assurance Consultant.}  
\textsuperscript{2Organization for the Coordination of the Fight Against Endemic Diseases.}  
\textsuperscript{3Whold HealthOrganization Regional Office for Africa}

\textbf{Background:} Medical products regulation should be enshrined in the national health or medicines policies to ensure that medicines in use are of good quality, safe and efficacious. However, this is not the case in some countries because the national regulatory systems in Africa are at different levels of development. Depending on each country’s legal system and colonial past, differences exist in regulatory infrastructure and different institutional arrangements are in place to oversee medical products regulation. Within this context and recent harmonization efforts, it is becoming imperative for countries to ensure that their medicines regulatory agencies are operational.

\textbf{Methodology:} A survey on agency model and quality management of medicines regulatory agencies carried out in 2015 analyzed the medical products regulating infrastructure in 47 African countries as well as opportunities offered by harmonization initiatives at sub-regional and continental levels. The purpose was to propose a model for regulatory bodies that will serve as prototype for countries desirous of establishing new ones or reviewing existing agencies.

\textbf{Results:} Findings in the study centered on the availability of national medicines policies and adequate provisions for medicines regulation to ensure access to safe, quality and efficacious medicines throughout the supply chain. The existing governance structure, whether defined by legislation or not, that is operational in the countries to ensure effective implementation of regulatory functions were also studied.

\textbf{Conclusion:} The survey proposes a model that sets up an autonomous or semi-autonomous agency linked to the Ministry of Health but has independence in operational, financial and decision making functions.

\textit{Keywords: Medicines regulatory systems, harmonization, regulatory infrastructure, legislation, governance, model agency, autonomous, semi-autonomous}
5.3. The Institute for Regulatory Science; A model for building Regulatory Capacity in Africa

D. Johns

Institute for Regulatory Science, National Department of Health, South Africa.

This presentation describes the Institute for Regulatory Science, a public – private partnership in South Africa comprising government, the national regulator, academia and industry and focused on rapidly boosting regulatory capacity in South Africa, in order to ensure the access to safe and effective health products. It details innovative partnerships designed to combine scarce training resources and maximize their reach through the online delivery of quality assured programs in regulatory science.

The courses on offer are designed to equip new entrants to regulatory field, with the knowledge, skills and competencies that will make them work ready and suitable for onward training in their chosen area of regulatory science. The initial course offerings will therefore be situated at the level of a Honours/Post Graduate Diploma, with onward articulation to Masters degrees. Each course will comprise elements that confer theoretical knowledge and build practical skills, which are then applied in a structured a work integrated learning / mentorship program. All courses will be based on international best practice and subject to extensive national and international referencing. Each qualification will be linked to a specific job code (Regulatory Affairs Officer) on the Organizing Framework for Occupations, which defines the responsibilities and competencies for all occupations in South Africa.

It is envisaged that the inaugural course offering - Regulatory Affairs Officer: Pharmaceutical (Quality) – will soon be complimented by similar qualifications for medicine safety and efficacy, inspectorate and audit functions, medical devices and in vitro diagnostics and complementary and alternate medicines. At the post entry level, advanced elements tailored for each regulatory work stream will be available as stand-alone short courses or as contributory elements to linked Masters qualifications, which may possibly be recognized as specializations.

In addition to anchoring these capacity efforts, the IRS will also monitor global developments and serve as a think-tank, in order to facilitate the strategic choices needed to achieve a step change (“leapfrog”) in regulatory practice.

Since the IRS was explicitly conceived as a resource that would consolidate and extend existing regional collaboration in regulatory training, the presentation will conclude by exploring how the IRS might best fulfill this larger role.

Keywords: Capacity building pharmaceutical product regulation
6.1. Regulatory Resources for Africa

J. Coates

1Innovative Pharmaceutical Association of South Africa (IPASA)

The Regulatory Resources for Africa (RRFA) website is an initiative derived from regulators and practitioners involved in the regulation of medicines, who saw the need to promote best regulatory practices in Africa.

Serving developing countries where information is not always easily accessible, this website aims to bring information on one platform, and make it available to all regulators and regulatory practitioners working within the African region.

The RRFA website is a knowledge hub and public resource of data on country-specific policies, regulations, guidelines, fees and processes for registering medicines. The website is built from information made available by interested parties.

The goal of the website is to:
- Make relevant information available in the public domain.
- Make information available on one platform.
- Allow for the sharing of information.

The vision is to include the most up-to-date country-specific policies, regulations and guidelines on the platform as well as include the corresponding harmonised documents for each African Region as they become available. We would like to encourage each National Medicines Regulatory Authority (NMRA) and each African Region to elect a person whose function it would be to ensure that updated documents are made available to the RRFA website administrators timeously so that they can be instantly shared with all interested parties.

The site has been made possible through a sponsorship from the Innovative Pharmaceutical Association South Africa (IPASA) and is open to all parties interested in medicines registration in Africa.

Through the submission of this abstract IPASA wishes to officially launch the website to the broader stakeholder network.

Keywords: Regulatory resources, website;www.rrfa.co.za
6.2. Regulation Of Medical Devices In Cote D’Ivoire: Where Are We?

M.C.A. Adjiri¹, A.C. Amonkou¹, R.Y. Amin Anon², R. Duncan¹

¹DPML, Cote D’Ivoire
²Pharmacie CYD NIKO, Cote D’Ivoire

Medical Devices (MD) are a heterogeneous group of instruments, apparatus, equipment, materials or software designed to be used in humans. The advent of new medical technologies, makes them an essential component in the field of health. They are used both in preventive, diagnostic, therapeutic medical and alternative practices. The demand for equipment and medical devices is high and is estimated to be at about 90% of imports. In Côte d’Ivoire to this day, there is a lack of specific regulations for medical devices. Filling that legal vacuum is necessary for training on registration. Presentation on the implementation strategy for 2007-2015 for the approval of medical devices.

Strategy before the marketing of devices: it is to ensure the review of administrative files according to the terms and defined procedures, Assessment during the testing and laboratory stage by evaluator’s following a common protocol, deliberations of the results by an ad hoc Committee for granting of marketing authorizations. Thus by this process, for TDR HIV/malaria, Côte d’Ivoire has approved 10 test for HIV and 11 for malaria. Review of a guideline and draft decree under development.

Strategy after marketing of the drug remains to define. Like drugs, medical devices (MD) contribute to medical progress and improvement of the care of patients, playing a role in increasing life expectancy and a decrease in the overall mortality rate. To better frame regulations on medical devices countries must participate in WHO trainings and meetings for strengthening the capacities of the NRA. The regulation of medical devices in Côte d’Ivoire is recent and deserves to be sufficiently implemented despite the lack of funding.

Key words: medical devices, regulatory approval and rapid testing, Côte d’Ivoire.
6.3. Law N°2015-536 Of 20 July 2015 Or The Official Recognition Of Medicine And Traditional Pharmacopoeia In Cote D’Ivoire

A.S.G Amari¹, E. Kroa²

¹Université Félix Houphouët-Boigny, Abidjan
²Ministère de la Santé et de la Lutte contre le SIDA, Abidjan Côte d’Ivoire

In Côte d’Ivoire, it took law No. 2015-536 of July 20, 2015 to officially recognize medicine and the traditional pharmacopoeia in Côte d’Ivoire. The objective of this work is to highlight the advances made by the law of July 20, 2015. Our study material was mainly composed of Act No. 2015-536 of July 20, 2015 on the exercise and the Organization of medicine and traditional pharmacopoeia in Côte d’Ivoire, community texts (WAEMU) but also decrees and national orders relating to this matter. We have described and analyzed these laws looking for progress made by the new legislation. It appears from this study that Act No. 2015-536 of July 20, 2015 have made significant advances for the rational use of medicine and the traditional Pharmacopoeia in Ivory Coast. After the official proclamation of the recognition, the law sets the definition for traditional medicine, its scope as well as the conditions and rules under which it can be practiced. The new law regulates the manufacture and import of traditional medicines, and provides for penalties in the event of infringement of the rules. Act No. 2015-536 of July 20, 2015 offers psychological and cultural liberation for the people who live it.

Key words: Recognition - medicine and traditional pharmacopoeias - Côte d’Ivoire
6.4. Prospects and challenges in pharmaceutical industry development in Africa for universal health coverage- A policy perspective

S. T. Shawa¹, I. Chergui¹, T. Chisango¹, J. Byaruhanga¹, G. Makateto¹, S. Mbokazi¹, M. G Harakeye-Ndayisaba¹

Department of Social Affairs, African Union Commission

Background:
There is recognition by African leaders that achieving sustainable universal health care in Africa is predicated on strengthening health systems and increasing capabilities on the continent for pharmaceutical development and this has led to increased efforts towards creation of a conducive policy environment to enable pharmaceutical manufacturing. The Pharmaceutical Manufacturing Plan for Africa (PMPA) adopted in Accra in 2007 provides a pathway towards promoting access to quality assured and affordable medicines and technologies. In July 2012 African leaders adopted the AU Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa, anchored on three pillars-More diversified, balanced and sustainable financing models; Access to medicines-local production and regulatory harmonisation and leadership, governance and oversight for accountability. While pillar two addresses directly the policy issues related to access to medicines the other two pillars reinforce financing and governance that are all critical for pharmaceutical development in Africa.

Progress / challenges:
Considerable progress has been made to scale up pharmaceutical access and manufacturing, with a particular focus on ARVs and ACT as well as other malaria commodities such as ITNs. Advancements have also been made in strengthening and harmonising regulatory systems at regional economic community (REC) level as well as at the continental level where various initiatives to enhance access to medicines have contributed significant progress. Inadequate human resource capacities, compliance with good manufacturing practices and other international quality standards, supply chain infrastructure, access to affordable technology and know-how, access to affordable financing, access to markets, policy coherence remain inadequate leading to the slow progress in promoting access to quality and affordable medicines with the African continent despite the political commitment and improvements of related regulatory and legislative environment.

Recommendations:
The realisation of the policy objectives of the AU requires that RECs and countries with comparative and competitive advantage and capabilities of pharma development to align their policies with PMPA and PMPA-BP. To scale up local production this should be interlinked and aligned to existing best practices and models on medicines regulation and harmonisation in Africa.
6.5. Strengthening The National Regulatory System To Promote Local Production Of Antimalarial Medicines In The Democratique Republique Of Congo (Drc)

R. Tuala Tuala\textsuperscript{1}, R. Mulongo\textsuperscript{1}, J. Fikiri\textsuperscript{1}, J. Mwenze\textsuperscript{1}, P. Tshiteta\textsuperscript{1}, K. Kanjinga\textsuperscript{1}, M. Thumm\textsuperscript{1}, D. Ngeleka\textsuperscript{2}, M. Soucy\textsuperscript{1}

\textsuperscript{1}Medicines Sciences For Health, (MSH) \\
\textsuperscript{2}National Drug Regulatory Authority DRC

Background
According to the Demographic and Health Survey 2013/14, malaria is the principal cause of morbidity and mortality in DRC. To ensure appropriate management of malaria in DRC, the Ministry of Health (MoH) recommends locally-produced quinine as treatment for severe malaria. However, deficiencies in the medicines regulatory system were allowing the import of cheaper, poor quality quinine. Uncoordinated and disorganized medicine registration and market authorization processes resulted in the approval of imported antimalarial medicines, including quinine, thereby hindering local production.

Methods
To ensure coordinated, streamlined and well-controlled registration processes, the USAID Systems for Improved Access to Pharmaceuticals and Services program worked with the National Regulatory Authority to establish a Medicine Registration Committee (MRC), develop standard operating procedures for the committee, and train MRC members. A database was created and a Registered Medicine Directory was developed and disseminated to Pharmacist Inspectors and Custom Services at the main entry points of imported medicines. Furthermore, online registration software was introduced to enhance efficiency.

Results
Medicine registration and market authorization processes are better coordinated and controlled, and registration meetings are held quarterly. As a result, the number of registered medicines increased from 400 in 2012 to over 4000 in 2015. Registration preference is given to essential medicines and locally produced products, resulting in an increased number of registered local medicines, from 64 in 2011 to 289 in September 2015. Specifically, the importation of quinine is no longer authorized and the production of local quinine increased from around 5 million to 8 million treatment courses for local consumption.

Conclusion
Medicine regulatory system strengthening has promoted local production. With additional support, local manufacturers can work toward compliance with Good Manufacturing Practices and meeting the WHO prequalification requirements, so that they can expand into new areas, including maternal and child health products.

Keywords: Regulatory System Strengthening, Local Production, Medicine Registration, Medicine Authorization, Management of Malaria
African Union Commission
Addis Ababa, Ethiopia
Email: ByaruhangaJ@africa-union.org

NEPAD Planning and Coordinating Agency
Midrand, South Africa
Email: amrhi@nepad.org

World Health Organisation, Regional Office for Africa
Brazzaville, Congo
Email: Kasiloo@who.int

World Health Organisation, Regional Office for Eastern Mediterranean
Cairo, Egypt
Email: Everardm@who.int