Policy Coherence for local production of pharmaceutical products and other means to improve access to medicine and medical products in the East African Community and beyond

UNCTAD-GIZ-EAC Secretariat Regional Workshop

Speke Resort Munyonyo, Kampala, Uganda
21-23 September 2015

Executive Summary

The United Nations Conference on Trade and Development (UNCTAD), Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) and the East African Community (EAC) Secretariat organised a regional Workshop for the promotion of policy coherence for local production of pharmaceutical products and other means to improve access to medicine and medical products in the East African Community and beyond. The Workshop was held in Kampala, Uganda from 21-23 September 2015. The Workshop was attended by representatives of partner states from Ministries in charge of industry and trade, medicine regulatory agencies, and generic pharmaceutical manufacturers from the EAC partner states. A representative of the West African Pharmaceutical Manufacturers association (WAPMA) and Federation of East African Pharmaceutical Manufacturers (FEAPM) also participated during the workshop.

During the Workshop, UNCTAD and EAC experts presented on the regional and international developments, the framework for local production of pharmaceuticals, on technology and innovation, progress on the implementation of the EAC Medicines Regulation Harmonization Guidelines, Regional Pharmaceutical Manufacturing Plan of Action (2012 – 2016), Common External Tariff, and Common Market Protocol. FEAPM members presented their views and comments on regional policy initiatives, developments at national level and their expectations on the way forward. WEAPMA representative shared the experience from Western Africa and Ghana. Several challenges and recommendations were identified based on the discussions during the plenary, targeted group and national group discussion among the workshop participants and partners (UNCTAD, EAC and GIZ).

Recommendations: the way forward for regional policy coherence in EAC

Based on the identification of the challenges and opportunities, as well as the important lesson from the experience of other regions, participants provided various recommendations that in their views can provides the means to address regional policy coherence to promote access to medicine an local production of pharmaceuticals. A summary of the recommendations include:

A. *To further strengthen the EAC level coordination: UNCTAD and patterns were requested to undertake comprehensive EAC level policy coherence analysis, taking into account the developments at national level. The EAC level policy analysis can be presented for Sectoral committees and other organs of the EAC.*

B. *Political commitment both at regional and national level for the development of the sector need to be reinvigorated, especially, to address the national level implementation of the Action Plan and other EAC initiatives, and provide for institutional arrangement for policy coherence, by operationalizing the national Steering committees that also have to, annually, report to the EAC Sectoral Council on Trade, Industry, Finance and Investment.*

C. *Incentives: tariffs and procurement: To strengthen incentives based on the experience of Ghana, including by developing a regional Essential Medicines List to provide for*

a basis for priority area for medicine regulation harmonization, processing of medicine evaluation and registration, regional harmonization of procurement policy, to expand preferential treatment in government procurement, to fully exempt customs duties on raw material and packing material; and to ensure customs classification of medicines according to the production capabilities of regional manufacturers;

- *Regulations and GMP capacity: to fast track joint inspection and proc*edures for mutual recognition framework of GMP inspection and certification, and product registration.

Several other recommendations were identified in the areas of training and capacity building, mainstreaming innovation, research and development, use of private–public partnerships (PPPs) and on the need to domesticate TRIPS flexibilities important for access to medicine.

Report

1. The Regional Workshop

The United Nations Conference on Trade and Development (UNCTAD), Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) and the East African Community (EAC) Secretariat organised a regional Workshop for the promotion of policy coherence for local production of pharmaceutical products and other means to improve access to medicine and medical products in the East African Community and beyond. The Workshop was held in Kampala, Uganda from 21-23 September 2015.

The Workshop was attended by representatives of partner states from Ministries in charge of industry and trade, medicine regulatory agencies, and generic pharmaceutical manufacturers from the EAC partner states. The EAC Secretariat, from the directorates for the Productive and Social Sectors and Customs and Trade, UNCTAD, Division on Investment, GIZ advisory programme for EAC facilitated the discussion. A representative of the West African Pharmaceutical Manufacturers association (WAPMA) and Federation of East African Pharmaceutical Manufacturers (FEAPM) also participated during the workshop. The workshop facilitated discussion on key features and implementation of the EAC Pharmaceutical Manufacturing Plan of Action, 2012-2016 and related regional industrial policy, the EAC Common Market Protocol, the ongoing negotiation of a regional health policy, and the implementation of the EAC medicine regulation harmonization.

2. Framework for Pharmaceutical production, Access to Medicine and EAC initiatives

Ermias Biadgleng, Legal Expert at UNCTAD outlined the framework for local production of pharmaceutical products as one means to promote access to medicine and the key issues for policy coherence. Industrial policy aims at developing a competitive (viable and innovative) and responsible local industry, whereas, health policy aims at promoting access to quality, safe and effective medicine by all. Industrial policy alone is insufficient to leverage the potential benefits of local pharmaceutical manufacturing for key health policy goals. Equally, health policy alone is insufficient to incentivize local industry to provide competitive and reliable health products and services. Hence, there is a need for systemic intervention – covering key policies & all factors that influence the interaction between health and industry polices. Policies in trade, investment and intellectual property rights influence the way the objective of health and industrial polices interact and support each other. Direct and indirect government support to local pharmaceutical manufacturing, such as investment incentives, could target priorities in the access to medicine needs of a country. Tariff and fiscal concessions, government procurement and trade facilitation can ensure the viability and competitiveness of local pharmaceutical production. In order to generate a functioning

framework for local production of pharmaceuticals and access to medicine, Mr. Biadgleng stated that it is essential to have a focused pharmaceutical strategic plan sponsored by both the Ministry of Industry and Ministry of Health, with input from all stakeholders, supported by institutional mechanism for coordination and consultation.

<table>
<tr>
<td>(A) Industrial Policy

Main Objective: To develop a viable local industry which is competitive , reliable, innovative, productive and responsible

Key factors from medical products development perspective:
1. Competitive: offers better prices
2. Reliable: complies with quality standards; ensures steady supply
3. Innovative: aims for technological change and invests in R&D
4. Productive: employment generation; human resource development; and supporting associated industries and suppliers
5. Responsible: shows corporate responsibility towards social conditions and environments
6. Strategic: balances current and future demands</td>
<td>(B) Health Policy

Main Objective: to promote health for all through universal health coverage in terms of prevention, treatment and rehabilitation

Key factors access to medical products development perspective:
1. Universal access to medical products through public sector supply system and/or social protection programs.
2. Availability of essential medicines; in appropriate formulations suitable for local use.
3. Affordable prices: for government procurement agencies and for out-of pocket expenditures by people.
4. Quality assurance: through effective regulation.
5. Uninterrupted supply: of essential medical products.
6. Rational selection & use by clinicians</td>
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<td colspan="2">(C) Shared Goals of Industrial and Health Policies for Local production for Improvements in Access to Medical Technology

➢ Strategic selection of essential medicinal products for local production
➢ Pricing of locally produced products that governments and people could afford
➢ Strict compliance to quality standards by the manufacturers
➢ Health security –an uninterrupted supply of essential medicines
➢ Innovation for development of formulation that are more suitable for local conditions</td>
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<td colspan="2">(D) Trade/ Procurement/Investment Policies: Government Support for Local Production for Access to Medicines

Direct support to reduce costs of manufactures: grants, subsidies, soft loans, provision of land, tax &duty exemptions for imported inputs for local production of essential medicines.

Indirect support of local production for improving access: strengthening regulations; develop national priority lists of medical products; improve financing of health services; facilitate access to foreign markets; development of regional pooled procurement mechanisms; introduce appropriate financing mechanisms; facilitate transfer of technology; regulatory harmonization; support incremental innovation and production; develop appropriate intellectual property regimes &appropriate investment policies and joint ventures; facilitate international cooperation for local production.</td>
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Thamara Romero, Legal Officer, UNCTAD, presented on technology, innovation and skill development in the pharmaceutical sector. Intellectual property policy is closely linked with the technological development level of a county. Taking the example of South Korea, in the 1960s & 70s, the technological capacity of the industry was limited to imitate existing technologies – known as a "duplicative imitation stage." Research and Development (R&D) investment by private sector was barely 39% of the total expenditure. In 1981, there were barely 232 patent filling by resident compared to 1,576 by non-resident. A flexible patent system at this stage helped South Korean firms to undertake reverse engineering and provided them with a robust public domain. Higher standards of IP protection at this stage will hinder, rather than facilitate technology transfer. Not only South Korea, but also, Germany, until 1968, Switzerland, until 1977, Sweden, until 1978 and India, until, 2005, excluded pharmaceutical product patents. At this stage second tier IP rights, such as utility models, can fit well with the innovative capacity of local firms. The capacity of the South Korean industry improved through time to reach the "creative imitation stage", where moderate IP rights can protect new assets and provide incentives. In the year 2000, there were 22,943 patent fillings by residents in South Korea compared to 12,013 by non-resident. Finally, many of the developed countries are at the "innovation stage" with the capacity to develop and market new products and technologies, supported by stronger IP rights commensurate with the increased inventive capacity.

From EAC Secretariat Ms. Jeniffer Gache, Senior Industrial Expert, Mr. John Patrick Mwesigye, Senior Health Officer (MRH) and Mr. Willy Musinguzi, the Principal Standards Officer presented the EAC initiatives and programmes on pharmaceutical production and access to medicine.

2.1. Tariffs, Medicine Registration and Anti-counterfeiting Measures

The EAC Treaty envisages harmonization of medicine registration procedures, development of Common Medicine Policy and harmonization of Health Policies and regulations. The Medicines Regulation Harmonization Guidelines were approved by the Council of Ministers in November 2015. The Guidelines require bioequivalence studies for all product registration in EAC partner states. The EAC Common Market Protocol guarantees free movement of capital goods, people, labour and services and call for further harmonization of social policies. A customs union has been established since 2006.

The EAC Common External Tariff (CET) covers all pharmaceutical products under its Chapter 30, among the eight tariff categories. All Pharmaceuticals attract 0% CET. According to Mr. Willy Musinguzi, Pharmaceutical products featured both in the intra-regional trade and imports from outside the region. Kenya's imports in 2013 from India increased mainly on account of increased importation of pharmaceutical products, among others. In the same period its exports to EAC partner states including pharmaceutical products declined. Yet, pharmaceutical products remained one of the main imports of Tanzania and Rwanda from other EAC Partner States. Partner States have various policy documents and laws including on distribution system, health and regulations that will affect the potential benefits of the CET for local pharmaceuticals manufacturing and intra-regional trade.

Although there is substantial progress on the harmonization of medicine regulations in the EAC region, currently there is no regional coordination mechanism on anti-counterfeiting measures and procurement of pharmaceutical products in EAC region. The EAC Anti-counterfeiting Bill was dropped by the EAC Council of Ministers during the meeting held in April 2015 and is replaced by draft provisions for the amendment of the Competition Act of 2006. The amendment applies anti-counterfeiting measures to protect trademarks and copyright. The EAC Competition Authority will have the power to harmonize the national legal framework on counterfeiting and piracy in the region. Partner states will be obliged to establish or designate an institution responsible for anti-counterfeit matters, and to enact laws prohibiting the manufacture or production, the possession or control in the course of trade, the sale, hire, barter or exchange, or the distribution of counterfeit goods for trade. They should also prohibit the importation into, the transit through, transhipment or export from a Partner State. As a safeguard for access to medicine, the amendment provides that its provisions shall not be construed as prohibiting the manufacture, importation, sale or dealing in medicinal products generally known as generic medicine provided such medicines are not counterfeit goods.

2.2. Manufacturing Plan of Action

The EAC Regional Pharmaceutical Manufacturing Plan of Action (2012 – 2016) is the regional roadmap to guide the Community towards evolving an efficient regional pharmaceutical manufacturing industry that can supply national, regional and international markets with safe, efficacious and quality medicines. It has six pillars to be implemented at regional (EAC Secretariat), partner states and firm level as well as in collaboration with international partners:

Pillar 1: Promotion of competitive and efficient pharmaceutical production;
Pillar 2: Facilitation of increased investment in pharmaceutical production;
Pillar 3: Strengthening of pharmaceutical regulatory capacity;
Pillar 4: Development of appropriate skills and knowledge on pharmaceutical production;
Pillar 5: Utilization of TRIPS (Agreement on Trade Related Aspects of Intellectual Property) flexibilities towards improved local production of pharmaceuticals;
Pillar 6: Mainstreaming innovation, research and development.

The total budget allocated for the Plan of Action until 2016 is USD 45,200, 000, out of which, pillar 6, 1 and 3 receive the most budgetary allocation, respectively.

The Plan of Action should be viewed in light of the EAC Industrialization Policy and Strategy (EACIPS), 2011, that identified manufacturing as its strategic focus, under a market led-private sector approach, but also based on comparative and competitive advantage, and emphasizing on strategic regional value chains with long backward and forward linkages with the rest of the economy. According to the EACIPS, pharmaceutical production is one of

the priority sectors for the region, along with other sectors,[1] and implementation of the Action Plan is part of implementation of the EACIPS. A steering committee and a joint working group between the Health and Industry to address the issue of development of the pharmaceutical industry in the region are established to fast track the implementation of the Plan of Action. So far:

A. Medicines Regulation Harmonization Guidelines (Pillar 3) covering medicines registration, Good Manufacturing Practice (GMP) inspections and quality management systems was approved by the Council of Ministers in November 2015. The implementation at national level is the next step;
B. EAC-PTB (Physikalisch-Technische Bundesanstalt) programme for "Support to Quality Infrastructure for the Pharmaceutical Sector", addressing pillar 3 and 4 was implemented with capacity building trainings on (i) Chemical Reference Standards for Quality Control of Pharmaceutical products; (ii) Calibration for the Pharmaceutical Sector, Proficiency Test on the analysis of antibiotic tablets; (iii) Proficiency Test with Ofloxacine; (iv) Introduction, Operation, Care, Trouble Shooting and Preventative Maintenance of High Performance Liquid Chromatography Systems and (v) preventive Maintenance of Gas Chromatography Equipment;
C. Word Health Organisation (WHO) – GMP and Pre-qualification Training was provided for 23 FEAPM Members under pillar 4;
D. With support of GIZ – trainings and development of a policy on the use of public health related flexibilities under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) (2009-2012) (Pillar 5); the Establishment of the Federation of East African Pharmaceutical Manufacturers'(FEAPM) (Pillar 1); and United Nations Industrial Organisation (UNIDO) – Industry-Academia internship programme launched in March 2015 (Pillar 4) were implemented. GIZ also supported the steering structure of the Plan of Action.

Ongoing implementation include the effort for the establishment of EAC Centre for Provision of Chemical Reference Substances (CRS) – as a core input in ensuring the quality of pharmaceuticals, and undertaking a situational analysis and post market surveillance. In going forward, priority areas include fast-tracking ongoing projects and mobilization of more partners, the development of national action/work plans; and updating of the Action Plan for implementation beyond 2016.

2.3. Procurement

EAC Partner states have put in place National Medical Stores Departments (NMSD's) that undertake a centralized procurement for the public sector. Among the NMSD's the most preferred method is International Competitive Bidding (ICB) – covering up to 95% of the total procurement, while the remaining is covered under restricted and local tenders as well as direct purchases. The NMSD's have similar funding mechanism using revolving funds, some

[1] The other five sectors are namely, agro-processing, fertilizers and agro-chemicals, petro-chemicals and gas, iron-ore and other mineral processing and energy and bio-fuels.

government funding, complementary financing via Health Insurances (National Health Insurance Fund (NHIF), National Social Security Fund (NSSF), Community Health Fund) and grants from Global Fund and development partners. According to Mr. John Patrick Mwesigye, the fragmented national procurement faces challenges from unreliability of funding. Pooled bulk procurement of medicine is necessary to ensure access to medicine, considering the fact that in the poorest countries of Africa and Asia, as much as 50% of the population lacks access to health supplies and the cost of newer products with proven advantage over older medicines, such as antiretroviral medicines for tuberculosis and new antimalarial, limits access to medicines in resource-poor settings. Access to health care is a fundamental human right, enshrined in international treaties and recognized by governments throughout the world. Currently, there is no specific law for regional pooled procurement in EAC. Based on the experiences of Caribbean and Gulf countries, and following the recommendations of the WHO, the factors that should support pooled procurement in EAC include:

- The harmonization of medicines regulations and mutual recognition of decisions of respective National Medicines Regulatory Authorities (NMRAs) on registration of medicines;
- Harmonization of policies and laws relating to procurement, as well as treatment guidelines and essential medicines list;
- Developing contractual, binding and funding arrangements among EAC Partner States, regional and national Capacity for coordination; and
- Establishing the necessary institutional mechanism, for building capacity, coordination, and information sharing on prices of health commodities supported by medicines pricing policy and procurement strategies, as well as for negotiation with suppliers.

The benefit of the pooled procurement can be enhanced further by investing and improving local capacity production. As a way forward, Mr. Mwesigye also suggested to piloting of products, such as anti-malarials, ARVs and Anti-TB. The overall goal of regional procurement remains to ensure access to medicine, although it can also help balance economic, industrial and consumer interest with the health objectives of controlling the quality of the supply and ensuring appropriate utilization.

3. National Experiences: EAC partner states and Ghana

Mr. Deo A Byaruhanga, national focal Point for the EAC Plan of Action at the Ministry of Trade Industry and Cooperatives of Uganda, presented the National Drug Policy (2002) that defines the goal, objective and strategy for local pharmaceutical manufacture in Uganda. The objective is to create an environment conducive to the establishment of increased national capacity for the production of essential drugs by producers that meet the relevant standards. In order to achieve the objectives, various incentives for the local manufacture of essential drugs, including tax incentives, preference in government procurement, reduced import tariffs,

reduced rates for electricity and water and advanced purchase commitment are implemented. The National Drug Policy also includes strategies for regular inspection, improving local pharmaceutical technical capacity in pharmaceutical production techniques, quality assurance and current GMP (cGMP). Currently, Uganda has about 6 large scale established pharmaceutical manufacturers. The Uganda Manufacturers Association is the main advocacy group.

The National Health Policy and National Medicines Policy of Tanzania also stipulates for the availability and affordability of medicines that are effective, safe and meet the quality requirements. The industrial policy promotes investments led by the private sector in all manufacturing sectors, including the pharmaceutical sector. The role of the government is to provide a conducive environment for the promotion of private investment. The Master Plan for the Pharmaceutical Sector (1992-2000) of mainland Tanzania is a comprehensive national plan for the procurement, storage, distribution and use of pharmaceutical products and is viewed as providing the opportunities for the local pharmaceutical industry to participate in the delivery of drugs to public sector. The Master Plan envisaged the development of Tanzanian standards for GMP. The government through the medicine regulatory agency has given timeline for manufacturers to comply with GMP. In addition, incentives include:

- 15% price preferential margin for local manufacturers made available by Medical Stores Department (MSD);
- VAT exemption on imported raw materials, packaging, capital goods;
- Facilitate and provide allocation of industrial plots for local pharmaceutical producers; and
- Facilitate long-term credit to raise production capital.

Currently, the contribution of domestic pharmaceutical industries in Tanzania is approximately 30% of the total value of consumed medicines. Pharmaceutical production occurs at secondary and tertiary levels (no raw manufacturing is taking place). Tanzania aims at promoting investment in manufacturing of bulk pharmaceutical raw materials and to conduct training on modern manufacturing technology. Currently, MSD is considering public-private partnership model to increase the share of local production.

Mr. Kwabena Asante-Offie, the Executive Director of WAPMA, shared the experience of West African region and Ghana in pharmaceutical manufacturing, including the recently concluded Economic Community of West African States (ECOWAS) Regional Pharmaceutical Plan. The main highlights of the West African and Ghanaian experience were:

- Following the adoption of the regional pharmaceutical manufacturing plan, WAPMA has visited international partners, including the WHO, Global Fund and United Nations Children's Fund (UNICEF) during a working missions to Geneva in order to elaborate the case for regional producers. The international organizations have offered various assistance for the implementation of the pharmaceutical manufacturing plan and the possibility to procure pharmaceutical and health products within the region;

- Since 2004, the Export Development and Agricultural Industrial Fund (EDAIF) of Ghana has been implementing a financial stimulus package for pharmaceutical manufactures that produce essential drugs in Ghana, including for the expansion projects;
- Ghana has also implemented various incentives, including provision of land, tariff and VAT exemption and other investment incentives;
- Currently, there is a consideration for the establishment of a centre for pharmaceutical and bio- equivalence research, initially, by collaborating with existing facilities and laboratories and later by establishing a permanent bio-equivalence and bio-pharmaceutical centre;
- In terms of procurement, the main current initiative is procurement by the West Africa Health organization (WAHO) – the Health wing of ECOWAS – for regional medicine buffer stock that had meaningful impact. In Ghana, manufacturers benefit from tenders that are restricted for local manufacturers;
- Ghana implements an import restriction that originally covered 14 pharmaceutical products, but later was reduced to 7 products due to the phasing out of certain medicine from the health system. There are ongoing efforts to expand the list;
- There are efforts for regional harmonization but in a narrower sense and focusing on registration dossiers requirements among the Anglophone countries. The French speaking countries already have their own system. UEMOA – West African Economic and Monetary Union – has achieved harmonization of certain medicines regulation procedures, processes and requirements in the eight Francophone member countries. In addition to the differences in medicine regulation system in the region, uneven infrastructure and enforcement power affects cooperation for harmonization of medicine regulations;
- Locally produced medicine in Ghana is currently outside the price range of the National Health Insurance Scheme.

4. Comments and open discussion

To facilitate open discussion and to generate adequate and well thought recommendations, the workshop employed methodology, involving:

- open plenary discussion responding to the presentation of EAC Secretariat, UNCTAD and WEAPM;
- targeted group discussion based on the expertise of three groups of participants: regulatory agencies, industrial development agencies and private sector. The target group discussion was structured along four themes: medicine policy and regulations, industrial and related polices, trade, procurement and supply management and innovation, technology and IP policy; and

- national group discussions where participants from the private sector, regulatory agencies and industrial development agencies from the six EAC partner states sat together to re-examine all key issues from their countries perspective.

During the open plenary discussion, the experience of Ghana, the bioequivalence requirement adopted by the Harmonized Medicine regulation of EAC, government procurement, import regulation and the operationalization of the Common Market Protocol are among the key issues that attracted the attention of most of the participants. Directors of FEAPM, Mr. Issah Hango (Head Production & Planning, Shelys, Tanzania), Mr. Pierre Claver Niyonizigiye (Director of Administration and Legal Affairs, SIPHAR, S.A, Burundi), and Dr Rogers Atebe, (Regal Pharmaceuticals, Kenya) outlined their comments and specific recommendations on the implementation Plan of Action and related initiatives.

FEAPM had conducted a study visit to Ghana in March 2014. FEAPM observed that the annual growth rate of the industry in Ghana has been over 10%. All of the registered companies attributed the positive developments to the measures introduced by the Government of Ghana, including corporate tax exemption, funding local pharmaceutical manufactures, import restriction, VAT exemption and duty free imports of 66 of 200 basic materials required for production, and up to 15% price margin preference for local products in government procurement against the lowest offer from exporters.

Mr. Niyonizigiye, compared the incentives offered by EAC Partners. Burundi offers 15% price protection/preference margin for locally manufactured medicines and it offers to provide the same preference for other EAC producers subject to reciprocity. In terms of tax and customs incentives, he stated that as of 1 July 2015 relevant inputs attract 18% VAT upon importation. Kenya and Burundi provide for tariff and VAT free importation of raw material and packing material, but VAT is levied on locally procured products. Ugandan approach is to reimburse all VAT collected from importation of raw material and packing materials, which are also exempted from tariff.

The EAC Medicines Regulation Harmonization is expected to improve access to regional market, provide opportunity for a better utilization of regional manufacturing capacity, and incentivise further investment as well as promote efficiency in terms of medicine evaluation and registration, reduction of time spent in multiple GMP inspection. However, currently there is a lack of a recognition framework for existing GMP certifications, and the incentive for the regional market is affected by the fragmentation of drug regulations at national level and payment of multiple fees. In addition, the EAC Medicine Regulation harmonization poses serious concerns for pharmaceutical manufacturers in terms of the cost of implementing guidelines especially regarding the bioequivalence study requirement for all products.

With respect to the utilization of TRIPS Flexibilities the main bottleneck has been the lack of domestication of TRIPS flexibilities in all EAC Partner States and lack of incentives to prompt utilization of TRIPS flexibilities. Addressing the anti-counterfeiting issues in

pharmaceutical sector, Mr. Biadgleng compared the role of medicine regulation and IP protection. IP focused anti-Counterfeit initiatives, for example, in Kenyan, will focus on protecting the interest of IP right holders compared to medicine regulation that focus on protecting consumers from fake, substandard, adulterated, or otherwise un-authorized medicine, irrespective of the status of IP protection.

5. Recommendations: the way forward for regional policy coherence in EAC

Following the presentations and open discussions participants were requested to identify what struck them most in trade, medicine regulation, industrial policy and innovation and technology from the international, regional and national deployments.

1. In trade policy, the experience of Ghana and ECOWAS that were highlighted by the participants are: the medicine regulatory agencies' ability to participate in trade policy making, in particular the use of specific/restricted tenders for local manufacturers; ECOWAS level cooperation for control of counterfeit, substandard and fake medicine; and, importantly, the ability of Ministry of Health Ghana to establish a negative list of medicines for importation, with the corresponding development at ECOWAS level
2. In the area of industrial policy, the amendment of the Ghanaian Trade Development, Agriculture and Industrial Fund to include funding for local pharmaceutical investment, the creation and implementation of incentive frameworks, such as VAT exemption, price regulations, preferential procurement, and allocation of land for pharmaceutical investment were highlighted.
3. For innovation, technology and IP policy - the lack of legislative formwork and policy to support research for the development of new medicinal products, and the insight on the use of reverse engineering to undertake product development were highlighted by participants;
4. Finally, in medicine policy, Ghana's proposal for establishment of centre for pharmaceutical and bio- equivalence research was considered exemplary.

Throughout the workshop, participants were raising the current challenges for the pharmaceutical sector development in EAC. There are a number of regional laws, policies that are yet to be developed and implemented, including harmonization of health policy, harmonization of medicine regulations relevant for research and clinical trials, development of a pooled regional procurement mechanism and harmonization of procurement regulations. Harmonization of anti-counterfeiting laws and broader trade policy issues is also required. Health insurance schemes can benefit from a better coordination and financing mechanism at regional level.

Among the existing regional laws and policies, implementation is said to be inadequate with respect to Article 35 of the Common Market Protocol that envisaged non-discrimination in government procurement for regional suppliers and the domestication of TRIPS flexibilities, preferably emulating the experience of Zanzibar. There are also emerging challenges arising

from the medicine regulation harmonization, since there is no capacity in the region to undertake bio-equivalence studies. The waiting period for registration of medicine, number of GMP inspections, fees for national medicine regulatory agencies, coupled with weak implementation of preferential procurement are practical problems manufactures face at national level.

Some participants underscored what they consider a more serious challenge for regional cooperation than the ongoing efforts for harmonization of policies and regulations. The EAC partner states are at various levels of development, financial, administrative and regulatory capacity, human resources and technological capacity, understanding of the sector and the political commitment to support the industry. The factors affecting industrialization, such as logistic, transportation and energy supply also vary among the partners. The underlining economic and capacity differences among partner states can affect the speed and scope of progress on regional policy initiatives.

Based on the identification of the challenges and opportunities, as well as the important lesson from the experience of other regions, participants provided various recommendations that in their views can provide the means to address regional policy coherence to promote access to medicine and local production of pharmaceuticals. The recommendations are summarized below.

A. Enhancing the EAC Level Coordination

To further strengthen the EAC level coordination:

- UNCTAD and patterns to undertake comprehensive EAC level policy coherence analysis, taking into account the developments at national level;
- The EAC level policy analysis can be presented for Sectoral committees and other organs of the EAC.

B. Political commitment, regional-national dimension, and institutional arrangement for policy coherence:

Despite the broad initiatives of EAC, participants underscored the problem of commitment and awareness of the Plan of Action at national level as well as the development and implementation of national action plans. The recommendations, in this regard, include:

- strengthening political leadership and commitment;
- fast tracking the national level implementation of regional policies;
- alignment of regional and national policies and strategy; and

- national Steering committees to be fully operation and to, annually, report to the EAC Sectoral Council on Trade, Industry, Finance and Investment.

C. Incentives: tariffs and procurement

Fiscal incentives, government procurement, the implementation of the Common Market Protocol, the amendment of the CET, are the measures most debated and elaborated during the Workshop. The experience of West African region and Ghana as presented during the workshop was well received. Participants, especially from the private sector, called for implementation of an East African incentive package inspired by the experience of Ghana. In this respect the participants, identified that:

1. Develop a regional Essential Medicines List – as a basis for priority area for medicine regulation harmonization, processing of medicine evaluation and registration, regional policy for preferential procurement and all other incentives;
2. Government pharmaceutical procurement:

    - should be treated separately, from the general government procurement rules;
    - should be expanded to include at least 20% higher price compared to the lowest offer from an international bidder;
    - adopt a regional drug procurement policy which aims at buying locally and increase of market share of local producers, and considering the common market framework, establish a uniform preferential margin (preferably 20%) for all regionally produced medicines and medical devices and apply the preferential procurement on a non-discrimination basis according to Art. 35 of the Common Market Protocol.

3. Amend the Common External Tariff:

    - to fully exempt customs duties on raw material and packing material;
    - ensure customs classification of medicines according to the production capabilities of regional manufacturers;

4. Review the internal fiscal and non-fiscal policies and laws for exemption of local taxes on imported and locally sourced inputs;
5. Establish permanent regional and national public-private dialogue on customs and fiscal reforms.

D. Regulations and GMP capacity

The second category of issues that attract much debate concerns medicine regulation and the technical capacity of the manufacturers to meet the standards. Four recommendations received wider consensuses in this area:

- Resolve outstanding harmonization issues and draw up procedures for mutual recognition framework of GMP inspection and certification, and product registration;
- The WHO – GMP Road Map being implemented in Kenya should also be implemented in other EAC Partner States;
- The implementation of the harmonized medicine regulation, poses challenge due to the capacity constraints of local producers. In this regard, it is important to agree on a transitional arrangement;
- To address the capacity constraints on part of manufactures, participants also called for further support towards GMP-improvement; and sustainable funding for capacity building activities.

As part of incentives for local pharmaceutical manufacturing, participants have recommended developing a regional Essential Medicines List.

E. Pertinent Flanking issues

Participants raised a number of issues, primarily, technology and investment related, but also as framework for a long term development of a pharmaceutical sector that contribute to access to medicine,

- Mainstreaming innovation, research and development within regional pharmaceutical industry through support for technology transfer, business linkages, promotion of foreign investment, private–public partnerships (PPPs) and linkages between manufacturers, academia and research institutions;
- Although there have been a number of developments in implementing TRIPS flexibilities in EAC region, Tanzania and other countries need to domesticate TRIPS flexibilities important for access to medicine.

F. The way forward for national policy coherence in EAC Partner states

Participants also engaged in a country group discussion to debate and identify the means to address current challenges for local production of pharmaceuticals and access to medicine in their respective country. The challenges, recommendations, and who should be involved, in health, industrial, trade, and innovation and technology identified by the national groups is provided as Annex I-V of this report.

1. A common theme among the national group discussion is the low level of implementation, or absence or inadequacy of existing policies and laws, with weak institutional capacity;
2. Other notable similarity concerns the request by participants that the Ministry of Finance of their respective countries needs to be involved to address the constraints for policy choices and implementation. Typical Ministry of Finance policy on revenue

generation affects tariff and VAT policies, while the policy on the expenditure side will affect budget allocation for government agencies and health facilities that implement policies relevant for the sector's development or for procurement of pharmaceuticals;

3. Again participants identified improving preference in government procurement as one key issue for the development of the sector, along with other tax incentives. While many suggested to increase the preference margin to 20%, Kenyan participants opted for a reservation of a certain percentage of expenditure by procurement agencies for local procurement;
4. For Rwanda and Burundi, there is a need to establish autonomous NMRAs;
5. Development of industrial policy, re-allocation of investment authority from Ministry of Finance to Ministry of Industry are outstanding issues for Burundi, among others;
6. Ugandan participants identified the need to undertake monitoring and evaluation of medicine, industrial and trade policies. In addition, Uganda needs to develop industrial parks with the appropriate facilities;
7. Participants from Burundi, Tanzania and Uganda also underscored the need to facilitate financing in pharmaceutical investment, preferably through the establishment of a fund;
8. Capacity building is necessary in pertinent policies for pharmaceutical production in Rwanda due to low level of understanding of the sector;
9. Tanzanian participants called for:
    a. 2.5% of VAT to be allocated for health insurance coverage (preferably credited to a dedicated account managed by the insurance fund i.e. NHIF);
    b. Effective engagement of Tanzania's National Coordination Committee for the EAC Plan of Action with Ministries of Health:
    c. Effective management of the preferential procurement mechanism i.e. Prompt disbursement of payments by MSD;
    d. Domestication of TRIPS flexibilities;
10. Kenyan participants identified recommendations that have regional dimension, in particular, the establishment of regional essential medicine list, phased approach to implementation of bio-equivalence studies, establishment of tariff classification of medicines for import (negative list), and regional price preference scheme for companies with WHO-GMP. In addition, they recommended
    a. for development of a national IP policy and strategy that promotes innovation as well as public health;
    b. Adoption prescription policy that requires the use of generic names.

Annex I: Burundi

Recommendations for the Improvement of Policy Coherence towards Access to Medicines

I. Health Policy		
Challenges	**Recommendations**	**Who do we have to involve**
1. Low level of implementation of the Health Policy	The Ministry of Health to put in place mechanisms for implementation of the Policy	- Ministry of Health, Ministry of Finance, Ministry in charge of social security, Ministry in charge of local government, Technical and Financial Partners
2. Low level of implementation of the subsequent pharmaceutical policy	The Ministry of Health to put in place mechanisms for implementation of the Policy	-Ministry of Health, -Ministry of Finance, Ministry in charge of social security, Ministry in charge of Trade and Industry, The pharmaceutical manufacturers, Technical and Financial partners.
3. National semi-autonomous regulatory authority not yet established	The ministry of health should establish national medicines regulatory authority	-President Office, -Ministry of health, -Ministry of justice, -Ministry of finance
4. Low Price control of pharmaceuticals	The Ministry of health in collaboration with the Ministry of Trade should put in place price control mechanisms	-President Office, -Ministry of health, -Ministry in charge of commerce and Industry, -Ministry of Finance
5. The policy does not address promotion of pharmaceutical production	The ministry of health should address promotion of pharmaceutical production in the policy	-Ministry of health, -Ministry in charge of trade and industry, -Ministry of Finance
II. Industry policy		
1. Absence of national industrial policy	1. Development of National Industrial Policy;	.Ministry in charge of Commerce and Industry, Ministry of Finance, . Ministry of Health; Ministry of environment, Chamber of Commerce and Industry.
2. Some aspects regarding investment facilitation are covered by the National Investment Code which is the responsibility of the Investment Authority, which is under the Ministry of Finance	2. The Investment Authority should be under the Ministry of Trade and Industry	.President Office, .Ministry of Commerce and Industry, . Ministry of Finance,
3. Only one pharmaceutical	The Government to put in place more incentives	.President Office, .Ministry of Commerce

manufacturer	measures particularly for the Pharmaceutical Industry, including facilitation of access to capital	and Industry, . Ministry of Finance,
Trade policy		
1. Incoherence between trade policy and health policy with regard to access to medicines	There should be concertation between ministry of trade and ministry of health for addressing the issue of access to medicines	President Office, Ministry in charge of trade and industry, Ministry of health Ministry of finance
2. High rates of customs duties	Burundi and EAC other Partners States should amend the ECT	EAC Ministries in charge of finance EAC Secretariat
3. High rates of internal taxes	Ministry in charge of finance should undertake fiscal reforms	Ministry of Finance
IV. Science, technology and innovation		
1. WTO TRIPS flexibilities not domesticated	The government should domesticate TRIPS flexibilities	.Ministry in charge of trade and industry, Ministry of health, Ministry of justice, Civil society organizations.
2. Low level of awareness of the TRIPS flexibilities in both public and private sectors	Ministry in charge of trade should sensitize the public and private actors on TRIPS flexibilities	Ministry in charge of trade and industry, Technical and financial partners

Prepared by: Pierre Claver NIYONIZIGIYE, Anitha NSHIMIRIMANA, and Bonaventure NYABENDA. Kampala 23rd September, 2015

Annex II: Uganda

Challenge	Recommendations	Who do we have to involve
Medicine policy		
The policy is not fully implemented	Engage stakeholders to do monitoring and evaluation to provide insight on how best to implement	NDA MOH, MFPDA, OPM
Policy does not promote new and upcoming innovators and entrepreneurs	Formulate mechanisms of supporting local manufacturers e.g. research, incubation	Ministries; finance, health, trade and industry
Limited funding for inspection and surveillance	Lobby for increase of funding for inspection and surveillance	NDA, Finance, Health
Lack of capacity financial and non-financial to implement policy	Undertake capacity building for policy makers	
Industry Policy		
Limited policy implementation	Undertake monitoring and evaluation to give insights on how best to implement	OPM, MTIC, MFPDA,
Limited infrastructure for promotion of local manufacturing	Service industrial parks with facilities that promote industrialization	UIA, MFPDA, MTIC, OPM
Lack of Political support to prioritize local manufacturing	Lobby and sensitize to gain political support	MTIC, MFPDA, OPM
Lack of fund to promote local manufacturing	Provide for a fund to promote local manufactures either through loan	MTIC, MFPDA, OPM
Low number of manufacturers (9) and underutilization of capacity 40%)	Undertake evaluation monitoring to formulate strategies	MTIC, MFPDA, OPM
Trade Policy		
Influx imported medicines	Review trade policy to increase share of local manufactured medicine	MTIC, MOH, MFPDA, NDA, NMS
Limited awareness of Buy Uganda, Build Uganda	Undertake sensitization of stakeholders	MTIC, MFPDA, MOH
Lack of capacity to implement the policy	Undertake capacity building programs	MTIC, MFPDA, OPM

Annex III: Rwanda

Challenge	Recommendations	Who do we have to involve?
Medicine Policy		
Fragmented regulatory functions in different institutions.	Establishment of Semi-autonomous regulatory authority with all regulatory functions	Ministry of Health, Rwanda Biomedical Centre, Ministry of Public Service and Labour, Prime Minister's Office
Lack of required skills to perform all regulatory functions	Development of capacity building programs	Ministry of Health, Ministry of Labour, in partnership with Stringent Regulatory Authorities
Lack of enough financial resources	Allocation of enough budget to implement regulatory activities	Ministry of Finance and Ministry of Health
Industrial Policy		
Lack of required skills to implement the industrial policy	Development of capacity building programs	Ministry of Trade and Industry, Ministry of Education (Vocational Trainings) , and Ministry of Health
Lack of enough of sufficient resources for full implementation	Allocation of enough funds from the government	- Ministry of Finance
Lack of specific incentives to promote pharma industry	Design specific incentives to promote the pharmaceutical industry	Rwanda Development Board, Ministry of Finance and Ministry of Trade and Industry
Lack of clear coordination between the Ministry of Industry and Health regarding the manufacturing of pharmaceuticals	Development of clear coordination mechanism	Ministry of Industry and Ministry of Health
Trade Policy		
Lack of required skills to implement the Trade policy	Development of capacity building programs	Ministry of Trade and Industry, Ministry of Education (Vocational Trainings) , and Ministry of Health
Lack of enough of sufficient resources for full implementation	Allocation of enough funds from the government	- Ministry of Finance
Low preference rates (10%)	Increase the preference rates to at least 20%	Ministry of Finance, Ministry of Trade and RDB
Innovation, Technology and IP Policy		
Low level of awareness on TRIPS flexibilities in private sector	Awareness campaign on TRIPS flexibilities	Ministry of Trade and Industry, Research Institutions and Rwanda Development Board
Lack of enough budget to support Researchers and academic institutions	Allocation of enough budget to promote innovation	Ministry of Finance , Ministry of Trade and Industry and Rwanda Development Board
Challenge	**Recommendations**	**Who do we have to involve?**
Medicine Policy		

Annex IV: Tanzania

Challenge	**Recommendations**	**Who do we have to involve?**
Medicine Policy		
Funding for health insurance	1. Use of 2.5% of VAT for health insurance coverage (for effectiveness there should be a dedicated account managed by the insurance fund i.e. NHIF)	2. Ministry of Finance 3. Tanzania Revenue Authority 4. Ministry of Health
Over dependence on imports	5. Effective implementation of a 20% preferential procurement for locally manufactured products	
	3. Medicine policies should also include other provisions that promote local pharmaceutical production (tax incentive, import classification)	
	4. Effective engagement of Tanzania's National Coordination Committee for the EAC Plan of Action with Ministries of Health, Finance and the National Health Insurance Fund (NHIF)	
Industrial Policy		
1. Adoption and implementation of incentives frameworks for supporting local pharmaceutical manufacturing : o Vat Exemptions; o Price Control; o Preferential Procurements.	1. Industrial policies should be reviewed to articulate specific provisions that promote local pharmaceutical manufacturing (tax incentive, import classification and preferential pricing).	o Ministry of industrialization o Ministry of Finance o Tanzania Revenue Authority (TRA) o Ministry of Health.
2. Lack of coherence between regional and national strategies e.g. Regional strategy provide for specific Incentives for promoting local pharmaceutical production while national strategy does not.	2. Effective engagement of Tanzania's National Coordination Committee for the EAC Plan of Action with Ministries of Health, Finance and the National Health Insurance Fund (NHIF)	
Trade Policy		
1. The 15% preferential pricing is not adequate to support local pharmaceutical manufacturers	1. Effective management of the preferential procurement mechanism i.e. Prompt disbursement of payments	• Public Procurement Regulatory Authority (PPRA) • Tanzania Revenue

2. Implementation of procurement policy on procuring from local pharmaceutical manufacturers is hampered by excessive delays in remitting payments.	2. Review of preferential pricing rate to 20%	Authority • Ministry of Finance • Ministry of Health • Ministry of Industrialization • Local Pharmaceutical Manufacturers
Innovation, Technology and IP Policy		
1. Lack of Fund to support local manufacturers, research and academic institutions.	1. Need to establish a fund that will support local manufacturers, researchers and academia. This fund should be managed by the Commission for Science and Technology (COSTECH)	• Ministry of Finance • Commission for Science and Technology (COSTECH) • Ministry of Industry and Trade • Tanzania Industrial Research Development Centre (TIRDO) • Business Registration and Licensing Agent (BRELA)
2. Lack of incentives that would encourage innovation, investments or technology transfer.	2. Effective engagement Tanzania's National Coordination Committee for the EAC Plan of Action with Ministries of Health, Finance and Policy Makers.	
	3. Non-domestication of TRIPS flexibilities in main land Tanzania	

Annex V: Kenya

Challenge	**Recommendations**	**Who do we have to involve?**
Medicine Policy		
No regional EML, and no updated national EML	Regional EML National EML, updated National Formularies, Institutional Formularies. Promote the use of the established list, procurement, healthcare providers, investors)	MOH (relevant department, NMRA) NMA(FKPM)
Bioequivalence [BE] requirement	Regional EML Phased approach to implementation of BE and stakeholder involvement	NMRA) NMA(FKPM)
Recognition of International GMP Certification	Local NMRA to be involved in all international GMP inspections	NMRA NMA(FKPM)
Medicines Policy favors imports over local production	Establish balance of interests; promote local production for sustainable access (imports to be secondary)	MOH MOI&ED NMA(FKPM
Local brands not promoted	Generic prescribing should be promoted	MOH (professional boards) Professional associations (KMA, PSK, KDA, etc)
Industrial Policy		
Unfair competition from imports (export subsidies schemes at source)	Establish classification of medicines for import (negative list)	MOH (NMRA) MOI&ED MOF
Incentives package unclear	Develop incentive package specific for local pharmaceutical manufacturing	MOH MOI&ED MOF NPMA Development partners (GIZ, UNCTAD, UNIDO, WHO)
Trade Policy		
Is WHO-PQ a trade barrier?	Regional companies who get WHO-GMP should be allowed to participate in international bids for medicine supply, in the regional Price preference scheme for WHO-GMP status companies	MOH KEMSA MOF [PPOA]
International procurements agencies not responsive to WHO-GMP	Ditto	ditto
Price preference in public	Implement and enhance to	MOH

procurement under PPDA not implemented	higher levels; and escalate to the region	PPOA KEMSA
	A minimum % say 40-70% of public procurement should be reserved for local manufacturers(upscale to regional)	Ministry of Finance (PPOA) Ministry of Health KEMSA
Innovation, Technology and IP policy		
TRIPS flexibilities not exploited	Domesticate the TRIPS flexibilities in national laws	Cabinet Judiciary MOH MOI&ED KIPI
	Promote awareness creation at all levels	Ditto
Kenya's Science, Technology and Innovation Policy and Strategy, Science & Technology Act 1977 and Vision 2030 should be reviewed to support innovation in biotechnology in the pharmaceutical manufacturing sector	Develop a national IP policy and strategy that promotes innovation as well as public health	Ditto

Abbreviations [local]

EML Essential Medicines List
FKPM Federation of Kenya Pharmaceutical Manufacturers
KDA Kenya Dental Association
KEMSA Kenya Medical Supplies Authority
KIPI Kenya Intellectual Property Institute
KMA Kenya Medical Association
MOF Ministry of Finance
MOH Ministry of Health
MOI&ED Ministry of Industrialization and Enterprise Development
NMRA National Medicines Regulatory Authority
NPMA National Pharmaceutical Manufacturer's Association
PPOA Public Procurement Oversight Authority
PSK Pharmaceutical Society of Kenya

Annex V: List of Participants

Country	Title	First Name	Last Name	Affilation
Civil society	Mr.	Bora	Lichanda	
National Focal Points-MRH Project				
Burundi	Mr.	Nyabenda	Bonaventure	National Medicines Regulation Officer, Directorate of Pharmacies, Medicines and Laboratories, MSPLS, Brundi
Rwanda	Mr.	Alex	Gisagara	EAC NMRO
National Focal Points-Industry				
Burundi	Ms	Anitha	Nshimirimana	Advisor to the Diratorate General of Industry, Ministry of Trade, Industry, Posts and Tourism
Rwanda	Mr.	Gasore	Olivier	Services Industry Development Policy Specialist, Ministry of Trade and Industry
Tanzania	Ms.	Caroline	Lyimo	Industrial Engineer, Ministry of Industry and Trade.
Kenia		Emmanuel	Allenga Makketi	Association of manufacturers
Uganda		Deo A	Byaruhanga	Ministry of Trade Industries and Cooperatives
Private Sector				
Burundi	Mr.	Pierre Claver	Niyonizigiye	Director of Administration and Legal Affairs, SIPHAR
Kenya	Dr.	Rogers	Atebe	Director Universal Corporation Ltd
Tanzania	Mr	Issa	Hango	Head Production & Planning, Shelys
Tanzania	Ms.	Michelle	Maungu	Project Manager, Secretariat, FEAMP
Uganda	Mr.	Michael	Maynard	Business Development Manager, Cipla (CQCIL), Chairman of Uganda Pharmaceutical Manufacturers Association (UPMA)

East African Community Secretariat Experts				
Tanzania	Mr.	John Patrick	Mwesigye	Senior Health Officer (MRH) East African Community Secretariat
	Mr.	Willy	Musinguzi	Principal Standards Officer EAC
Tanzania	Ms	Jennifer	Gache	Senior Industrial Engineer
ECOWAS/WAHO				
Ghana	Mr.	Kwabena	Asante-Offei	Executive, Secretary of West African Pharmaceutical Manufacturers Association (WAPMA) and the Pharmaceutical Manufacturers Association of Ghana (PMAG)
Press				
	Mr.	Muheebwa	Hillary	Contributor Intellectual Property Watch
Medicines and Products inspection				
Tanzania	Mr.	Adonis	Bitegeko	Manager Medicines and Complementary Products Inspection and enforcement TFDA