Report of the High-Level Stakeholder Meeting on:

The AfCFTA: Opportunities for pooled procurement of essential drugs and products and local pharmaceutical production for the continent

Held on Thursday 21 November 2019

At the United Nations Conference Centre Addis Ababa, Ethiopia

African Union

United Nations
Economic Commission for Africa

ideas for a prosperous Africa

INTRODUCTION

The United Nations Economic Commission for Africa (ECA), Government of Seychelles-representing Small Island Developing States (SIDS), African Union Commission (AUC) and the Intergovernmental Authority on Development (IGAD) convened a high-level Stakeholders meeting titled "**AFCFTA: Opportunities for pooled procurement of essential drugs and products and local pharmaceutical production for the continent**" on the 21st of November 2019 at the United Nations Conference Center, in Addis Ababa. The initiative is a contribution towards the achievement of the global 2030 Agenda Sustainable Development Goals (SDGs), the African Union's Agenda 2063 aspirations, and operationalization of the African Continental Free Area (AfCFTA) and the Pharmaceuticals Manufacturing Plan for Africa (PMPA) by ensuring that private sector and public sector collaboration yield tangible results.

The AFCFTA-Anchored Pharmaceutical project aims to address socio-economic-related challenges facing African member countries relating to access to equitable, safe and affordable medicines and the creation of fiscal space to the African Governments given the emerging trend of rising government debts. The project has a three strand approach: the facilitation and advocacy of local production of maternal and child care medicines and products; pooled procurement of the same in Small Islands States and countries that include Seychelles, Madagascar, Comoros, Mauritius, Djibouti, Eritrea, Rwanda, Sudan and IGAD anchored by Ethiopia and Kenya; and ensuring quality standards of medicines and products with the support of the AUC Agencies.

The overall objective of the meeting was to seek buy-in and gauge political will of the African Ministers of Finance and Health of the targeted countries and create a platform for dialogue with relevant private sector stakeholders for a better understanding of the landscape and market constraints on the supply side. Furthermore, the high-level stakeholders meeting aimed at:

1. Facilitating a platform for concrete actions that will improve access to safe and affordable essential medicines in maternal and child care medicines and products utilizing pooled procurement frameworks as well as catalyzing local production in Africa by leveraging on the PMPA and harnessing high-level political commitment and workable solutions;
2. Providing an opportunity to share lessons learned from other regions, share knowledge, actively engage and network with intra-African actors within the health sector for the successful implementation of the AFCFTA-Anchored Pharmaceutical pilot project for the attainment of SDGs and Agenda 2063 aspirations;
3. Seeking guidance on how to leverage on the AfCFTA for pooled procurement and local production of selected and identified pharmaceutical drugs and products; and ensuring quality standards of identified medicines and products for pooled procurement and local production.

A roadmap for implementation of the recommendations emanating from the meeting was also considered.

The High-Level Stakeholders Meeting was convened in two parts. Part one was a high-level discussion of the Ministers of Finance and Ministers of Health as well as relevant government agency representatives of the targeted countries with the aim of seeking their buy-in on the AfCFTA-anchored Pharma Initiative; and part two was a dialogue between the private sector actors and stakeholders present, with the aim of encouraging a vibrant discussion and alignment on the way forward to ensure that the AfCFTA-anchored Pharma Initiative becomes a reality.

The concept note, programme of work, justification for the initiative and list of participants are

attached as Annex 1 -4.

MINISTERIAL SEGMENT: OPENING SESSION

Welcome remarks: Ms. Thokozile Ruzvidzo, Director, Gender, Poverty & Social Policy Division, United Nations Economic Commission for Africa

Ms. Ruzvidzo welcomed the participants and summarized the meeting objectives and expected outcomes. Acknowledging all partners as well as the UN family, she emphasized the importance of the initiative noting that this meeting was convened as part of ECA's mandate to deliver on Agenda 2063 and the 2030 Agenda for Sustainable Development.

Furthermore, Ms. Ruzvidzo highlighted the linkage between health and economic growth, and informed participants that this is one of the pilot projects anchored by the recently ratified AfCFTA. The initiative she remarked contributes to economically sustainable access to safe medicines and the realization of the Pharmaceutical Plan for Africa (PMPA), through localized manufacturing and pooled procurement at the same time ensuring quality standards of medicines.

In conclusion, Ms. Ruzvidzo reaffirmed ECA's commitment to turning Ideas into Action, and the importance of bringing together all stakeholders including the African Union Commission government, donor agencies, development partners and the private sector to create "the Africa we want" together.

Remarks by His Excellency Jean Paul Adam, Minister of Health, Republic of Seychelles also representing Small Island States

In his opening remarks, Minister Jean Paul Adam, expressed his gratitude to all partners for supporting the initiative and attending the meeting at short notice. He observed that such commitment highlights the importance of an engagement such as this one being convened. Reflecting on the establishment of the AfCFTA and the promises it makes for collective prosperity, and the recognition of health as a pillar for prosperity, he remarked, that Universal Health is essential for Universal wealth.

The Minister reaffirmed his commitment to making medicines more affordable and accessible, recognizing the role of free trade in addressing the constraints that many African countries are already facing. In highlighting the issues, he noted that Seychelles is the smallest country in Africa, and has the highest GDP in the continent. He further explained that the high GDP hides some vulnerabilities such as access and a high cost of medicines per capita as Seychelles is a small market for medicines, and remarked that all other small state islands also face this reality as well. The Minister shared that because of the country's population size, they are sometimes unable to get quotations from companies based on the small quantities required.

In order to address this problem, Seychelles had approached WHO Afro, which had undertaken a feasibility assessment for pooled procurement. He further shared that his country has reached out to other countries, to work on a positive list of medicines, which can be procured together. The minister also highlighted the importance of widening the base for pooled procurement, recognizing initiatives of RECs, and appreciating the approach as consistent with the AfCFTA's building block approach. The existence of similar successful practices in other parts of the world, like Latin America and the Caribbean was also cited.

Appreciating the platform created, the Minister stated that such platforms provide an opportunity to share information, avoid duplication and maximize benefits. Also emphasized was the importance of examining existing needs, while taking the future into account, and in doing so factoring limitations like finance. The Minister called on partners to come to agreement on what can be done, being practical yet ambitious. In addition, the Minister highlighted the importance of ensuring "African businesses are a part of the growth story," in order to guarantee that Africa does not remain in the "price taker" box. Placing emphasis on ratifying the African Union led African Medicines Agency (AMA), as critical, the Minister noted that it will pave the way for harmonization of standards and regulatory frameworks as well as necessary components for pooled procurement. The Minister further noted the importance of exploring innovative financing options such strategic funds, levies and bonds considering the paucity of domestic resources. In concluding, the Minister thanked all the partners and stakeholders and emphasized that this was part of the journey towards Universal Health Coverage.

Remarks by Her Excellency Lia Tadesse, State Minister, Ministry of Health, Federal Democratic Republic of Ethiopia

The Minister in her remarks thanked the organizers, and welcomed all participants to Addis, to discuss on the opportunities for pooled procurement of essential drugs and products and local pharmaceutical production for the African continent. She recognized the positive strides made in Africa, particularly in the health sector, attributing the same to the political will, commitment and partnerships made with development partners, as well as robust private sector engagement.

The Minister stressed that a platform such as the one being established will "lay the foundation for strong partnerships among countries, particularly with regards to improving supply chain management of medicines, thereby renewing Government commitment to ensuring the uninterrupted availability of pharmaceutical drug supplies and commodities for their citizens." Sharing Ethiopia experience of the health sector, the Minister remarked that Ethiopia's progress in developing its local manufacturing is anchored on the country's development of pharmaceutical industrial parks, and roll out of investment incentive schemes. She also shared an example of pooled procurement implementation in Ethiopia, which enabled the country to save US$130million on the procurement of essential drugs, and US$2.5 million on Malaria commodities annually. Furthermore, she stated that the initiative also allowed the country to get better price deals than the global fund both on HIV and Malaria commodities. In her concluding remarks, the Minister noted that such a practical example illustrates what can be achieved at a continental level and she assured the meeting participants that initiatives such as this one is a good start towards achieving a healthy and prosperous Africa, where good health is affordable and equitable.

Remarks by Her Excellency Amira Elfadil, Commissioner for Social Affairs African Union Commission

The Commissioner for Social Affairs of the African Union relayed greetings from the Chair Person of the African Union Commission to the participants and reaffirmed that the Commission recognizes this project as one of the steps to leveraging the environment created by AfCFTA. In her intervention on the linkages between the AfCFTA and the pharmaceuticals industry, the Commissioner highlighted that evidence shows that movement and displacement of persons is mostly intra-continental and includes skill based movement advocating that the Protocol of the Free

Movement of Persons should be part of the initiative. Furthermore, she expressed appreciation for the current AfCFTA momentum and the leadership of AfCFTA champion Niger's President Mahamadou Issoufou.

Additionally, the Commissioner called on all partners to push for the ratification of African Medicines Agency (AMA), which will promote the adoption and harmonization of medical products regulatory policies and standards, scientific guidelines, and coordinate existing regulatory harmonization efforts in the Regional Economic Communities and Regional Health Organizations. AMA will further provide regulatory guidance, scientific opinions and a common framework for regulatory actions on medical products, as well as on priority and emerging issues and pandemics. Updating the meeting on the ratification, she informed the participants that currently 7 countries have signed AMA and only 1 has ratified. There is a need for 15 ratifications for AMA to be operational and urged African Member States the need to demonstrate their commitment and do the needful.

Furthermore, the Commissioner called on the AfCFTA-anchored initiative to use the existing structures and building blocks to allow for synergies and effective use of resources. She appreciated the involvement of RECs in the initiative and informed the meeting that the AU institutional reforms call for some AUC functions to be moved to RECs who are considered to be the building blocks of the Union. The Commissioner further notified the meeting on the MOU signed between the AUC and WHO that prioritized three areas: advocacy on AMA for high-quality, safe and efficacious medicines; strengthening their collaboration with the African Union development Agency (AUDA)- NEPAD African Center for Disease Control, with a particular focus on emergency preparedness; and implementation of the agreement on universal health coverage. She also informed participants of discussions with African Development Bank (AfDB) to establish a fund for the local manufacturing of pharmaceuticals which also supports pooled funding.

In conclusion, the Commissioner expressed the need to consolidate the gains, to ensure that the gains accrue to the African citizens, to move towards Universal Health coverage and affirmed the AUC's commitment to the initiative.

Remarks by Representative of His Excellency Dr Workneh Gebeyehu, Executive Secretary, IGAD, Dr. Anthony Tirotich

Dr. Anthony Tirotich highlighted Intergovernmental Authority on Development (IGAD)'s mandate to support on cross boarder health, and hence the relevance of IGAD's involvement in the pilot project. He stated that Africa currently produces less than 2% of its medicine it consumes, and that this demonstrates the need to support local pharmaceutical manufacturers. He further informed the meeting that the region has up to 100 manufacturers, and that IGAD is planning on supporting manufacturers to comply with local regulations, and strengthen their production capacity. Moreover, Dr. Tirotich advised the meeting that there are opportunities for South-South cooperation within the initiative citing a case where Kenya supported Somalia in the procurement of multi-drug-resistant tuberculosis (MDR-TB) drugs.

In addition, Dr. Tirotich apprised the meeting that IGAD carried out a survey in June 2019 which showed that 21% of oxytocin injection samples tested did not meet quality specifications, implying that women who may need this product during childbirth may be exposed to substandard medicines which may not be as effective as a quality-assured product. Regarding the US Pharmacopeia support, IGAD is working on medicines quality control and quality assurance systems across the

region. Dr. Tirotich brought to the attention of the meeting the availability of resources within the region (e.g. Kenya has supported Somalia in the past) and the need for sharing of resources in our effort to improve access to affordable medicines and products. We can achieve economies of scale and IGAD has significant resources (~150million) committed to do so and the Authority has even developed a web portal for sharing information.

In conclusion, Dr. Tirotich called on all the Ministers of Health and Finance of pilot AfCFTA-anchored Initiative to address issues relating to regulatory environment which can potentially limit the success of this initiative and emphasized the need for a framework to guide the Initiative.

Remarks by Ms. Vera Songwe United Nations Under-Secretary-General and Executive Secretary of the Economic Commission for Africa

The Executive Secretary summarized the background on the initiative, recalling discussions to explore health-financing opportunities during the African Business Forum held in February 2019, and how ECA came to the realization that resources that need not be spent were being used. This discussion was anchored on the AfCFTA, which provided solutions to the supply chain and demand constraints being experienced in the Pharmaceutical sector by allowing Africa continent to bring "everything under one banner."

The Executive Secretary also cited figures on health in Africa to highlight why this initiative is important that included the fact that over 50% of children who die under the age of 5 are in Africa yet the continent is only 11% of the world population but it carries 25% of global illness with 75% of HIV/ AIDS patients being Africans. She acknowledged the work done by WHO and UNAIDS and Mr. Sidibé for his role in advocating for a people-centered approach to health and development to achieve social justice. The Executive Secretary also shared ECA's hopes to leap frog the initiative building on the AfCFTA momentum, and help countries free up resources that can be channeled towards school feeding programs, investments, and job creation.

The Executive Secretary further explained that the development of the AfCFTA-anchored Pharma Initiative project, championed by ECA, IGAD, and the Small Island Developing States (SID) also aims at mobilizing public and private sector partnerships to advance health outcomes and shape health markets in Africa. Utilizing a "three-strand approach", she explained that the Initiative is set up to manage pooled procurement of pharmaceutical products on the continent, facilitate local production and to ensure a sustainable safeguard of quality standards of medicines and products. This Initiative exemplifies how the AfCFTA can be operationalized.

Moreover, the birth of the AfCFTA-anchored Pharma Initiative presents the agreement's multi-sectoral approach by advocating for health and wellness sector as an input to inclusive and sustainable development. She stated that the Pharma Initiative is part of the AfCFTA's promise to transform Africa into a manufacturing hub and a leading exporter of manufactured products to the rest of the world.

On the issue of creation of the fiscal space, and using the space to ensure young girls get access to quality medicine, the Executive Secretary noted that ECA and its Partners wants to go one step further by illustrating that, "if Africa was to begin to produce and consume its own medicine, it will create 16 million jobs", that would mean, not only will more African children live past 5 years of age, but once the child is of age, he/ she will have job opportunities within the continent. For all this to happen, Africa needs to ensure that the drugs are standardized, and this is where AMA comes into play. She emphasized the importance of making sure pharmaceutical manufacturers are

certified, making the link between the initiative and AMA by stating that "just as much as this is about a pooled procurement, it is also about harmonization" and "competition tomorrow is not going to be about where we produce, it is going to be about certification". The Executive Secretary urged member states to ratify the AMA, reiterating its importance for the success of the initiative. The selection of the Horn of Africa and SIDs for the pilot was further justified stating the reasons taken into consideration included the size of the market of the potential manufacturers, existing initiatives within the region, as well as the high prices being experienced within Small Island states. She also stated the opportunities for scaling up of the initiative and looking into regions such Sahel and others upon completion of the pilot phase.

In closing, the Executive Secretary highlighted the business opportunities for private sector engagement, and re-emphasized the need to come together to turn Africa's development challenges into business opportunities leveraging on the AfCFTA. She concluded by stating that the significance of the AfCFTA's implementation serves as an invaluable platform for Africa to address its short-to-medium term structural deficiencies in the pharmaceutical industry. Through harmonized regional and national pharmaceutical regulatory standards, pooled procurement and manufacturing of pharmaceutical drugs and products, the AfCFTA will significantly contribute to Africa's ability to increase access to medicines and improve public health and economic development.

Remarks by the Honorable Christopher Bazivamo, Deputy Secretary General in charge of Productive and Social Sectors, East African Community and also a Former Minister

Mr. Bazivamo representing Ambassador Libérat Sezibera Secretary-General of the East African Community (EAC) highlighted that the EAC has provisions for Pooled Bulk Procurement, specifically, Chapter 21 (Article 118) of the EAC Treaty which advocates for; "development of a common drug policy which would include establishing quality control capacities and good procurement practices". He noted that recently, the council of ministers had made a decision on health priorities and that a manufacturing roadmap exists within EAC. There are currently 65 manufacturers in the community; the East African Community has improved the regulatory environment and harmonized regulations that can support this AfCFTA-anchored Initiative's pooled procurement process elements. He further informed the meeting that domestic production covers about 25 % of member State's needs, and the products portfolio coverage of about 66 % of the disease conditions. In conclusion, Mr. Bazivamo briefed the meeting that EAC targets to reduce its reliance on import from 70 % to 50 % and intends to have at least 50% of procurement come from the national medicine agencies. Furthermore, he stated that the EAC is committed to supporting the development of local industry and recognized that pooled procurement is one of the ways that can be used for industry development.

Presentation on the rationale of the AfCFTA-anchored Pharmaceutical Initiative by Stephen Karingi, Director, Regional Integration and Trade Division, United Nations Economic Commission for Africa

A presentation on the rationale of the project and making the case for the AfCFTA-anchored pharmaceutical initiative was made by Stephen Karingi. As an introduction to the above subject he reminded the meeting that health is central for productivity and that health and the pharmaceutical sector is a low hanging fruit for Sustainable Development given that the global pharmaceutical

market is expected to reach $259 billion by the year 2030 , and it can create up to 16 million jobs in Africa.

Mr. Karingi emphasized that the AfCFTA-anchored pharmaceutical project aims to address access to safe, affordable medicines and other related socio-economic challenges faced by several African countries, while at the same time promoting sustainable social and economic growth through the realization of the Pharmaceutical Plan for Africa (PMPA). The rationale for the project was given as the mismatch between the demand and supply in the pharmaceutical industry in Africa. He cited that whereas 25% of global disease burden is in Africa, the continent consumes less than 2% of medicines it manufactures. Furthermore, the Director used statistics to illustrate the challenges faced within the continent and the increasing gaps between demand and supply.

Regarding Government risings debts trend, Mr. Karingi observed that on average medicines consume 45-60% of Africa's healthcare budget while 70% of the budget is spent on medicine imports with significant variation across countries. Concerning lost productivity, the Director stated that according to WHO estimates, 97 Million lives will be saved by reaching SDG goals and nearly 50% of Africans went without medical care in the past year. He further stated that the current tendency of global pharmaceuticals was to focus on non-communicable diseases, while Africa still deals with communicable diseases, which further exacerbates our ability to access medication. The Director also identified supply side constraints including market forces, limited access, unattractive markets for generic production and disincentives for smaller manufacturers. Mr. Karingi emphasized that the proposed framework is a game changer and a new approach to addresses both the demand and supply side constraints. Leveraging on the AfCFTA and the PMPA not only making sure people have access to affordable medicines but also ensures that medicines industries are capable of responding to the African needs and meeting evolving health burden.

In conclusion, Mr. Karingi reminded the meeting on the objectives of the Initiative; firstly; pooled procurement, secondly local production and thirdly quality. Giving further details, Mr. Karingi informed the meeting that countries of interest were: Seychelles, Madagascar, Djibouti, Comoros, Eritrea, and Mauritius, Rwanda anchored by Kenya and Ethiopia and IGAD due to a similar Initiative being undertaken by the REC, and products of interest were: Maternal, Neonatal and Child Health (MNCH); Amoxicillin DT and Oxytocin injection and commodities (as part of WHO essential medicines). Additionally, the Director advised the Meeting that the AfCFTA-anchored Initiative was now in Phase 3 which entails Engagement and Dialogue and Agreed Roadmap which is what the meeting is about, with phase 1 having been stakeholder identification, phase 2 -Best Practices and Case Studies similar initiatives.

DISCUSSIONS

Discussions were moderated by Her Excellency Amira Elfadil, Commissioner for Social Affairs African Union Commission. She called on each partner to present their case specific initiatives and ideas.

Dr. Said Fazul Ahamada, Director General, Ministry of Health, Comoros affirmed that this AfCFTA-anchored Initiative brings together efforts to reduce the costs of medicines and seeks to provide access to quality medicines. Furthermore, Dr. Ahamada emphasized commitment of the Comoros and said that the Ministry of Finance was also on board, and sought for support in advocacy.

Mr. Rashid Aman, Chief Administrative Secretary, Ministry of Health and Representative of the Cabinet Secretary, Ministry of Health, Kenya informed the meeting that Kenya as part of its devolution strategy is implementing pooled procurement as part of the journey to universal health coverage agenda, piloting the model in four counties. The country invested US$40Million in one year in the 4 counties, in the devolution programme and 70% of the funds was spent is on health service and technologies, which underscores the importance of the sector and percentage cost to government. For the success of UHC, Kenya needs to ensure affordable, and products that are of high standards.

Mr. Aman noted the benefits of pooling, which include bringing down the cost through economies of scale, ensuring the quality of products and uplifting local production of pharmaceutical. He said Africa has high out of pocket expenditure, which is dragging citizens down into poverty. As Kenya rolls out the UHC to all counties, it anticipates the cost will go up 4 folds, and hence the importance of trying to find ways to reduce cost and installing efficiencies in systems. Kenya's experience with KEMSA in improving its processes in pooled procurement and promoting local industry and facilitating national tenders for manufacturers can be shared with all countries. Additionally, Mr. Aman stated that Kenya has also learned the importance of creating a regulatory environment, that supports local manufacturers was important, given that about 40 of the 66 manufacturing firms in EAC are in Kenya. In this regard, Kenya intends to provide preferential treatment in procurement to its local manufacturers, visa vis national tenders for the production of essential medicines.

In conclusion, Mr. Aman reminded the meeting that there are various configurations in pooled procurement besides the international donor level. With that said, at the domestic level, there is still room for improvement. In Kenya for instance, faith-based institutions provide about 40% of the medicine, where they use pooled procurement. "We can start at the domestic level, move to the regional level and eventually observe pooling happening at the continental level'. To the excitement of the meeting he said "Kenya is fully committed, ready and will to support this initiative"

Dr. Gulshan Ramrekha, Deputy Permanent Secretary, Ministry of Health and Quality of Life, Mauritius advised the meeting that in July 2019, Mauritius hosted the pooled procurement conference for 6 countries in Africa. Admittedly, Mauritius faces constraints in procuring drugs, because of the small quantities required for a population of 1.4 million and the stringent quality requirements of their free health care system. He said this initiative provides a solution to this problem, by bringing together countries that have similar constraints. Mauritius does not manufacture any drug, but as part of providing solutions, Mauritius is currently setting up a pharmaceutical park, and aims to attract investors, which can supply both domestically and, to other African countries. He also said that pooled procurement is a welcomed initiative.

Ms. Nicole Mahavany, Pharmacien Inspecteur Ministry of Health, Madagascar stated that as part of the WHO study, Madagascar has shared their list of needed drugs. Like the other small island states, they use public fund to buy medicines, and purchases through a central procurement system but more often, they do not have access to qualified suppliers. She said Madagascar's approach is to try and attract private sector. In conclusion, she stated that Madagascar supports pooled procurement as part of the solution for Africa.

Dr. Gisagara, Representative of the Ministry of Health, Rwanda highlighted that many regional blocks have adopted pooled procurement to reduce cost of medicines and government spending. Examples include, the Pan American health organization, WHO and the Eastern Caribbean drugs service. He said the known benefits include improvement in access and procurement service,

addresses corruption in procurement, enhances standardization of products, rationalizes selection, and reduces cost. He, however, noted that pooled procurement can be a barrier to the development of a local production if there are no safeguards, and conducive regulations. Mr. Gisagara introduced social insurance systems as another innovative method that can help ensure viability and provide incentives. He highlighted that Rwanda, as the first one to sign and ratify AMA, is committed to the initiative.

Dr. Margaret Nqomondo, Representative of the African Union Development Agency–New Partnership for Africa's Development (AUDA-NEPAD) stated that the Agency is committed to supporting this initiative. She further highlighted to the meeting that there exists a 2005 Decision of the AU Summit on local production and the Agency has been promoting increased local production through working with the Regional Economic Communities. Additionally, the Agency is carrying out an exercise on harmonization of laws in order to support local production. Dr. Ngomondo emphasized that ensuring that the pharmaceutical market is sound and its products meet international standards is part of their mandate. Furthermore, the Agency has been working with RECs to ensure coherence and alignment of policies, regulations and international standards.

Additionally, Dr. Ngomondo stated that AU model provides framework to improve regulation and there is correlation between what AUDA is doing and what this AfCFTA-anchored Initiative intends to undertake. She stated that AUDA sees this Initiative as addressing the challenges faced by local manufacturers, and erasing of the notion that African pharmaceutical companies can never be as competitive in production as their Asian counterparts due to the size of domestic markets. AfCFTA reverses this argument by showing that we have the numbers and the markets. Moreover, she emphasized there is need for policy coherence and suggested that partners need to make sure that there is communication and coordination among stakeholders engaged in different initiatives. As such, they are advocating for the ratification of AMA.

Dr. Senait Fisseha, the Director of international programs at the Susan Buffet Foundation, expressed commitment to support the initiative and further emphasized the importance of Africa owning its data" in this initiative. She also said making AMA a reality and focusing on local production is key.

Representatives of United Nations Entities and Multilateral Organizations

UNFPA highlighted the need to undertake a demographic analysis is required to guide the Initiative as well as to address the economic dimensions and asked if it was possible to include family planning and reproductive health products. It was noted that UNFPA is a partner on the initiative.

UNAIDS has been working on access to medicines since the days of the HIV pandemic and contributed to the PMPA. Therefore, UNAIDS can share experiences with access to medicines and HIV for the past 10 years and the successes achieved. To the initiative, they will bring expertise and south-south cooperation in support of the AU. Furthermore, UNAIDS highlighted the importance of working with private sector and the role of advocacy and Intellectual Property Rights.

UNCTAD reiterated that Intellectual Property Rights (IPR) are at the core of UNCTAD's work as they look forward to supporting initiative. Additionally, there is need to support the regulatory authorities on issues of IPR more so as the AUC starts the Phase II of the AfCFTA negotiations in recognition in order to support African productive capacities in the right way. UNCTAD also emphasized the critical role experts in this meeting have in advocating affordable medicines and

ensuring the inclusion of specific elements to medicines.

UNDOC (Development Office of Coordination) highlighted that they are committed to ensure that at country level, members States participating in the initiative work with Resident Coordinators and that the initiative is included in the country programmes. The representative said coordination for implementation is critical for the success of this kind of an Initiative and that is why UNDOC has been created.

WHO noted the importance of: data in informing supply and demand for this AfCFTA-anchored Initiative going forward, the need to significantly reduce dependency on imported medicines by 2020, and to combat counterfeit drugs. Looking beyond pooled procurement, WHO implored Africa to change its narrative by utilizing its own data. Furthermore, there was emphasis on the importance of legislative frameworks to ensure that medicines included in this initiative benefit from the initiatives being given to manufacturers. In conclusion, emphasis on the importance of quality assurance in the production or pooled procurement of medicines and drugs, the need for capacity development in order to strengthen the players and to ensure the players that remain can meet quality standards, is crucial.

The Minister of Health from Seychelles commenting on the observation by Kenya on the need for coordination and avoiding duplication, stated that there will likely be some overlap, for example the initiatives among the RECs can prove this point. In pooled procurement, EAC has done something; SADC is still having a conversation but neither has a sufficient system. The way forward is for countries to commit to what they need, start from somewhere, and then move to partnering with big countries, creating building blocks towards a continental level initiative. He explained that experience from initiatives such as these shows that some start bottom-up, others top-down but in the end everyone meets in the middle and that is ok. He also noted the AMA's role and its importance and urged its ratification.

EAC's Dr. Bazivamo reminded the meeting that ECA is not promoting local manufacturing vis a vis pooled procurement keeping in mind global pharma. He expressed that the existing 65 producers in their region, most if not all, are working under their capacity because they cannot compete against big pharma. There is a need to develop a list of locally produced products that should be given preferential treatment and or be protected. However, he stated that there is need statistical evidence to identify the products that qualify whereas quality is also a qualifying criterion. In conclusion, he affirmed that when it comes to health there should be no compromise with quality.

Key Takeaways and Recommendations

(i). Explore financing mechanisms that African governments can tap into such Social bonds and strategic fund etc.

(ii). Take inventory of medicines listed on UN emergency medicines that local manufacturers can produce.

(iii). Institutionalize the aims of the initiative, namely: saving lives, creation of the fiscal space and actualization of the PMPA.

(iv). Coordination, clarity on roles and responsibilities and time lines must be developed.

(v). Develop a continental online platform for sharing of information to which NEPAD-AUDA is willing to provide.

(vi). Identify non-tariff barriers that affect the pharma sector.

(vii). Mainstream policies that encourage banks to start looking within countries and the African region. It is feasible and Africa can do it.

(viii). Identify existing manufacturing capacities and to strategize and document how to utilize them.

PUBLIC AND PRIVATE SECTOR DIALOGUE ON THE CURRENT LANDSCAPE AND OPPORTUNITIES

The session was a dialogue between the public and private sectors. Mr. Stephen Karingi, Director, RITD/ECA presented a brief recap of the ministerial session. The recap was followed by brief remarks by Ms. Vera Songwe and presentation of the Landscape on the State of Play and Lessons learnt from other Models and Initiatives regionally and Globally by Maraki Fikre, ECA and a brief report on progress on the Pharmaceuticals Manufacturing Plan for Africa was presented by the AUDA-NEPAD Representative Dr. Janet Byaruhanga.

Ms. Songwe called on the private sector to share their side of the story. She further explained the nature of the health sector as regressive; for example, "poor people spend good money buying bad drugs," and called on the private sector to help address this issue. She observed that AfCFTA will not be actualized if the private sector is not fully engaged. Helping alleviating Africa's health challenges such as the 50 % mortality rate of children under-five mortality in Africa are crucial. If this type of challenge continues, the continent will never attain its development aspirations and goals.

Additionally, Ms. Songwe highlighted the productivity loss emanating from people not attending work due to illness. This is further exacerbated by illicit, expired and counterfeit drugs that the continent continues to be exposed to. The fact that poor people spend good money buying bad drugs points to the need for the private sector to fill the gap and crowd the marketspace with the right, good, well-regulated drugs that will heal and not harm or kill the future generation of this continent, primarily its children.

Landscape on the State of Play and Lessons learnt from other Models and Initiatives regionally and globally

The presentation focused on highlighting key models, best practices and case studies globally and regionally across the three main objectives of the AfCFTA-anchored pharma initiative, namely, (i) pooled procurement models, (ii) examples of incentives and interventions that have successfully encouraged local manufacturing of pharmaceutical products and medicines and, (iii) quality assurance of medicines and products.

ECA's Dr Fikre, stated that pooled procurement models can be different from one context to another and usually it is a long process that start with simple data sharing and information process. The presentation highlighted the best practice of the Eastern Caribbean Drug Service (OECA) that has been in place for more than 20 years and across 9 countries and demonstrated an average of 40% cost savings to governments. Regionally, the presentation highlighted initiatives such as the

RECs' harmonization initiatives under the EAC and SADC and discussed the opportunities of leveraging on already started "building blocks" to then think of how the AUDA-NEPAD led AMRH and AMA can come in to scale such initiatives to a continental level. The presentation made the final points highlighting the key successful factors of any pooled procurement models which are sustainable financing mechanisms, good database and information of prices and suppliers and regional cooperation mechanisms that engage private sector solutions to build trust and confidence.

The second section of the presentation focused on summarizing how private sector partnerships across procurement, supply chain, logistics, technology, financing and skill development are important enablers to reduce the gap between demand and supply of medicines within the continent. Examples such as private sector engagement across logistics implemented in Ukraine and Uganda which showed significant cost savings and created a fiscal space for governments and channel the resources to other healthcare investments were highlighted. Further examples demonstrated ways to engage private sector industry players to meet public health outcomes across affordability, access to safe medicines.

The third part of the presentation focused on summarizing key strategies and interventions that have critical impact on stimulating the market on the supply side and the increase of local production of pharma across the continent. Measures such as the creation of industrial parks such as in the cases of Ethiopia and Ghana; or specific government regulatory reforms such as procurement policies that incentivize local manufacturers and others across key financial/investment support were described. Key opportunity lies in reflecting how to leverage on the PMPA strategy to facilitate business linkages and capacity building platforms to further accelerate local initiatives as this one being considered here.

Finally, the presentation identified the need for a clear coordination across the various regional agencies and initiatives started and emphasized the need to better understand each of the countries' needs and demands and the mechanism on how to consolidate the various elements, share best practices and engage the various private sectors in way that will address the initiative's overall framework and aims.

PHARMACEUTICALS MANUFACTURING PLAN FOR AFRICA

AUDA-NEPAD's Dr. Janet Byaruhanga, presented an update on the PMPA and the on-going harmonization of the regulatory environment initiative and further observed that these initiatives aims at reducing the time for approval of medicines. Additionally, Dr. Byaruhanga informed the meeting that regional initiatives such as ZAZIBONA was already bearing fruits of their work. Furthermore, she said the NEPAD-AUDA was also spending time on advocacy for the ratification of the AMA treaty which would significantly accelerate progress.

Dr. Byaruhanga informed the meeting that the local production mandate was given to NEPAD-AUDA during the height of the HIV pandemic and aimed to contributing to diversification and lowering the price of medicines. Moving forward, she advised that each country should have a strategy in order to assist countries effectively. NEPAD- AUDA has established a database on pharmaceuticals which can be leveraged on as part of the initiative, as well as some learning modules, and they are also in the process of establishing a funding mechanism that will enable SMEs to access technology and cheaper loans in support of the pharmaceuticals industry.

Ms. Arancha González, Executive Director, International Trade Centre gave a brief summary

of the presentation made and encouraged dialogue from both public and private sector. She added that this is an investment opportunity based on a competitive framework and the implementation of the AfCFTA. She reiterated AFCFTA as a game changer in the engagement of the private sector and accelerating towards UHC.

The **Minister of Health, Seychelles,** recapped the challenges SIDS face, such as the difficulties in getting quotations from suppliers due to the size of demand and challenges on product certification. He further stated that SIDs were stuck with heritage suppliers dictating the price, and unable to explore other service providers due to financial limitations. He called on the private sector to share their side of the story during this discussion.

Mr. Cheick-Oumar Sylla, IFC Country Manager for the countries Ethiopia, Eritrea, Djibouti, Sudan, South Sudan, highlighted the need for transparency with the private sector and emphasized that "Procurement is logistics and nothing else". He said IFC was willing to work with governments to explore what needs to be unlocked for the private sector to engage. He further noted that governance issues can be a limitation factor for progress and suggested public and private sector engagement on reforms, research and development on the types of products that are required as well as improved coordination, as critical going forward.

The Federation of African manufacturers stated that the reason why Africa is still importing 70% of its pharmaceuticals is simply because Africans don't want to buy from their local manufacturers. If lessons from India, China and Bangladesh are catalyzed, the local manufacturers in these countries reached the level they are because they had support which includes a domestic market's willingness to purchase from them. Furthermore, he noted that constraints facing local manufacturers are on many fronts including forex and finance. Therefore, for pooled procurement to be effective, harmonization of regulations is necessary.

CIPLA Uganda informed the meeting that they were the largest manufacturer in East Africa and has pooled procurement for ARV and Malaria, and donors are purchasing from them. On the Quality elements, CIPLA's representative mentioned that there were only a handful of manufacturers that have WHO pre-qualification in Africa. He said economies of scale that competitors have in other regions and standard and certification are among the issues that limit local manufacturers from going into the donor segment of the market. There is also the need to address the issue of pricing holistically - including security of supply provided by African manufacturers, employment, transfer and indigenization of skills. It is estimated that 40% of price goes back as revenue to the government in terms of different taxes. Tenders do not take this into account and therefore governments need to reflect on such kinds of elements if a sustainable-pooled procurement mechanism is to be implemented. Highlighting some of the benefits, he mentioned that 70% of CIPLA's sales are in Uganda.

PHARCO Corporation said they have seven manufacturing plants in Egypt and they produce 700 Million packs/year. He said access to information and data in terms of pooled procurement and accordingly ability of local manufactures to participate could be improved by a public website alerting companies of tenders. The main impediment is still the regulatory framework (both regulation and infrastructure). Preferential pricing strategies need to be explored as a way of growing the industry and reducing the price.

Crown Agent, highlighted the importance of harmonization and the need to take into consideration the fact that most of the imported medicines are not specific to African gene variants that influence

drug metabolism. Only 2% of genetic material used for pharmaceutical research comes from the African continent. For precision medicine to become a reality and a market in Africa we need more research and more data that is applicable to indigenous populations.

Other Private Sector actors

Other private sector actors observed that 65 % of our finance is from development partners which calls for reflections on the quality of medicines when they leave the market. This may call for support through incentives or subsidization.

It was also mentioned that a lot of manufacturing firms within the continent were working below capacity therefore there is room to scale up and reduce costs. Initiatives such as the AfCFTA-anchored Pharma Project can move 7-10% of expensive drugs towards 0 %. It was also noted that many Africa governments have great polices, which however, are yet to be implemented. This calls for political commitment which can be translated in actual policies and actions. On the issue of subsidized production, it was noted it can be feasible, as long as regulations are in place. If Africa does not produce locally, the continent will continue to run the risks of unhealthy populations. People, product, and pricing are the important factors in this area.

NEPAD-AUDA expounded on AMA regulatory framework explaining that it was set up in 2009 to address the issue relating to efficient registration of drugs and products. The aim is to reduce time and to serve as an incentive to local manufacturers that want to get into this space. This calls for the private sector to engage actively. AU remains committed to carry initiatives to understand market intelligence issues, establishment of a Pharma database resource, a learning management system with all the capacity required and training that can be taken online, Africa-pharma fund and the technical support necessary to avail cheaper loans (for SME's).

Trade & Development Bank stated that in order to finance a manufacturer, the bank first looks at the cash flow and the contracts in hand. In the case of pooled procurement, involving multiple countries, insurance may be needed to assure they can pay per contract. It was emphasized that before looking at setting up the manufacturing plants, there is a need to first explore what is already existing and apprised the meeting that in Egypt alone, there is over 150 manufacturing companies. The bank expressed its intention to explore opportunities to support the areas of up-grading quality standards.

Ms. Songwe, intervened to guide the discussion placing emphasis on the fact that ECA and Partners were advocating for private sector led industry and the envisaged fiscal space cannot be used for incentives but for job creation and productivity. She urged the participants to reflect on the question: "How can we make African Pharma market profitable, and African healthcare affordable." The AfCFTA should be used as a job creation engine. Considerations on local content will come with the implementation of the AfCFTA. There is a need to ratify the AMA which will help with standardization. Answering the question on the limited list of drugs, she said the medicines considered in this initiative are limited to mother and child only.

The Chairperson of SAGMA urged the meeting to note that not all countries can be hubs and have pharma manufacturers given that the sector is very specialized and requires specific skills. The chairperson also highlighted the role of the associations as bodies that monitor applicants interested in manufacturing pharmaceuticals as well as look into support on skills development.

The **Deputy Minister of Health, Kenya** reiterated that it is the duty of governments to maintain

balance between public good and economic development and in that regard price matters. On the issue of importance of creating a level playing field, and not treating all procurement as the same, it should be noted that the pharmaceutical sector is both an industrial and economic development avenue as well as life -saving industry and hence it should be treated differently. On incentives: Kenya gives up to 15% for local manufacturing in procurement but the government should also consider whether the import countries get subsidies, which may have negative bias against a level playing field. Finally, the Deputy Minister concluded by stating that, "let's see how Africa can build its local industries first and then maybe someday the continent can export, and the African governments and its private should aspire to such kind of development."

The Minister of Health, Seychelles stated that going forward, there are some commonalities between private and public wants, which are to procure a good product at an established, transparent price. Private sector is saying they can do more, but there are barriers and the barriers are in some instances, technical as well as regulatory- but one of the biggest barriers is scale. Pooled Procurement is about addressing economies of scale and rest of the challenges.

Furthermore, he noted the need to address the issue of information transparency. There is scope for financial institutions to bank roll a lot of these processes, but this must be accompanied by well-articulated laws, and government guarantees that companies can use to get loans. The two game changers identified were AMA (which implies a significant move towards a level playing field) and the AfCFTA which leverages on the non-tariff continental market.

THE WAY FORWARD

The presentation on the way forward describes the intended road map towards the operationalization of the initiative. The presentation highlighted two main strategic objectives namely savings lives and creating fiscal space in order to achieve 2030 Agenda and Africa 2063 goals. The meeting encouraged the project partners to continue engaging the various entities and stakeholder and conduct specific country level scoping missions under a phase 4.

The key agreements and recommendations that emanated from the way forward discussions included:

1. Consensus that the main goal of the AfCFTA-anchored Initiative is saving lives by ensuring equity in access to medicines and products especially for marginalized rural populations and women as well as safeguarding quality and sustainability of supply of pharmaceutical drugs and medicines;

2. Agreement that creating fiscal space for African governments can be contributed to from cost savings from efficiencies and affordability emanating from pooled procurement frameworks and facilitation of local pharmaceutical production on the continent. For the private sector, it is about ensuring an enabling environment for the private sector to bridge the gap in the health sector leveraging on the AfCFTA;

3. The two Game Changers for this Initiative were AMA which needs ratification for continental scale up and AfCFTA which is already in force and serves as both catalysts in getting countries commitments;

4. Agreement that ECA (as the Secretariat) makes a compilation of the state of play in the targeted

pilot countries, needs, constraints, strategic interventions, a roadmap, as well as a monitoring and evaluation mechanism for the implementation of the AfCFTA-anchored Pharmaceutical Initiative and recommendations arising from the meeting;

5. Agreement that since the AfCFTA and the Treaty Establishing the African Medicine Agency (AMA) are the game-changers for the African Pharmaceutical Initiative, ECA may use relevant platforms and engagements to assist member states to ratify the AMA;

6. Consensus that long-term leadership commitment and political will is vital for the success of the AfCFTA-anchored Pharmaceutical Initiative;

7. Agreement that over and above political will, there should be mobilization for investments into the sector through designing appropriate incentives and forging the necessary partnerships. This will also reduce the current unsustainable situation where most African countries are heavily reliant on donor funding;

8. Agreement that the issues of availability of as well as access to: quality data on the pharmaceutical industry, pharmaceutical production trends and patterns, pharmaceutical exports, pharmaceutical imports, price structures, pharmaceutical operations, pharmaceutical innovation initiatives, et cetera - is essential in the implementation of the Pharma Initiative. There is need for a comprehensive continental database. This should be complemented by the creation of digital platforms, websites and other online marketing initiatives by stakeholders operating in the pharmaceutical industry to allow for information sharing and transparency;

9. Agreement that with respect to funding pharmaceutical industry initiatives, public-private-partnerships (PPPs) are an enabler with international best practice facilitating knowledge and technology transfer;

10. Consensus that skills development and capacity building are key. There is need for massive investments in Research and Development (R&D) in local pharmaceuticals production and pooled procurement of medications in Africa in order to strengthen innovation and develop strategies that support the growth and development of the pharmaceutical industry. R&D will also assist to move towards the local production of pharmaceutical products that are suitable for Africans as opposed to over-reliance on procurement of medicines which does not address the continent's epidemiological changes.

CLOSING SESSION

Closing Remarks were made HE Jean Paul Adam Minister of Health, Seychelles. The Minister thanked all the participants for the quality contributions. He reemphasis that concrete steps which we can take together can be seen and all stakeholder are leaving as supporters of pooled procurement and local production. He advocated for small steps towards the bigger goal starting with the current selected countries.