African Union

Analysis of the current state of development of the local pharmaceutical manufacturing and regulatory capabilities in the African Union (AU) recognized Regional Economic Communities (RECs)

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ABBREVIATION LIST

EAC – East African Community

ECCAS – Economic Community of Central African States

ECOWAS – Economic Community of West African State

AfCFTA – African Continental Free Trade Area

AIDA – Accelerated Industrialization Development of Africa

AMRH – African Medicines Regulatory Harmonization

API – Active Pharmaceutical Ingredient

AU – African Union

AUC – African Union Commission

BRICS – Brazil, Russia, India, China, South Africa

CTD – Common Technical Document

CEN-SAD – Community of Sahel-Saharan States

COMESA – Common Market for Eastern and Southern Africa

GDP – Good Distribution Practices

GMP – Good Manufacturing Practices

IGAD – Intergovernmental Authority on Development

MRH – Medicines Regulatory Harmonization

NEPAD/AUDA – New Partnership for Africa's Development/African Union Development Agency

NMRA – National Medicines Regulatory Authority

PMPA – Pharmaceutical Manufacturing Plan for Africa

UNAIDS – Joint United Nations Programme on HIV/AIDS

UNIDO – United Nations Industrial Development Organization

RCORE – Regional Centres of Regulatory Excellence

REC – Regional Economic Community

RHO – Regional Health Organization

SADC – Southern African Development Community

WHO- World Health Organization

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Acknowledgement

The African Union Commission wishes to express its appreciation to African Union Recognized Regional Economic Communities (RECs), for their commitment to the implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA) and for participating in the analysis of the current state development of the local pharmaceutical manufacturing and regulatory capabilities in the AU recognized RECs, by providing invaluable responses to the questionnaires sent out to them by the Commission and participating in the validation consultations.

The Commission wishes to particularly express its appreciation to the Joint United Nations Programme on HIV/AIDS (UNAIDS) for its financial and technical contributions including the design and e-publishing of this report.

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Finally, to the team at the Department of Health, Humanitarian Affairs and Social Development of the African Union Commission (former Department of Social Affairs) for the research assistance, analysis and drafting of the report.

FOREWORD

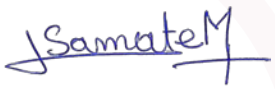
The first analysis of the current state of the development of the local pharmaceutical manufacturing and regulatory capabilities of Africa Union (AU) recognized Regional Economic Communities has been developed by the Department of Health, Humanitarian and Social Development, with the support of African Union Recognized Regional Economic (RECs) and the Joint United Nations Programme on HIV/AIDS (UNAIDS).

During the last decades promoting sustainable access to quality and affordable medicines and integrating local production and harmonized regulation, as part of, the overall health systems strengthening package has been of significant concern to African leaders. An effective pharmaceutical industry in Africa shall not only impact the African health system and its capacity to respond to the health needs of the people but also will contribute to the overall socioeconomic development of the continent.

For this reason, the African Union Commission with the support of its development partners has been at the forefront in galvanizing the necessary political will and providing the leadership to the broad range of processes required for promoting a sustainable local pharmaceutical industry and harmonized medicines regulatory system. The Commission has made significant efforts building strategic partnerships, and engaging governments in the implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA). Success has been made in establishing the African Medicines Regulatory Harmonization (AMRH) Initiative in 2007 (Assembly/AU/DEC-413(XVIII)) and the development of the AU Model Law on Medical Products Regulation (Assembly/AU/Dec.1-17(XXVI)) and implemented through the African Union Development Agency (AUDA-NEPAD). The Commission is also making progress towards the establishment of the African Medicines Agency (AMA), which shall serve as a continental medicines regulatory agency, and on setting up a Fund for African Pharmaceutical Development (FAP-D) in very close collaboration with the African Development Bank (AfDB).

The report findings on the current state of the development of the local pharmaceutical manufacturing and regulatory capabilities of AU recognized RECs, revealed that there is progress in the implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA), however, the progress is uneven across AU recognized REC's. Some RECs are still in the "set-up" phase while others are more advanced. Specific challenges were identified in three main areas included the following: a) Adoption and Implementation of Pharmaceutical Regulatory Frameworks; b) Business Environment and Partnerships; and c) Human Resources, Technical and Financial Capabilities. However, all RECs have indicated that there is a need to sustain political leadership, foster more partnerships, increase financial resources and strengthen capacity building

The invaluable information that have been obtained and detailed within the report provides opportunity for in-depth policy and strategic engagements that shall be required to further advance pharmaceutical production agenda at the level of each AU recognized Economic Community. The Commission in collaboration with AUDA-NEPAD shall continue to provide the requisite support to all AU Recognized RECs in-order to broker the requisite strategic engagements, to ensure access to safe, efficacious and standard medicines, medical products and technologies, through harmonized regulatory systems and regional collaboration that will result in boosting local and regional manufacturing capacities and moving Africa towards achieving the aspiration of a 'healthy and well-nourished Africa' by 2063.



H.E. Amb. Minata Samate Cessouma
Commissioner for Health, Humanitarian Affairs and Social Development
African Union Commission

EXECUTIVE SUMMARY

Analysis of the current state of development of the local pharmaceutical manufacturing and regulatory capabilities of the African Union and its recognized Regional Economic Communities (REC's) by means of a questionnaire was used to assess the current state of the initiatives related to the development of the local pharmaceutical manufacturing and regulatory capabilities at the regional and sub-regional levels, to accelerate the implementation of the PMPA-AMRH and further engage the RECs in this process. The analysis of the questionnaire response reveals progress has been made in the implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA), however, the progress is uneven through the REC's even though most of them have committed to prioritize local pharmaceutical production. Some are still in the "set-up" phase and some are more advanced.

Specific challenges have been identified in three main areas: a) Adoption and Implementation of Pharmaceutical Regulatory Frameworks; b) Business Environment and Partnerships; and c) Human Resources, Technical and Financial Capabilities. But all RECs have identified that there is a need to sustain political leadership, foster more partnerships, increase financial resources and strengthen capacity building. More specifically, some measures have been identified as being critical in the development of the sector, which include all actors and RECs to adopt a more unified "consortium approach" (as referred in the implementation plan of the PMPA Business Plan), incentive packages creating more opportunities for technology transfers, fairer and more protective trade agreements with specific tariffs on imports and tax exemption for manufacturers, trainings on the use of TRIPS Flexibilities, and lessons learnt from the South-South collaboration.

Regarding the roles of the RECs and their respective Regulatory Health Organizations (RHO's) in further advancing the local production agenda and accelerating the implementation of the PMPA, there is a need to take a closer look at the specific gaps and needs identified in the report to conduct further discussions and identify collective next steps

BACKGROUND

During the 9th Ordinary Session of the Assembly of the African Union in Accra 2007 Heads of State and Governments endorsed the Pharmaceutical Manufacturing Plan for Africa (PMPA) (EX. CL/Dec.361(XI)) and committed to the development of a competitive self-reliant pharmaceutical industry and ensure access to medicines to all Africans ((Assembly/AU/Dec.55 (IV). The African Union Commission (AUC) and NEPAD were mandated (Assembly/AU/Dec.55) to develop necessary guidance to support Member States and Regional Economic Communities to further advance the Local Production agenda and in coordinating efforts with partners The pharmaceutical sector has been identified as a priority to deliver public health benefits but also contribute to the industrialization of the continent as stated in the (Accelerated Industrial Development of Africa Framework (AIDA)) EX.CL/379 (XII).

AIDA Action Plan overall seeks the development and implementation of an industrial policy with priority accorded to maximizing the use of local productive capacities and inputs, adding value to and local processing of the abundant natural resources of the country, and to the development of small-scale and rural industries, including the informal sectors as well as intermediate and capital goods industries with high linkages to other sectors of the economy as potential sources of employment creation To accelerate implementation of the PMPA, a PMPA business plan was developed in 2012 by the African Union Commission and NEPAD with the support of UNIDO, WHO, UNAIDS and partners EX.CL/Dec.436 (XIII). The PMPA business plan outlines a recommended approach to strengthen the continent's ability to produce high quality, affordable pharmaceuticals which will contribute to improved health outcomes, eventually boost and sustain industrial and economic growth.

To address the challenges caused by weak and fragmented regulatory systems across the continent, the African Medicines Regulatory Harmonization (AMRH) Initiative was established and serves to ensure that African people have access to essential medical products and technologies. AMRH is a programme of the African Union (AU) implemented as part of the PMPA. Under the theme "Strengthening of Health Systems for Equity and Development in Africa", the AU Conference of Health Ministers (AUCHM) in April 2007 responded to the AU Assembly Decision 55 (Assembly/AU/Dec.55 (IV) taken during the Abuja Summit in January 2005 which mandated the African Union Commission (AUC) to develop the PMPA within the framework of the NEPAD. The AMRH initiative has received political support, mobilized financial and technical resources, driven by harmonization efforts within several AU recognized REC'S namely EAC, ECOWAS, IGAD and SADC, facilitated inter-Regional Economic Community communication and coordination, promoted peer-learning and fostered partnerships.

AU recognized (RECs) are regional groupings of African states and are the pillars of the AU. All were formed prior to the launch of the AU and have developed individually and have differing roles and structures. The purpose of the RECs is to facilitate regional economic integration between members of the individual regions and through the wider African Economic Community (AEC), which was established under the Abuja Treaty (1991). This Treaty, which has been in operation since 1994, ultimately seeks to create an African Common Market using the RECs as building blocks.

.The African Union recognizes eight RECs (listed below):

1. **Arab Maghreb Union (UMA)**
2. **Common Market for Eastern and Southern Africa (COMESA)**
3. **Community of Sahel–Saharan States (CEN–SAD)**

4. **East African Community (EAC)**
5. **Economic Community of Central African States (ECCAS)**
6. **Economic Community of West African States (ECOWAS)**
7. **Intergovernmental Authority on Development (IGAD)**
8. **Southern African Development Community (SADC)**

TABLE 1: List of RECS and their Member States

REGIONAL ECONOMIC COMMUNITY	MEMBER STATES
UMA	Algeria, Libya, Mauritania, Morocco, Tunisia
COMESA	Burundi, Comoros, DR Congo, Djibouti, Egypt, Eritrea,, Ethiopia, Kenya, Libya, Madagascar, Malawi, Mauritius, Rwanda, Seychelles, Sudan, Swaziland, Uganda, Zambia, Zimbabwe
CEN-SAD	Benin, Burkina Faso, Cabo Verde, Central African Republic, Chad, Comoros, Côte d'Ivoire, Djibouti Egypt, Eritrea, Gambia, Ghana, Guinea, Guinea Bissau, Kenya, Liberia ,Libya, Mali, Mauritania Morocco, Niger, Nigeria, São Tomé and Príncipe Senegal, Sierra Leone, Somalia, Sudan, Togo Tunisia
EAC	Burundi, Kenya, Rwanda Tanzania, Uganda, Tanzania, South Sudan
ECCAS	Angola, Burundi, Cameroon, Central African Republic, Chad, Congo, DR Congo, Equatorial Guinea, Gabon, São Tomé and Príncipe
ECOWAS	Benin, Burkina Faso, Cabo Verde, Côte d'Ivoire Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, Togo
IGAD	Djibouti, Eritrea, Ethiopia, Kenya, Somalia, South Sudan, Sudan, Uganda
SADC	Angola, Botswana, DR Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia ,Seychelles, South Africa, Swaziland Tanzania, Zambia, Zimbabwe

Some RECs have established specialized institutions referred as Regional Health Organization (RHO) to oversee the planning and implementation of health programs, including pharmaceutical production and regulation. AU recognized RECs and their respective RHOs have been major actors in the implementation and domestication of the PMPA and AMRH initiative, by facilitating the harmonization and the creation of enabling regulatory environments for manufacturers to grow and

strengthen the local pharmaceutical market, but also by sharing knowledge, coordinating country initiatives, and fostering partnerships with the private sector.

Regional Centres of Regulatory Excellence (RCOREs) have been designated by NEPAD Agency to strengthen regulatory capacities on the continent. RCOREs have been established to support National Medicines Regulatory Authorities (NMRAs) through trainings and sharing expertise in different areas of regulatory science. Initially, 11 were selected to support eight different functions (including core regulatory functions, pharmacovigilance, Medicine Registration, Licensing of Manufacture/Import/Export/Distribution…). To date (end 2017), 15 RCOREs are operational.

JUSTIFICATION

The pharmaceutical production in Africa has not yet reached the capacity to meet the tremendous needs of medicines and health products on the continent. Despite encouraging examples of local manufacturing which include essential medicines in few regions, Africa is only producing 3% of the medicines it consumes while bearing one of the biggest shares of the world disease burden (25%). To meet the health targets of Agenda 2030 and Agenda 2063, address the growing numbers of non-communicable diseases, and end AIDS, TB and Malaria by 2030, the universal access to affordable and quality-assured medicines and medical products need to be achieved on the continent. The overreliance on imports of medicines and active pharmaceutical ingredients (APIs), the lack of enabling environment for local manufacturers, the gaps in harmonization and weak regulatory capacities, are all challenges hindering the development of local production capacities in Africa.

METHODOLOGY

A questionnaire was elaborated end of 2018 and sent out by the African Union Commission (AUC) on May 2019 to the Regional Economic Communities Liaison Offices to collect inputs from AU recognized RECs and RHOs on the current status of their pharmaceutical manufacturing and regulatory capacities. The analysis was carried out jointly by the African Union Commission and UNAIDS. The questionnaire will be used to assess the current state of the initiatives related to the development of the local pharmaceutical manufacturing and regulatory capabilities at the regional and sub-regional levels, to accelerate the implementation of the PMPA-AMRH and further engage the RECs in this process. The analysis represents an opportunity to identify gaps and needs of the RECs and RHOs in order to better support their role of catalyser for the growth of the local pharmaceutical market.

Between June and September 2019, responses from six RECs (and their RHOs when applicable) out of the eight AU-recognized RECs were received which include EAC, ECCAS, ECOWAS, IGAD, SADC and UMA.

This report was produced by the African Union Commission and UNAIDS through the collection, consolidation and analysis of the six responses from above. The report will serve as a basis of discussions and to conduct an orientation involving the AUC, NEPAD/AUDA, RECs and other partners, which will aim at leveraging the collaboration and exchanges of knowledge between the RECs and China toward the strengthening of pharmaceutical manufacturing and regulatory capacities in Africa.

The questionnaire comprises of three sections:

1. Adoption and Implementation of Pharmaceutical Regulatory Frameworks
2. Business Environment and Partnerships
3. Human Resources, Technical and Financial Capabilities

A review and analysis of the responses of each REC individually will be first presented in the report. Key messages have been developed for each part. Responses to the questionnaire have been consolidated and will be presented with an analytical summary. Limitations of the questionnaire will also be outlined.

RESPONSES TO QUESTIONNAIRE

SECTION A: Adoption and Implementation of Pharmaceutical Regulatory Frameworks:

1. Is your region following the guidelines of the Action Plan for the implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA)?

YES	**4**	EAC, ECCAS, ECOWAS, IGAD
NO	**1**	UMA stated they are not implementing and following European and American guidelines instead (may be considered partial implementation)
PARTIAL Implementation	**1**	SADC pointed out that the SADC Pharmaceutical Business Plan borrows tenets/strategies from the PMPA

2. Has your region adopted a Medicines Regulatory Harmonization (MRH) Project aligned with the African Union AMRH Program?

YES	**5**	EAC, ECCAS, ECOWAS, SADC, IGAD
NO	**1**	UMA

If yes, please state the name, date of launch or intended launch of the MRH Project in the REC:

List of identified MRH programs as reported by RECs below:

- East Africa Community Medicines Regulatory Harmonization Program (Mar 2012)
- West African Medicines Regulation (Nov 2017)- ECOWAS
- SADC MRH Project (June 2019)
- ECCAS initiated/adopted regulations to improve harmonization (did not specific program name)
- IGAD has ratified an MRH program but it is not funded (did not specify program name

3. Is your REC hosting a regional centralized medicines regulatory and oversight body? If yes, what are the challenges it faces in the REC overseeing National Medicines Regulatory Authorities (NMRAs)?

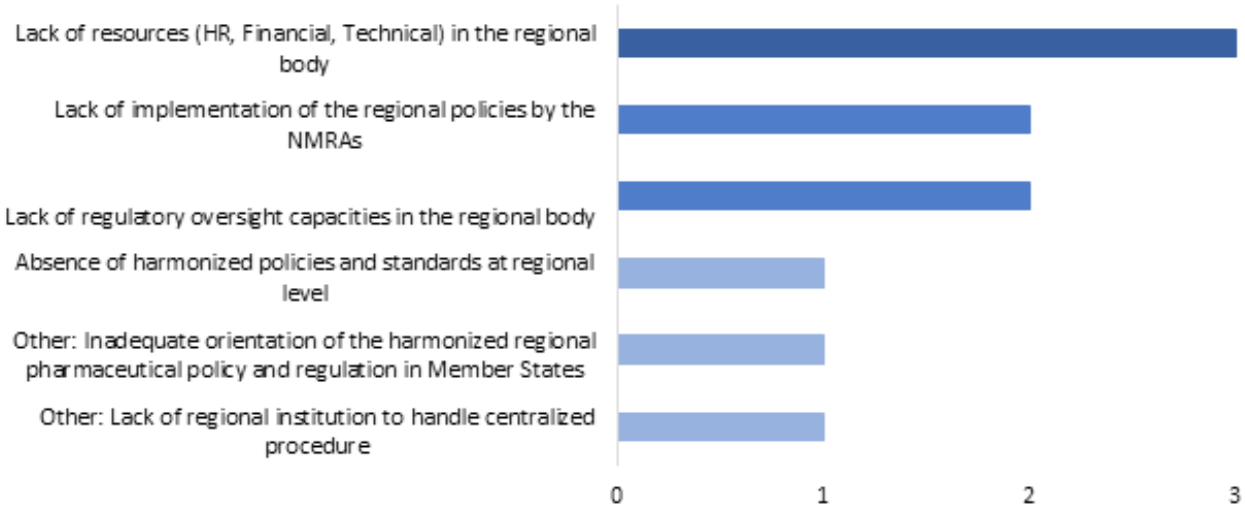
Is your REC hosting a regional centralized medicines regulatory and oversight body?

YES	**3**	EAC, ECOWAS, SADC
NO	**3**	ECCAS, IGAD, UMA

If yes, what are the challenges it faces in the REC overseeing National Medicines Regulatory Authorities (NMRAs)?

Main challenges have been collected and consolidated in Figure 1 below:

FIGURE 1: CHALLENGES FACED BY THE REGIONAL CENTRALIZED MEDICINES REGULATORY AND OVERSIGHT BODY IN THE REC OVERSEEING NMRAS



SECTION B: Business Environment and Partnerships

1. What are the top three countries generating the highest revenues from pharmaceutical manufacturing production in your region by order of importance?

Top three countries per RECs stated in Figure 2 below:

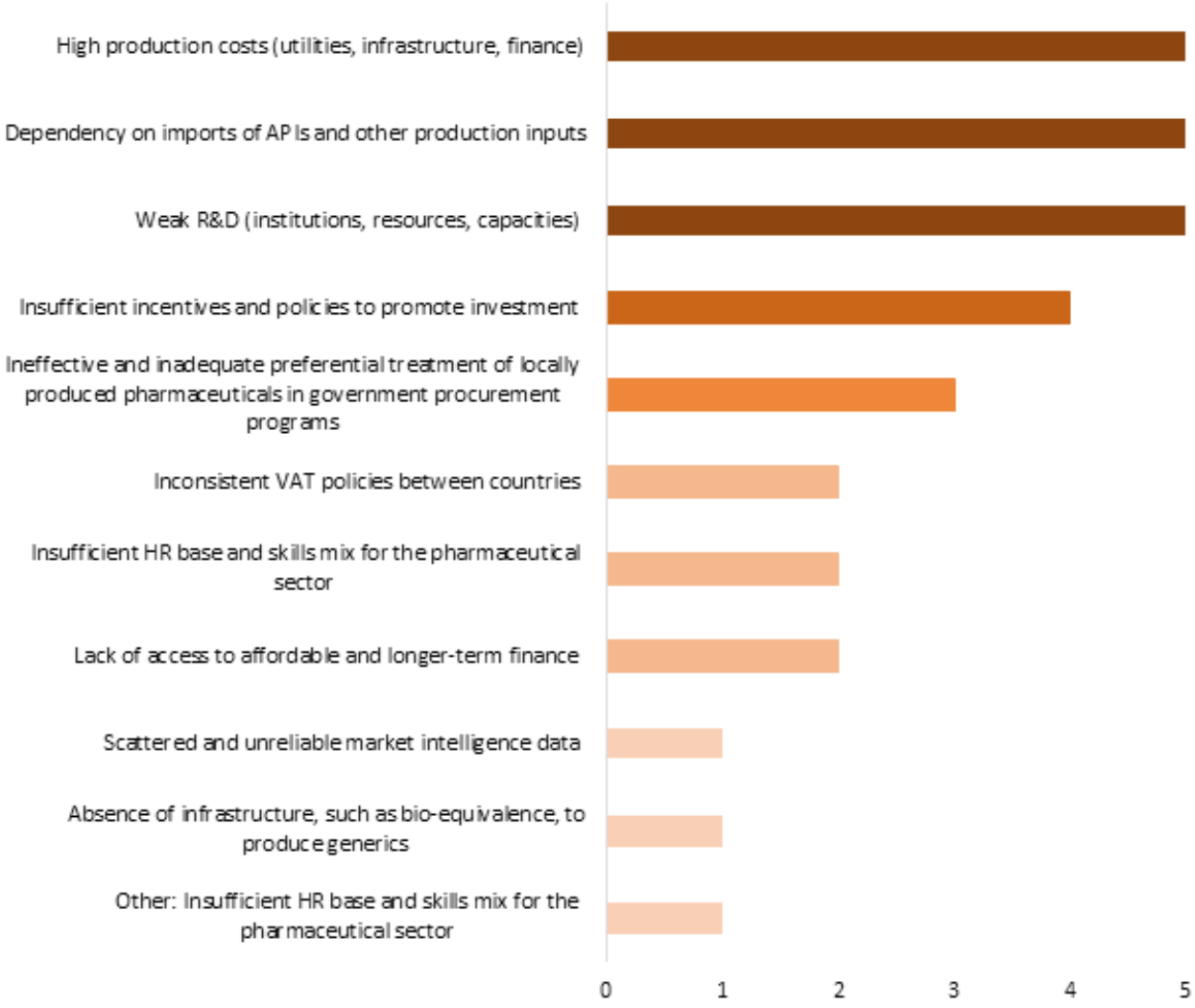
REC	Top three countries regarding revenue-generation from pharmaceutical manufacture
EAC	Kenya*, Tanzania*, Uganda
ECCAS	No response
ECOWAS	Côte d'Ivoire, Ghana, Nigeria
IGAD	Ethiopia, Kenya, Sudan
SADC	South Africa, Tanzania*, Zimbabwe
UMA	Algeria, Morocco, Tunis

*Note: some Member States belong to more than one REC as indicated in the table 1.

2. What are the biggest challenges/barriers faced by your region to boost local pharmaceutical production?

RECs have reported the largest barriers to boosting local pharmaceutical production by order of importance as stated in figure 3 below:

FIGURE 3: LARGEST BARRIERS TO BOOSTING LOCAL PHARMACEUTICAL PRODUCTION IN THE REGIONS



3. What are the main incentives to settling pharmaceutical manufacturing facilities within your region?

Protectionist measures are needed to incentivize local production such as:

- Tariffs on finished pharmaceutical products that can be produced in the region
- Elimination of domestic sales tax on pharmaceuticals

ECOWAS provided facility design and financial support for WHO GMP Compliance and Pre-Qualification. Four industries in Nigeria have obtained WHO GMP Compliance.

SADC indicated that Special Economic Zones can be used as a good incentive.

Please state the most effective incentive/s already implemented to promote the settling of pharmaceutical manufacturing facilities at regional level.

Responses are being consolidated in Figure 4 and Figure 5 below:

FIGURE 4: MAIN TARIFF INCENTIVES TO SETTLING PHARMACEUTICAL MANUFACTURING FACILITIES IN REGIONS

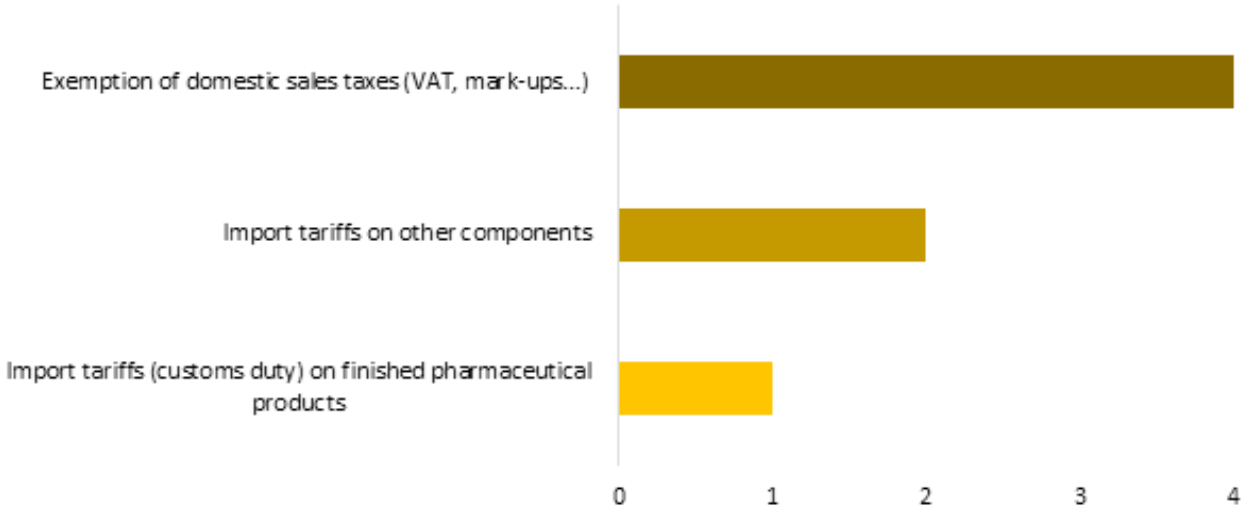
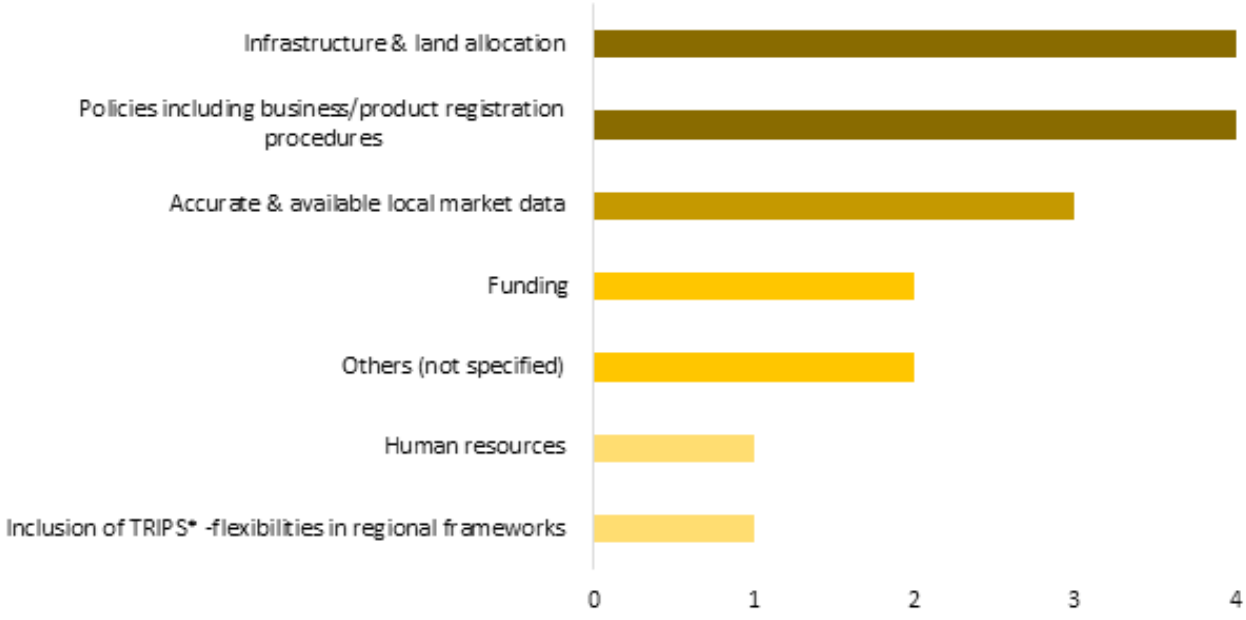


FIGURE 5: MAIN NON-TARIFF INCENTIVES TO SETTLING PHARMACEUTICAL MANUFACTURING FACILITIES IN REGIONS



4. What are the top three trading partners (countries) of your REC by total volume of IMPORTS of pharmaceutical products?

China only	None	
India only	1	ECCAS
Both China and India	3	EAC, IGAD, SADC

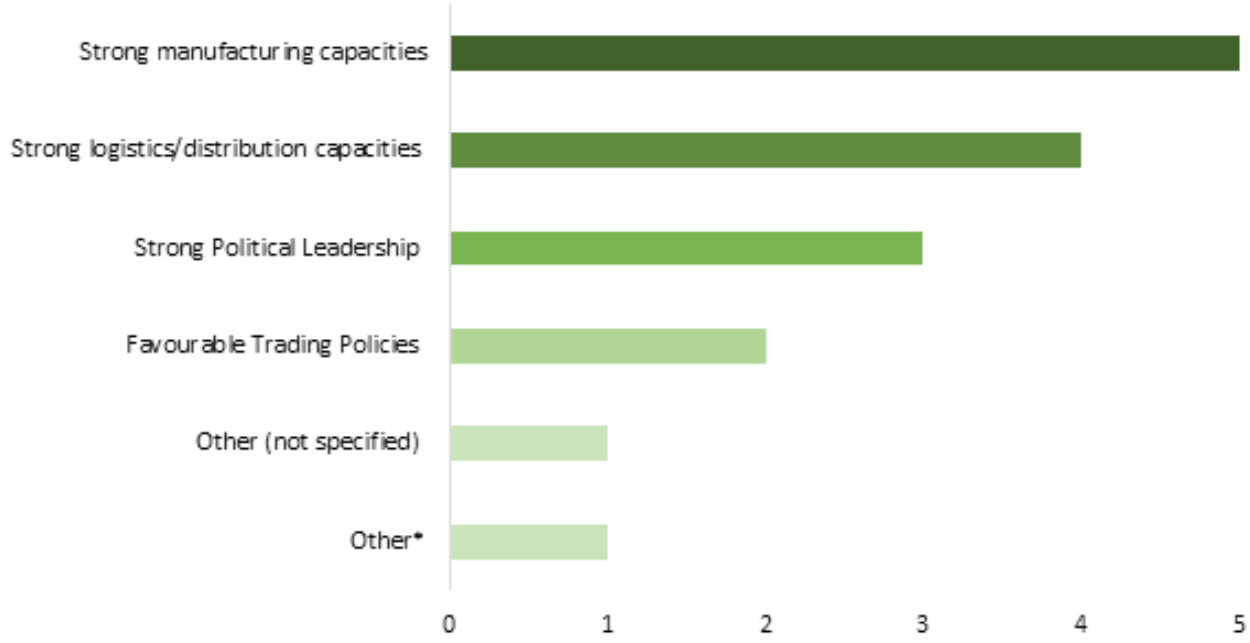
If possible, please indicate the trading partners in terms of imports by order of importance.

REC	Response
EAC	India, China, Africa
ECCAS	France, India, Morocco
ECOWAS	Cote d'Ivoire, Ghana, Nigeria (all members of ECOWAS)
IGAD	India, China, Middle-East
SADC	China, India, South-Africa
UMA	Europe, Asia, Gulf regions

Please state three reasons why these countries are preferential trading partners of pharmaceuticals with your REC.

Responses from RECs have been consolidated in figure 6 below:

FIGURE 6: WHAT MAKES CERTAIN COUNTRIES PREFERENTIAL TRADING PARTNERS (IN TERMS OF IMPORTS) OF PHARMACEUTICALS



*There is a limited pharmaceutical production in ECCAS, hence relying mainly on imports and donations.

5. What are the three trading partners of your REC by total volume of EXPORTS of pharmaceutical products by order of importance?

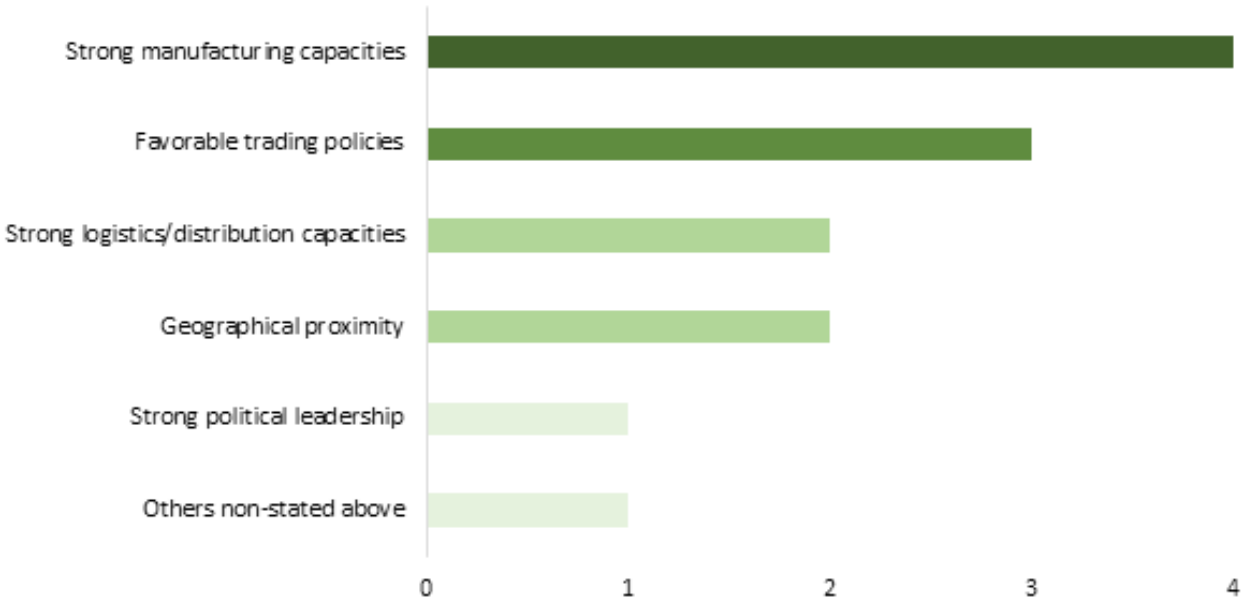
REC	Response
EAC	India, China, Africa
ECCAS	Not applicable/low local production (Only Cameroon)

REC	Response
ECOWAS	Cote d'Ivoire, Ghana, Nigeria (all members of ECOWAS)
IGAD	Eastern Africa, West Africa, Central Africa
SADC	South-Africa, Zimbabwe
UMA	Europe, Asia, Gulf regions

Please state 3 reasons why above countries are preferential trading partners of pharmaceuticals with your REC.

Responses from RECs have been consolidated in below figure 7:

FIGURE 7: WHAT MAKES CERTAIN COUNTRIES PREFERENTIAL TRADING PARTNERS (IN TERMS OF EXPORTS) OF PHARMACEUTICALS



6. Has your region identified the key Pharmaceutical Trade Associations of manufacturers and distributors in your region?

	Identified	Not identified	Not identified
Key Pharmaceutical Trade Associations of manufacturers	**3**	**3**	ECCAS, IGAD, UMA
Key Pharmaceutical Trade Associations of Distributors	**3**	**3**	IGAD, SADC, UMA,

7. Is your region engaged in activities with Pharmaceutical Trade Associations of manufacturers and distributors in your region? If no, what is the main reason why your region has not engaged with any Pharma Trade Associations?

Engaged	**5**	EAC, ECOWAS, IGAD, SADC, UMA
Not Engaged	**1**	IGAD

8. What measures AUC could be taking to help foster more partnerships between local and foreign companies to boost the local pharmaceutical sector?

Top measures that the AUC could assist with:

a. Technology Transfers

b. Free trade

c. Policy coherence/business linkages and partnership between Industry, Trade, Health, and Investment services

Specific measures suggested by RECs include:

a. ECCAS states the AUC could "facilitate[e] the purchase of materials."

b. ECOWAS states the AUC could "create[e] a common platform for exchange between local and pharmaceutical companies to enable technology and knowledge transfers and possible business merging."

Suggested measures by the RECs have been reported as follow:

1. Encouragement of local manufacturing.
2. Regular strategic investment for a dialogue between public and private companies.
3. Facilitation of product purchases.
4. Inspection of manufacturing companies.
5. Collaboration and partnership initiatives should be based on ensuring an understanding that "quality and safe medicines are a 'public health good' and not just business and that it is a right for every citizen."
6. Support regional pharmaceutical conferences.
7. Broker funding Arrangements; public-private Partnership arrangements; market access like procurement guarantees.

9. A. Has your region engaged in South-South collaboration initiatives to develop the local pharmaceutical production at the regional level?

Engagement in South-South Collaboration No engagement in South-South Collaboration	**YES**	**4**	EAC, ECCAS, SADC, UMA
	NO	**2**	ECOWAS, IGAD

If yes, which country? List at least one example of an engagement of your REC in South-South collaboration initiative in the pharmaceutical sector.

India	**2**	ECCAS, UMA
China and India	**1**	EAC
India, China and others	**1**	SADC

Some challenges were reported during South-South Collaboration. ECOWAS answered no and mentioned that the conditions were not favourable and trading partners preferred exporting to the REC rather than supporting development of local production); SADC indicated that no concrete steps were made beyond expressions of interest. UMA is the only REC which has highlighted one successful collaboration initiative (implementation of new manufacturing facilities with support of India).

10. . Has your region established any regional partnership agreements with the BRICS (Brazil, Russia, India, China, South Africa) on local pharmaceutical production?

YES	**2**	ECCAS, UMA
NO	**3**	ECOWAS, IGAD, SADC
OTHER	**1**	EAC

If yes, in which country? (and what is the scope of this agreement)

- EAC was unsure and asked to refer to its Trade Department
- ECCAS: India
- ECCAS and UMA did not share scope agreement
- UMA: with India through establishment of Indian factories and with Russia through technology transfer and export

SECTION C: Human Resources, Technical and Financial Capabilities

1. Does your REC have a focal point on pharmaceutical production?

YES	3	ECOWAS, SADC, UMA
NO	3	EAC, ECCAS, IGAD

Notes: UMA provided the website for the Moroccan Association for Pharmaceutical Industry as a focal point (www.amip.ma).E-mail addresses of focal points have not all been collected through the questionnaires.

2. Has your REC identified any needs to strengthen your Human Resources and/or technical capabilities in the pharmaceutical industry?

YES	4	EAC, ECOWAS, SADC, UMA
NO	2	ECCAS, IGAD

If yes, what kind of support would your REC require from an external partner? Types of technical assistance support needed:

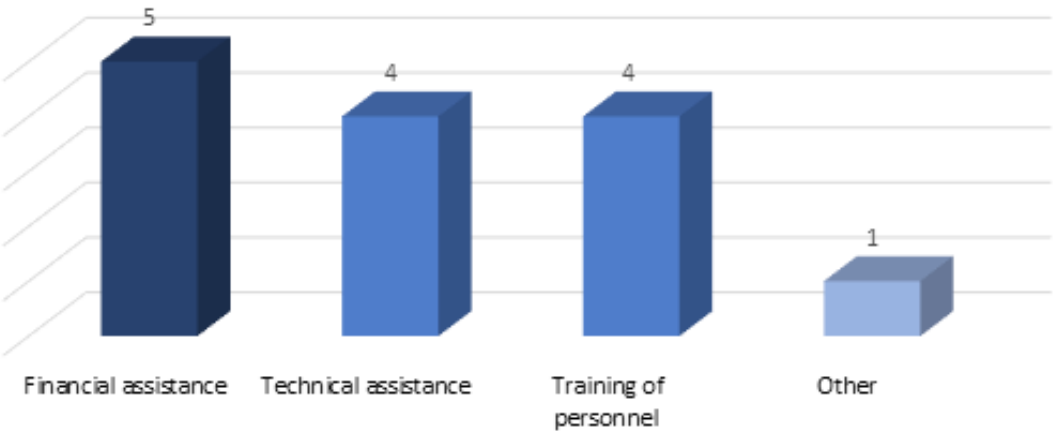
a. Technology transfer

b. Upgrading facilities and improving standards

c. Situational analysis and recommendations

In figure 8 specific needs to boost local production:

FIGURE 8: IF THERE IS A NEED TO STRENGTHEN HUMAN RESOURCES AND/OR TECHNICAL CAPABILITIES IN PHARMACEUTICAL INDUSTRIES, THEN WHAT KIND OF SUPPORT WOULD THE REC REQUIRE FROM AN EXTERNAL PARTNER



3. Is the issue of pharmaceutical production/manufacturing highlighted in any of the REC and/or affiliated Regional Health Organizations' regional strategic plans?

All 6 responding RECs have indicated that the issue of pharmaceutical production/manufacturing was integrated/highlighted in their own respective regional strategic plan or their affiliated Regional Health organization's strategic plan.

If yes, does the issue of pharmaceutical production have a specific budget allocated?

3 RECs (EAC, ECOWAS, SADC) have identified that a budget has been allocated for addressing specifically the pharmaceutical production issue.

EAC	Budget is incorporated in the EAC Pharmaceutical Manufacturing Plan of Action
ECOWAS	$150,000 USD
ECCAS	No response
SADC	$50 Million USD
IGAD	Not funded
UMA	Not applicable

4. Are there any specific activities being carried out/to be carried out in that regard?

Four out of the six responding RECs indicated that a specific activity related to the development of the pharmaceutical industry within their region is being carried out/will be carried out.

If yes, please list at least one activity in the pharma sector from your REC or health regional strategic plan to carried out/to be carried out.

i. EAC: "With costed (budgeted) implementation plan but no funds to support its implementation."

ii. ECCAS: Yes (no details given)

iii. ECOWAS: "137 staff of the local pharmaceutical producers across the region trained in the use of the harmonized Common Technical Document (CTD) for medicines registration for human use.

iv. IGAD: no specific activity within its region

v. SADC: "Harmonization of Common Technical Document. Pooled procurement and Zazibona" *

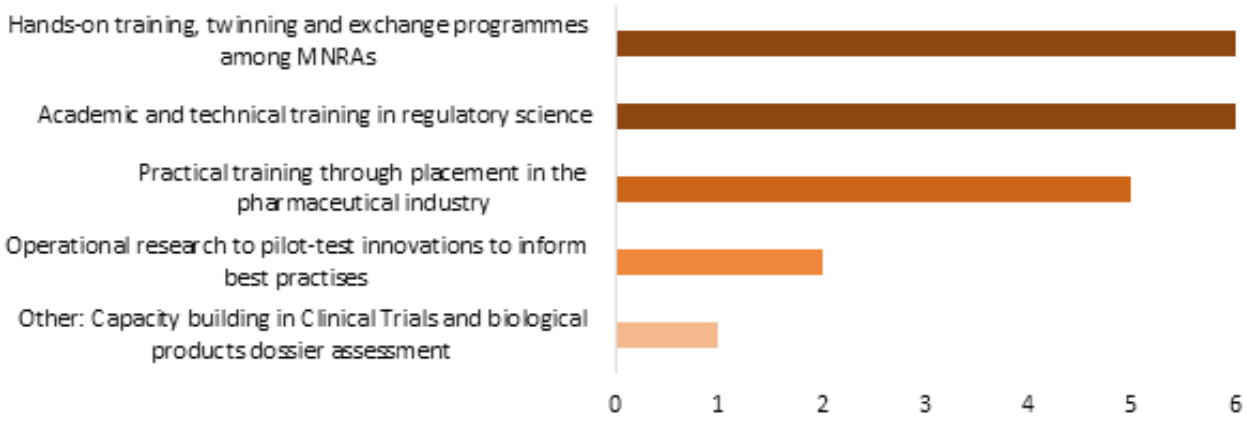
vi. UMA: no specific activity within its region

*Zazibona is a harmonization initiative involving 13 member states of SADC. Initiated in 2013 by Botswana, Namibia, Zambia and Zimbabwe. Activities include among others: medicine registration; inspection; work share.

5. Is your region hosting one of the Regional Centres of Regulatory Excellence (RCOREs)? If your region is hosting a RCORE, which of its function (s) would need to be strengthened?

YES	**5**	EAC, ECOWAS, IGAD, SADC, UMA
Not applicable	**1**	ECCAS

FIGURE 9: WHICH FUNCTIONS NEED TO BE STRENGTHTNED IF THE REGION IS HOSTING ONE OF THE REGIONAL CENTRES OF REGULATORY EXCELLENCE?



6. Have you supported a country in your REC to apply to NEPAD Agency to become one designated AU RCOREs? If no, state the reasons why.

YES	**2**	ECOWAS, UMA
NO	**2**	IGAD, SADC
N/A	**1**	ECCAS

Notes: IGAD "There was no framework for engagement of Member States." SADC did not share details on the reasons why.

OVERVIEW OF RESPONSES TO QUESTIONAIRES

SECTION A: Adoption and Implementation of Pharmaceutical Regulatory Frameworks

Key finding 1: Most Regional Economic Communities (5 out of 6) have developed their own pharmaceutical regional strategy in line with the PMPA Business Plan to the exception of UMA (European and American guidelines). Good progress observed across the RECs in the implementation of the PMPA.

Key finding 2: A majority of RECs (5 out of 6) have either initiated or adopted a MRH Project/Program to promote regulatory harmonization within its region of which half (3 out of 6) have reported hosting a regional centralized medicines regulatory and oversight body.

Key finding 3: RECs have reported mostly facing 3 main challenges in ensuring regulatory harmonization and overseeing National Medicines Regulatory Agencies (MNRAs) ranking by order of importance:

(1) lack of resources (Human resources, financial, technical) in the regional body,

(2) lack of implementation of the regional policies by the NMRAs, and

(3) lack of regulatory oversight capacities in the regional body.

Summary:

Since the adoption of the PMPA Business Plan, progress has been observed across 6 of the 8 African Union recognized Regional Economic Communities towards the development of the pharmaceutical sector. Thanks to a strong leadership and prioritization of the sector (5 out 6 RECs have integrated the development of the pharmaceutical sector in their regional strategic plans), advanced progress has been made on regulatory harmonization in some of the RECs who have adopted MRH Programs (in 5 RECs). However, the biggest challenges to the development of the local market of pharmaceuticals remain the lack of funding and specific technical expertise both in the RECs and their regional oversight bodies, leading to difficult coordination between the National Medicines Regulatory Agencies and poor implementation of the regional policies at national levels.

SECTION B: Business Environment and Partnerships

Key finding 4: All RECs have identified top 3 countries generating the highest revenue in pharmaceutical manufacturing production, which include some continental leading countries in manufacturing of pharmaceuticals.

Key finding 5: Majority of the RECs (5 out of 6) have reported facing 5 main barriers to boosting local pharmaceutical production in their regions

(1) high production costs (utilities, infrastructure, finance),

(2) dependency on imports of Active Pharmaceutical Ingredients and other production inputs,

(3) weak R&D (institutions, resources, capacities); followed by

(4) insufficient incentives and policies to promote investment (4 RECs out of 6), and

(5) ineffective and inadequate preferential treatment of locally produced pharmaceutical in government procurement programs (3 RECs out of 6).

Key finding 6: Majority of RECs (4 out of 6) have reported exemption of domestic sales taxes

(WAT, mark-ups...) being the first most effective incentive to settling pharmaceutical manufacturing facilities within their region, while only 2 RECs reported import tariffs on other components.

Key finding 7: Majority of RECs (4 out of 6) reported infrastructure and land allocation, policies including business/product registration procedures as being the main non-tariff incentives to settling pharmaceutical manufacturing facilities in their regions, followed by accurate and available local market data (by 3 RECs out of 6).

Key finding 8: No REC has reported having China as the only trading partner by total volume of imports of pharmaceutical products, 3 out of 6 RECs reported trading with both China and India, and only one REC mentioned India only. Majority of RECs (5 out of 6) have identified 3 main trading partners of imports both located in Africa (4 out of 6) and abroad, China and India being reported the most (3 RECs).

Key finding 9: Majority of RECs (5 out of 6) reported choosing preferential trading partners for imports based on their strong manufacturing capacities, 3 out of 6 RECs then answered strong logistics/distribution capacities; and 3 out of 6 RECs stated) strong political leadership. China and India have been listed as top exporters. Top exporting trading partners are not always based on favourable trade policies nor geographic proximity. The most stated reason behind the choice of the trading partner its strong manufacturing capacities.

Key finding 10: Half of interviewed RECs (3 out of 6) have successfully identified both key pharmaceutical trade associations of manufacturers and distributors within their region.

Key finding 11: Majority of RECs (5 out of 6) are engaged in activities with Pharmaceutical Trade Associations of manufacturers and distributors, only one reported no engagement because of the lack of human resources, technical and/or financial capabilities.

Key finding 11: RECs have suggested that the African Union Commission could further assist in 3 main areas:

(1) promotion of technology transfers,

(2) facilitate free trade/liberalization,

(3) policy coherence/facilitate business linkages and partnerships (mainly with private sector);

2 RECs gave examples of specific measures in the facilitation of purchase of materials and creation of a common platform for local and foreign pharmaceutical companies to foster technology transfers and exchanges of knowledge.

Key finding 12: Most RECs (4 out of 6) have been engaged in South-South collaboration initiatives to develop the local production at regional level of which 2 reported with India, 1 with China and Inia, and 1 with India, China and others. One of the two RECs not engaging stated that the modalities of the collaboration did not help in supporting and strengthening local production.

Key finding 13: Only 2 RECs of 6 have established regional partnership agreements on local pharmaceutical production with one the BRICS countries (India named twice, Russia once). Only 1 REC indicated the agreement scope: support in the establishment of factories in the region (with India) and technology transfers (with Russia).

Summary:

In overall, all responding RECs have established regulatory frameworks (MRH programs) and adopted business enabling policies (such as domestic sales tax, infrastructure and land allocation, and preferential business or product registration policies) to promote the development of local pharmaceutical markets and support Member States manufacturing capacities. Leading countries in the manufacturing of pharmaceuticals on the continent have been well identified by the Regional Economic Communities and often largely contribute to meet some of the needs in pharmaceuticals and health products in their region and beyond through exports to other RECs Engagement with the private sector through Local Pharmaceutical Trade Associations of manufacturers and distributors which are not always well identified (only half of the responding RECs) varies across the RECs. However, majority of the RECs have indicated that there are significant barriers to boosting local production which are linked the low availability or lack on the continent of the critical production inputs and infrastructures (APIs, production equipment and facilities, R&D) as well as the lack of protectionist policies (tariff and non-tariff) and incentives to attract foreign investments (including technology transfer and funding).

India and China have been reported both by the majority of the RECs to be their main trading partners of pharmaceuticals (to the exception of one REC out of 6), which indicated that trade agreements are not always based on the most favourable terms, but depend on the strong manufacturing and logistics capacities of the counterparts to meet the domestic demand. Outside China and India, trade relations with other BRICS countries seem relatively limited, only mentioned once in the questionnaires (South Africa, Russia). There is insufficient information on the nature and scope of the agreements and South-south collaboration initiatives (only one REC mentioned technology transfer and support in setting up of factories locally). Finally, RECs have requested more support from the African Union Commission and external partners primarily in support of the establishment and negotiations of partnerships with the foreign countries and private sector, as well as more policy guidance and trade liberalization.

SECTION C: Human Resources, Technical and Financial Capabilities

Key finding 14: Half of the responding RECs (3 out of 6) have a focal point assigned on the pharmaceutical production. However, one REC indicated an Association as focal point.

Key finding 15: Most of the RECs (4 out of 6) have identified the needs to strengthen their Human resources and technical capabilities in the pharmaceutical industry. They indicated that they would require technical assistance from external partners on

1) technology transfer,

(2) upgrade of facilities and improvements of standards,

(3) conducting situational analysis and formulating recommendations.

Key finding 16: Majority of RECs (5 out of 6) have identified the need to have firstly access to Financial assistance, then 4 out of 6 indicated in second and third the need for technical assistance and training of personnel.

Key finding 17: All 6 responding RECs have indicated that the issue of pharmaceutical production/ manufacturing was integrated/highlighted in either their own regional strategic plan and/or in their affiliated Regional Health organization's strategic plan. 3 out of 6 have allocated specific budget for the development of the pharmaceutical production (2 RECs specified having allocated 50 million USD and 150 000 USD respectively).

Key finding 18: 4 out of 6 RECs have indicated that a specific activity related to the development of the pharmaceutical industry within their region was being carried out/will be carried out and gave examples of these initiatives:

(1) recruitment of trained staff for harmonization of Common Technical Document (CTD) and medicines registrations,

(2) harmonization of Common Technical Document (CTD) and pooled procurement.

Key finding 19: Majority of RECs (5 out of 6) have reported hosting one Regional Centre of Regulatory Excellence designated by NEPAD/AUDA (RCOREs). 5 RECs hosting one RCORE and 1 REC not hosting a RCORE indicated the need to strengthen in priority

(1) hands-on training, twinning, and exchange programs among MNRAs,

(2) academic and technical training in regulatory science. Followed by the need to strengthen

(3) practical training through placement in the pharmaceutical industry reported by 5 RECs.

Key finding 20: Only 2 RECs out of 5 have indicated to have supported the country in its application to host one Regional Centre of Regulatory Excellence designated by NEPAD Agency/AUDA. One of the responding RECs which indicated not having supported the application, mentioned there was not ~~-e~~xisting/available framework for engagement with Member States.

Summary:

In overall, all 6 RECs have indicated facing lack of sufficient funding and trained human resources which are critical to build, sustain or further develop their manufacturing and regulatory capacities. Only half of them have allocated a specific budget to this end with various level of engagement based on their funding/resource mobilization capacities. It was reported that assistance from external partners is needed to address the gaps in funding, knowledge and technical expertise. Some RECs have invested in recruitment/staffing and trainings to strengthen their regulatory capacities. The Regional Centre of Regulatory Excellence designated by NEPAD Agency/AUDA have covered most of the RECs (5 out of 6 RECs are hosting a RCORE), which they expect to provide additional support to NMRAS, with targeted and practical trainings of personnel in the field, as well as more exchanges of knowledge. Finally, most RECs reported not having taken part in assisting Member States with the application process to host a RCORE.

Validation of Report: Key Recommendation

SECTION A: ADOPTION AND IMPLEMENTATION OF PHARMACEUTICAL REGULATORY FRAMEWORKS

1. The registration process for products is tedious and expensive in some member countries which are an impediment and a challenge. Renewal of high fees every two years is too heavy and discourages research.
2. Farms in Africa should be strengthened to produce Active Pharmaceutical Ingredients (API's).
3. It is advantageous to have a regulatory oversight body as this attracts investors and makes the process of investment more efficient and effective additionally allowing for engagement with the African Continental Free Trade Agreement (ACfTA) to bolster regional collaboration I boosting local manufacturing.
4. PMPA needs to be revised with its spectrum broadened and implementation across regions increased. The revision of the PMPA needs to encompass not only industrialization but take into consideration the key health components especially regional harmonization processes.

5. A roadmap should be developed to support RECs to domesticate the PMPA.
6. Monitoring tools for the PMPA need to be strengthened at the national and regional levels.
7. Capacity building at the level of the RECs is key to curbing these challenges on advancing the PMPA agenda.

SECTION B: BUSINESS ENVIRONMENT AND PARTNERSHIPS

1. The AfCFTA should be leveraged as it allows for market accumulation and the benefit of economies of scale.
2. Innovative financing of the pharmaceutical sector needs to be improved and in particular concessionary funding to boost the local manufacturing sector.
3. It is not recommended that each country to have their own pharmaceutical manufacturing plants however; each member state should have an equitable contribution to regional manufacturing and the supply chain could be diversified to allow inclusion of countries within regions.
4. It is also recommend that in lieu of individual industrialization in the pharmaceutical sector, a shared benefits of industrialization to member states and the region is the advised manner to proceed.
5. EAC recommends that each REC has a Centre of Excellence to allow each REC to oversee and engage in regional intelligence, data research and development. There is potential for REC's to establish central intelligence data platforms however, an assessment should be done to see what information is valid and relevant
6. There needs to be market protection for the manufacturing of basic specific molecules, enhanced common tariffs and preferred public procurement.
7. A mechanism needs to be put in place to make sure that the regional market is available to regional producers.
8. Protection of markets to advance market opportunities is very important. The specifics of how markets are protected and which exact markets of member states are protected shall need to be determined and further interrogated.
9. Strategic partnerships are needed to advance technological transfers, research and development within regions.
10. Partnerships and policy development between member states, the private sector and industry need to be better defined to make sure the interest of member states is taken into consideration.
11. Innovative ways to access funding that does not lead to high interest and debt being incurred by local pharmaceutical manufacturers are paramount to boost the development of the pharmaceutical sector.

SECTION C: HUMAN RESOURCES, TECHNICAL AND FINANCIAL CAPABILITIES

The AUC should engage and assist the RECs to improve partnerships for resource mobilization.

WAY FORWARD (AREAS OF INTEREST)

Below questions have been informed by the results of the questionnaire to help guide the discussions and to generate more questions from the parties involved these questions will lead to sound recommendations being drawn up for actionable deliverables:

1. How can the Regional Economic Communities play fully their role as a catalyser for advancing the local pharmaceutical production agenda? What are the key determinants?
2. What concrete actions can be taken at the regional levels (Regional Economic Communities) to support countries in creating enabling environments for the local manufacturers (both in producing and scaling-up production for exports to other regions/parts of the world)?
3. What do Regional Economic Communities need to effectively address the lack of regulatory harmonization and different level of manufacturing capacities between their Member States?
4. How can Regional Economic Communities fully benefit from North-South and South-South collaboration initiatives/agreements to boost their local manufacturing capacities?
5. How can inter-regional dialogue and collaboration be further enhanced to drive local manufacturing production and support negotiations with investors/trading partners outside the continent?
6. As referred in the PMPA Business Plan, what would the Regional Economic Communities define as their roles and responsibilities in the consortium of partners? For the African Union Commission and development partners?
7. How can the private sector play a bigger role in sustaining national and regional efforts to boost local production of pharmaceuticals?
8. How can Regional Economic Communities be further engaged to identify a "package of solutions" for effective implementation (as per page 85 of the PMPA Business Plan) which include among some:
    a. Availability of funding to conduct activities under PMPA
    b. Level of mutual trust between organizations and individuals who represent them
    c. The Development of legal basis for the consortium of partners
    d. Development of a shared and adaptable work plan with roles and responsibilities identified with the measures which include the RECs and other partners reflecting the realities on the ground
    e. Governance and reporting structures for the consortium
    f. The African Union Commission to lead the PMPA Business Plan and monitor evaluation

CONCLUSION

There has been steady but slow and disparate progress in the implementation of the Pharmaceutical Manufacturing Plan for Africa across the different Regional Economic Communities since its adoption 13 years ago. Important challenges and gaps are hindering the development of the pharmaceutical manufacturing and regulatory capacities on the continent but have been identified. There is no sign of lack of continental leadership or commitments to further advance the agenda on local production. High-level political commitments have been made and have prioritized to build a self-reliant, competitive and robust pharmaceutical industry to meet the needs for affordable and quality-assured medicines and health products for all African citizens. The AUC and NEPAD/AUDA have been playing a critical role in paving the way forward by developing in policy guidelines such as the PMPA Business plan for the accelerated implementation of the PMPA, the AMRH Initiative and set up of the RCOREs, the African Union model law on Medical Product Regulation, in advocating for the establishment of the African Medicines Agency to fight against counterfeited and substandard medicines and medical products. But gaps remain, especially in terms of technical and financial support, as well as lack of qualified personnel as stated by the Regional Economic Communities in the questionnaire. The AUC has called for the establishment of the Fund for African Pharmaceutical Development (EX.CL/Dec.970 (XXXI), July 2017), which will address the lack of funding critical for the development of the pharmaceutical manufacturing sector on the continent.

With the African Continental Free Trade Area (AfCFTA) in force and by leveraging the existing frameworks (AMRH programs), the RECs have a big role to play in leading and accelerating pharmaceutical regulatory harmonization but also in creating enabling business environments. Policies can prioritize locally manufactured and quality-assured medicines and health products; help production scale-up and guarantee larger market access through trade liberalization; establish robust procurement lines for the purchase of Active Pharmaceutical Ingredients (APIs) for instance from foreign countries and ensure finished products are manufactured locally; foster technology transfers, joint-ventures and attract foreign investments to boost manufacturing capacities within their region.

Annex

Report of the virtual validation meeting held with AU) recognized Regional Economic Communities (RECs) on 31st August 2020 on the Analysis of the current state development of the local pharmaceutical manufacturing and regulatory capabilities in Africa Union (AU) recognized Regional Economic Communities (RECs)

INTRODUCTION

During the 9th Ordinary Session of the Assembly of the African Union in Accra 2007 Heads of State and Governments endorsed the Pharmaceutical Manufacturing Plan for Africa (PMPA) (EX. CL/Dec.361(XI)) and committed to the development of a competitive self-reliant pharmaceutical industry and ensure access to medicines to all Africans ((Assembly/AU/Dec.55 (IV). The African Union Commission (AUC) and NEPAD were mandated (Assembly/AU/Dec.55) to develop necessary guidance to support Member States and Regional Economic Communities to further advance the Local Production agenda and in coordinating efforts with partners.

The pharmaceutical sector is been identified as a priority to deliver public health benefits but also contribute to the industrialization of the continent as stated in the (Accelerated Industrial Development of Africa Framework (AIDA) (EX.CL/379 (XII)). AIDA Action Plan overall seeks the development and implementation of an industrial policy with priority accorded to maximizing the use of local productive capacities and inputs; adding value to and local processing of the abundant natural resources of the country. AIDA also seeks the development of small-scale and rural industries, including the informal sectors as well as the intermediate and capital goods industries with high linkages to other sectors of the economy as potential sources of employment creation.

To accelerate implementation of the PMPA, a PMPA business plan was developed in 2012 by the African Union Commission and AU-NEPAD with the support of UNIDO, WHO, UNAIDS and partners (EX.CL/Dec.436 (XIII)). The PMPA business plan outlines a recommended approach to strengthen the continent's ability to produce high quality, affordable pharmaceuticals which will contribute to improved health outcomes, eventually boost and sustain industrial and economic growth.

The Commission in close collaboration with the Joint United Nations Programme on HIV/AIDS (UNAIDS) Liaison Office to the AU and ECA conducted an analysis of the current state of development of the local pharmaceutical manufacturing and regulatory capabilities of the African Union and its recognized Regional Economic Communities (REC's). This was done through a questionnaire to assess the current state of the initiatives related to the development of the local pharmaceutical manufacturing and regulatory capabilities at the regional and sub-regional levels, to accelerate the implementation of the PMPA-African Medicines Regulatory Harmonization (AMRH) and further engage the RECs in this process.

ATTENDANCE:

The following participants attended the meeting;

i. African Union Commission – Department of Social Affairs: Health, Nutrition & Population Division

ii. Arab Maghreb Union (UMA)

iii. The Community of Sahel–Saharan States (CEN-SAD)

iv. Common Market for Eastern and Southern Africa (COMESA)

v. East African Community (EAC)

vi. Intergovernmental Authority of Development (IGAD)

vii. Southern African Development Community (SADC)

viii. West Africa Health Organization (WAHO)

ix. The Joint United Nations Programme on HIV/AIDS (UNAIDS)

OPENING REMARKS

a) **Dr. Aissatou Clemence Habi Bare, Director, UNAIDS Liaison Office to the African Union and the UN Economic Commission for Africa** in her opening remarks highlighted that Africa is relying heavily on importing medicines and only produces 3% of the medicines it needs. This has seen Africa on the backbench on the supply of essential medicines and it needs to be addressed on short, medium and long-term plans. COVID-19 has demonstrated more than ever that Africa needs strong pharmaceutical production, distribution, and regulatory systems for the health security of the continent and sustainable development as well. The UNAIDS Executive Director Winnie Byanyima has made access to medicines one of her top priorities. That is why UNAIDS launched in May 2020 a global call for a Peoples' Vaccines, joined by the chair of the African Union, H.E Cyril Ramaphosa, the AUC Chairperson, H.E Moussa Faki Mahamat and other African leaders to urge for equitable rapid manufacturing and distribution plan for COVID-19 vaccine and treatment including on the continent. In support of the agenda on local production, ,the AUC, AUDA-NEPAD & UNAIDS have carried out some joint initiatives such as the "Access to Medicines and Local Production Orientation" in partnership with the Bill and Melinda gates foundation, held on the side-lines of FOCAC in 2018 and a mapping of pharma opportunities in 21 African countries was conducted by UNAIDS country office in China . She emphasized the need for African countries to have innovative and effective ways of thinking, planning and investing in the health sector. This is an incredible opportunity to push for the local pharmaceutical production in Africa, which represents an investment in African health. The RECs have an important role to play in this as they can facilitate information sharing, coordinate policy harmonization and advance regional approach for a more robust regional value chain as well as maximize the trade exchanges while seizing the opportunity of the recently adopted African Free Trade Area. To identify the needs and the gaps in the local pharmaceutical production in Africa, the Department of Social Affairs of the AUC in partnership with UNAIDS undertook this study and presented the report attached. The remarkable response from the RECs was welcomed. UNAIDS through its three Regional Support Teams and Country Offices in Africa as well as our Country Office in China is committed to to support the African Union Commission. the way forward is to be discussed and will be under the leadership of the African Union.

b) **Dr. Margaret Agama-Anyetei, Head of Division, Health, Nutrition and Population, AUC** recognised all participants and extended greetings and best wishes for a successful meeting on behalf of the Director of Social Affairs Mrs Cisse Mariam Mohammed, who was not able to attend the meeting due to competing schedules. She further thanked the Regional Economic Communities for their participation and UNAIDS for the partnership, collaboration and support.

PRESENTATION OF THE DRAFT ANALYSIS OF THE CURRENT STATE DEVELOPMENT OF THE LOCAL PHARMACEUTICAL MANUFACTURING AND REGULATORY CAPABILITIES OF THE AFRICA UNION (AU) RECOGNIZED REGIONAL ECONOMIC COMMUNITIES

Dr. Margaret Agama-Anyetei presented the draft Analysis of the current state development of the local pharmaceutical manufacturing and regulatory capabilities of the Africa Union (AU) recognized Regional Economic Communities (AU-R-RECs). Her presentation focused on the scope and the methodology of the draft report, its structure, and discussion questions derived from the responses to the questionnaire completed by the RECs.

A questionnaire was developed at the end of 2018 and sent out by the African Union Commission (AUC) on May 2019 to the Regional Economic Communities Liaison Offices to collect inputs from AU recognized RECs and RHOs on the current status of their pharmaceutical manufacturing and regulatory capacities. The questionnaire was designed to assess the current state of the initiatives related to the development of the local pharmaceutical manufacturing and regulatory capabilities at the regional level to accelerate the implementation of the PMPA-AMRH.

The analysis of the questionnaire was carried out jointly by the African Union Commission and UNAIDS. The analysis represents an opportunity to identify gaps and needs of the RECs and Regulatory Health Organizations (RHOs) in order to better support their role of catalyser for the growth of the pharmaceutical industry across in Africa. Between June and September 2019, responses from six RECs (and their RHOs when applicable) out of the eight AU-recognized RECs were received which from EAC, ECCAS, ECOWAS, IGAD, SADC and UMA. The draft report serves as a base for discussion and to be used as a basis to inform an orientation involving the AUC, NEPAD/AUDA, RECs and other partners. The proposed orientation which will be used to leverage collaboration and exchanges of knowledge between the RECs and China with the aim of strengthening the pharmaceutical manufacturing and regulatory capacities in Africa.

The analysis responses reveal that there is progress in the implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA); however, the progress is uneven through the REC's. Some RECs are still in the "set-up" phase while others are more advanced. Specific challenges were identified in three main areas: a) Adoption and Implementation of Pharmaceutical Regulatory Frameworks; b) Business Environment and Partnerships; and c) Human Resources, Technical and Financial Capabilities. However, all RECs have indicated that there is a need to sustain political leadership, foster more partnerships, increase financial resources and strengthen capacity building

More specifically, some measures have been identified as being critical to the development of the sector. These include all stakeholders and RECs in order to adopt a more unified "consortium approach" (as referred in the implementation plan of the PMPA Business Plan). This would include incentive packages creating more opportunities for technology transfers, fairer and more protective trade agreements with specific tariffs on imports and tax exemption for manufacturers, trainings on the use of TRIPS Flexibilities, and lessons learnt from the South-South collaboration.

Regarding the roles of the RECs and their respective Regulatory Health Organizations (RHO's) in further advancing the local production agenda and accelerating the implementation of the PMPA, there is a need to take a closer look at the specific gaps and needs identified in the analysis report to conduct further discussions and identify collective

DISCUSSION ON THE DRAFT REPORT

Following the presentation of each of the sections of the report representatives provided inputs and responded to questions (see annex) raised following the analyses of each section

SECTION A: ADOPTION & IMPLEMENTATION OF PHARMACEUTICAL REGULATORY FRAMEWORKS

a) The Community of Sahel–Saharan States (CEN-SAD)

The CEN-SAD representative highlighted that in their region there are some countries with production units, which are well developed but still, need resources to improve implementation of their frameworks. Production of medicines is more often limited to the production of generic medicines calling for the support from member states to set up more pharmaceutical plants, emphasizing that significant work needs to be done in this regard. CEN-SAD welcomed the draft report but also highlighted the issue of medicines regulation that is a huge challenge as the cost of registration in some member states is very high. In the CEN-SAD, region there is production of non-generic medications however, the registration process is tedious and expensive in some member countries, were fees are comparable to fees that are charged multi-nationals. Renewal of high fees every two years is too heavy and discourages research. It was the opinion of the representative that Africa has a lot of medicines and ingredients that do not receive due value. The representative recommended that farms in Africa could produce Active Pharmaceutical Ingredients (API's). The representative apologized for not responding to the questionnaire earlier and kindly requested that the questionnaire be shared in order for CEN-SAD to complete so that they develop at the same pace as other REC's.

b) East African Community (EAC)

The representative expressed their appreciation of the report and highlighted its relevance to the EACs development. The EAC is an active member of the Africa Regional Medicine Harmonization Initiative (AMRHI) as a pilot region. The EAC underscored that the private sector is keener than member states to invest where there is sound regulatory frameworks in place. Member states have not demonstrated the same keenness to collaborate and work together. In addition, it's the private sector that provides useful feedback on the implementation of programs, as current monitoring mechanism and tools are not effective. It is advantageous to have a regulatory oversight body as this attracts investors and makes the process of investment more efficient and effective additionally allowing for engagement with the African Continental Free Trade Agreement (ACfTA) Regulatory oversight bodies allow for even distribution of standards across local manufacturing industries and the align government organs and joint regulatory harmonization programs. There is still quite a lot that needs to be done however Implementation challenges would be eased by a centralized regulatory oversight body. The high regulatory fees that are charged are an impediment and a challenge.

c) West African Health Organization (WAHO)

The Representative stated that the PMPA is very relevant however needs to be revised and its spectrum broadened and implementation across regions also needs to be increased. A revision of the PMPA to encompass not only industrialization but take into consideration the key health components especially regional harmonization processes. A lot of development and lessons learnt have accrued since the inception of the PMPA

however structures and systems in place currently are not solid enough or well integrated. The PMPA needs to look at both the industry and health as they complement each other and include the components of disease and laboratories. Aside from the ECOWAS and EAC, SADC has domesticated the PMPA. Other RECs do need support to do the same so there should be a roadmap to aid other RECs to domesticate the PMPA. A centralized regulatory and oversight body is important as the RECs are the pillars on which the AMA will stand and as such the RECs have an important role to play. Monitoring tools need to be strengthened at the national and regional level Most challenges faced in the pharmaceutical manufacturing and regulation sector has been lack of resources, both financial and human capital. Capacity building is key to curbing these challenges as well.

SECTION B-: BUSINESS ENVIRONMENT & PARTNERSHIPS

a) East African Community (EAC)

The representative stated that the African Continental Free Trade Area (AfCTA) provided opportunities to create potential for the purchase of raw material within the continent. Currently raw materials are exported and finished products are imported. Purchasing of raw materials from within the continent is limited due to a lack of skill and because there are no economies of scale on the continent. Distribution of pharmaceutical ingredients across member states will be facilitated, to contribute to the equitable participation of all member states. Local manufactures should be the preferred option as well as an enhanced common external tariff to promote local products. This is necessary if the pharmaceutical sector is to grow to the next level.

Regional policies guide national policies because of the trade that already exists within the regional level. Some of the challenges hampering production is the cost of local manufacturing. Innovative financing of the pharmaceutical sector need to be improved and in particular concessionary funding to boost the local manufacturing sector in this regard, some countries such as Bangladesh and India are interested in funding the EAC.

It is not necessary for each country to have their own pharmaceutical manufacturing plants however each member state should have an equitable contribution to regional manufacturing. EAC recommends that each REC has a Centre of Excellence to allow each REC to oversee that would engage in regional intelligence, data research and development. The EAC has not completed its central intelligence data platform which is critical to drive investment and the confidentiality and protection of data There needs to be market protection for the manufacturing of basic specific molecules, enhanced common tariffs and preferred public procurement especially due to competitive external competition. The EAC has agreed on a list that is subject to procurement task force.

The representative highlighted that there are polices in place that improve logistic chain management such as one stop border posts. There are investment policies that support private sector engagement. The EAC is finalizing on its investment policy (to include supplying the Global Fund) and code to enhance the engagement of the private sector, market access, protectionism and funding. Strategic partnerships are needed to advance technological transfers, research and development. More centres of excellence are required for the region to benefit from regional collaboration.

b) Southern African Development Community (SADC)

The representative stated that the draft report needs to be populated with more data from member states in the RECs. There should be a protected market for essential

medicines. The representative considered market access to be a pertinent issue. Market are not entirety accessible to certain pharmaceutical products because markets are flooded by donor products. The member states are not procuring essential medicines as donors are procuring at low price globally. There needs to be a way to make sure that the regional market is available to regional producers.

SADC has embarked on pooled procurement led by Tanzania to promote regional manufacturing and economies of scale. The first point of call if a product cannot be obtained on the national market or in the sub-region should be other regions of the continent. The global market should be last sought in order to support the regional producers. The potential of RECs to support the production of Active Pharmaceutical Ingredients is a rather tricky area, because although Africa has the potential the field is dominated globally, as the industry that is a major job creator and it is very competitive to enter. Each country having its own pharmaceutical manufacturing plant is not practical, but remains a challenge to the industrialization plans of member states and as such is not an easy decision to make at a domestic level. The shared benefits of industrialization to member states and the region is the advised manner to proceed. In SADC data is available on import and exports but needs to be complimented by additional data in order to strengthen available information.

c) West African Health Organization (WAHO)

The representative highlighted the potential of the African Continental Free Trade Agreement (AfCFTA) to address the current challenges related to partnerships, protectionism, tariffs, North-South & South-South trade and the purchase of raw materials. Protection of markets to advance market opportunities is very important The specifics of how markets are protected and which exact markets of member states are protected shall need to be determined, further interrogated.

On the matter of partnerships, the beneficial aspect has to be looked into to make sure the interest of member states is taken into consideration. Partnerships and policy development between member states, the private sector and industry need to be better defined with clarity as to the benefits of the relationships. ECOWAS has expanded its partnerships, strengthen collaboration and by doing so expand its initiatives.co Funding can boost local manufacturing and there should be innovative ways to access funding that does not lead to high interest and debt being incurred by local pharmaceutical manufacturers. The proposed Fund for Africa's Pharmaceutical Development (FAP-D) would be beneficial and it is recommended that the modalities for the operation of FAP-D should consider the regional needs, On API's only two (2) countries produce API's on the continent.

With regards to each country having its own pharmaceutical manufacturing plant, this is not practical but different entities of the value chain can be manufactured by different countries such as capsules, packaging and so forth. The supply chain could be diversified to allow inclusion of countries within regions. Although ECOWAS is not fully involved in supply chain management it is envisaged that every member state would then have a role to play in the supply chain and value addition of the manufacturing industry. Alignment of the strengths of what countries are producing within the regions to create a market that is accessible and favourable. Protectionism that is given some thought would be welcome. Some member states already have protected markets for essential medicines (e.g. include Ghana and Nigeria). A list of a basket of essential medicines that are protected is important for the ECOWAS region that is guided by regulation and harmonization initiatives.

There is potential for REC's to establish central intelligence data platforms however, an assessment should be done to see what information is valid and relevant. ECOWAS has hired a consultant to tackle this as well as research and development. There are polices in place that improve logistic chain management such as the public procurement pool.

SECTION C: HUMAN RESOURCES, TECHNICAL & FINANCIAL CAPABILITIES

a) West African Health Organization (WAHO)

The representative recommended that the AUC engages and assist the RECs to improve partnerships for resource mobilization. The AUC should lead in facilitating beneficial partnerships.

KEY RECOMMENDATIONS AND OUTCOMES

SECTION A: ADOPTION AND IMPLEMENTATION OF PHARMACEUTICAL REGULATORY FRAMEWORKS

1. The registration process for products is tedious and expensive in some member countries which are an impediment and a challenge. Renewal of high fees every two years is too heavy and discourages research.
2. Farms in Africa should be strengthened to produce Active Pharmaceutical Ingredients (API's).
3. It is advantageous to have a regulatory oversight body as this attracts investors and makes the process of investment more efficient and effective additionally allowing for engagement with the African Continental Free Trade Agreement (ACfTA) to bolster regional collaboration I boosting local manufacturing.
4. PMPA needs to be revised with its spectrum broadened and implementation across regions increased. The revision of the PMPA needs to encompass not only industrialization but take into consideration the key health components especially regional harmonization processes.
5. A roadmap should be developed to support RECs to domesticate the PMPA.
6. Monitoring tools for the PMPA need to be strengthened at the national and regional levels.
7. Capacity building at the level of the RECs is key to curbing these challenges on advancing the PMPA agenda.

SECTION B: BUSINESS ENVIRONMENT AND PARTNERSHIPS

1. The AfCFTA should be leveraged as it allows for market accumulation and the benefit of economies of scale.
2. Innovative financing of the pharmaceutical sector needs to be improved and in particular concessionary funding to boost the local manufacturing sector.
3. It is not recommended that each country to have their own pharmaceutical manufacturing plants however; each member state should have an equitable contribution to regional manufacturing and the supply chain could be diversified to allow inclusion of countries within regions.

4. It is also recommend that in lieu of individual industrialization in the pharmaceutical sector, a shared benefits of industrialization to member states and the region is the advised manner to proceed.
5. EAC recommends that each REC has a Centre of Excellence to allow each REC to oversee and engage in regional intelligence, data research and development. There is potential for REC's to establish central intelligence data platforms however, an assessment should be done to see what information is valid and relevant
6. There needs to be market protection for the manufacturing of basic specific molecules, enhanced common tariffs and preferred public procurement.
7. A mechanism needs to be put in place to make sure that the regional market is available to regional producers.
8. Protection of markets to advance market opportunities is very important. The specifics of how markets are protected and which exact markets of member states are protected shall need to be determined and further interrogated.
9. Strategic partnerships are needed to advance technological transfers, research and development within regions.
10. Partnerships and policy development between member states, the private sector and industry need to be better defined to make sure the interest of member states is taken into consideration.
11. Innovative ways to access funding that does not lead to high interest and debt being incurred by local pharmaceutical manufacturers are paramount to boost the development of the pharmaceutical sector.

SECTION C: HUMAN RESOURCES, TECHNICAL AND FINANCIAL CAPABILITIES

1. The AUC should engage and assist the RECs to improve partnerships for resource mobilization.

NEXT STEPS AND CLOSING REMARK

Dr. Margaret Agama-Anyetei thanked all the participants for their rich inputs noting that their contribution addressed and gave a sound insight into several questions that arose from the questionnaire and opportunities that can be capitalized on to advance this agenda. She also extended appreciation to UNAIDS for their support in the development of the draft analysis report and their continued engagement to advance the agenda.

She highlighted how the current pandemic impacted procurement as the continent had to look into itself to procure the materials needed. AMA has 16 signatures and 4 ratifications to date and the sooner it is established the more support the continent will receive with regards to regulation. She also emphasised the important role the RECs have in engaging member states to sing and ratify the AMA Treaty. She reiterated that there is a need to draw on the RECs expertise to improve local pharmaceutical manufacturing capacity. There is a need to have in place the right policies across all RECs in order to drive the initiatives discussed.

The AU member States have called for the establishment of the **Fund for African Pharmaceutical Development (FAP-D)** (EX.CL/Dec.970 (XXXI), July 2017), which will address the lack of funding critical for the development of the pharmaceutical manufacturing sector on the continent. This is an ongoing initiative in collaboration with the African Development Bank (AfDB) & African Export-Import Bank (AFREXIM Bank).

Following the AUC Chairperson's (H.E Moussa Faki Mahamat) visit to China in 2018, the AUC and China agreed to focus on Programme for Infrastructure Development in Africa (PIDA). The two sides also agreed to accord high priority to investments in pharmaceuticals. (***Communique on the visit of the African Union Commission Chairperson to the People's Republic of China, 8-9 February 2018***) https://archives.au.int/handle/123456789/7889. The analysis report will provide background for a mission to China which was originally scheduled for February 2020 and will now take place in 2021.

In addition, in partnership with AU-NEPAD the Commission shall set up a working group to make proposals on what the relationship between the AMA and the existing AMRH initiative should be.

In conclusion, Dr. Margaret Agama-Anyetei, informed the meeting that the finalized analysis report shall be presented to AU Policy Organs prior to being officially launched.

ANNEX: DISCUSSION QUESTIONS

SECTION A: ADOPTION & IMPLEMENTATION OF PHARMACEUTICAL REGULATORY FRAMEWORKS

1. How relevant is the PMPA to RECs and member states within their economic blocks? Does the PMPA need to be revised to be made more relevant?
2. Do RECs consider it to be advantageous to host a Centralised Medicines Regulatory and Oversight body?
3. How do the RECs see a centralized regulatory and oversight body relating to the future Africa Medicine Agency (AMA)?
4. How can the challenge of 'lack of regulatory oversight' be improved in order to improve the lack of implementation of regional policies by the National Medicines Regulatory(NMRs)?
5. What needs to be done to effectively address the lack of regulatory harmonization and standards at the regional level?
6. Are monitoring tools and information feedback mechanisms in place to provide feedback to NMR's

SECTION B-: BUSINESS ENVIRONMENT & PARTNERSHIPS

1. What do the RECs see as the potential of the African Continental Free Trade Agreement (AfCFTA) to address the current challenges related to partnerships, protectionism, tariffs, North-South & South-South trading and the purchase of raw materials?
2. Do what extent is policy development at the REC level influencing sectorial policies such as agriculture, education, finance & investment, research and trade.
3. How can funding boast local manufacturing and what should be the criteria to access the funds if available?
4. Should each country have its own pharmaceutical manufacturing plant?
5. Should there be a protected market for essential medicines? Can RECs agree to a common essential medicine list for each region?
6. What is the potential of RECs to support the production of Active Pharmacological ingredients?
7. Do RECs have the potential to establish central intelligence data platforms?

8. What are the opportunities for RECs to centrally support R&D?
9. Do RECs have policies in place that improve logistic chain management and what are the modalities for implementation of these policies?
10. Are there investment policies that support private sector engagement?

SECTION C: HUMAN RESOURCES, TECHNICAL & FINANCIAL CAPABILITIES

1. Do RECs and their member states have Human Resource plans for the development of the pharmaceutical manufacturing sector?
2. Do RECs and member states have resource mobilization plans to attract both external and domestic resources?
3. What plans are in place to attract the support of external partners including member states?
4. Have RECs developed investment/business plans to attract the private sector?
5. Do RECs and member states have communication and feedback mechanisms in place?
6. What purpose does Infra-structure and land as an incentive serve?
7. What is the extent of sharing and communicating best practices for scale up?
8. Do MOU's exist between RECs for the export of pharmaceutical products?

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Regional Economic Communities (RECs) Consultation on the draft report 'Analysis of the current state development of the local pharmaceutical manufacturing and regulatory capabilities of Africa Union (AU) recognized Regional Economic Communities'

31 August 2020

14:00-15:00 EAT

Virtual Consultation

DRAFT AGENDA

I. Opening

i. Dr. Aissatou Clemence Habi Bare, Director, UNAIDS Liaison Office to the African Union and the UN Economic Commission for Africa

ii. Dr. Margaret Agama-Anyetei, Head of Division, Health, Nutrition and Population, AUC

II. Presentation of findings and recommendations of the draft report '*Analysis of the current state development of the local pharmaceutical manufacturing and regulatory capabilities of Africa Union (AU) recognized Regional Economic Communities*'

i. Dr. Margaret Agama-Anyetei, Head of Division, Health, Nutrition and Population, AUC

III. Discussion

IV. Recommendations and next steps

V. AOB

VI. Closing

31 August 2020		
Time	**Agenda item**	**Responsible**
14:00-14:10	I. **Opening** i. Dr. Aissatou Clemence Habi Bare, Director, UNAIDS Liaison Office to the African Union and the UN Economic Commission for Africa ii. Dr. Margaret Agama-Anyetei, Head of Division, Health, Nutrition and Population, AUC	**AUC/DSA**
14:10-14:20	I. **Presentation of findings and recommendations of the draft report 'Analysis of the current state development of the local pharmaceutical manufacturing and regulatory capabilities of Africa Union (AU) recognized Regional Economic Communities'** i. Dr. Margaret Agama-Anyetei, Head of Division, Health, Nutrition and Population, AUC	**AUC/DSA**
14:20-14:45	II. **Discussion**	**RECs**
14:45-15:00	III. **Recommendations and next steps** IV. **AOB** V. **Closing**	**AUC/DSA**
	End of Virtual Consultation	

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