AUDA-NEPAD
COVID-19 RESPONSE WEBINAR SERIES

THEME: "AFRICAN INDUSTRIAL CAPACITY TOWARDS CRITICAL PHARMACEUTICAL AND MEDICAL SUPPLIES"





HOSTED BY:

AUDA - NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

DFSAfrica

POST WEBINAR REPORT
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EXECUTIVE SUMMARY



The AUDA-NEPAD COVID-19 inaugural series of webinars on galvanising African industrialisation to supply pharmaceutical and medical products brought together a broad range of individuals with expertise and interest in Africa's pharmaceutical sector. The webinar presentations focused on the challenges that must be scaled by the African pharmaceutical industry in order to defeat COVID-19 and future pandemics.

The keynote address by Dr. Ibrahim Assane Mayaki, CEO of AUDA-NEPAD stressed the need for theses series of webinars to facilitate concrete actions by African governments, regional economic communities and private sector players on the continent to develop and use Africa's pharmaceutical sector as a catalyst to development of solutions and best practises to combat COVID-19 in Africa. His speech focused on seven critical issues that must be addressed in order for Africa to leverage its industrial capacity to produce critical pharmaceutical and medical supplies to combat COVID-19 while continuing the trajectory of promoting the growth of Africa's pharmaceutical industry.

The Regional Director of the WHO in Africa, Dr Matshidiso Moeti emphasised the need for national governments to cater to the priority products needed for COVID-19 by citizens. She stated that the WHO country representatives are on hand to support governments across Africa with the WHO priority list. She stated that COVID-19 should be an opportunity to strengthen Africa's pharmaceutical industry. This would be achieved by strong political commitment from the authorities; thereby providing the required funding to increase the availability of expertise, strengthening national regulatory systems and the need to create policies promoting use of local goods.

Speaking on behalf of the Federation of African Pharmaceutical Manufacturers Associations, the CEO of Kiara Health Dr. Skhumbuzo Ngozwana framed the debate as a national and continental security issue. He stated that "perhaps, the biggest threat to security of supply of medicines and pharmaceutical products in Africa is from pandemics such as COVID-19, Ebola, MERS, SARS, and the emergence of drug resistant strains of organisms…". He said such challenge will emerge as a strain on global supply chain and due to Africa's limited financial resources or smaller volume purchases and perceived lesser strategic importance to supplier countries, Africa will inevitably be at the back of the queue for any product supplies.

Dr. Skhumbuzo posited that Africa needs local solutions where we can, when we can, and whilst we can; otherwise COVID-19 will overwhelm Africa's health systems. The shutdown of the global supply chain should teach Africa a painful lesson that we cannot rely solely imported pharmaceutical products. The hard evidence suggests that Africans must embrace local manufacture of pharmaceutical products in order to make the African pharmaceutical sustainable.



The CEO of the African Society for Laboratory Medicine Dr. Nqobile Ndlovu stated that the only way to beat COVID-19 is to scale up the testing capabilities across Africa and governments must ensure that there is continuous and uninterrupted availability of testing supplies. He stated that the only way to achieve efficient supply is by developing local capacity to manufacture test kits.

Furthermore, Dr. Ndlovu emphasized that African countries must move towards decentralised testing units through the use of technology. Most African countries have started off with centralised testing in their National Reference Labs (NRL) but this would not suffice in the long run. He commended African countries (South Africa, Senegal and Nigeria) who have developed in-house COVID-19 testing capabilities.

Dr. Margaret-Ndomondo Sigonda, Head of Health Programs at AUDA-NEPAD, contributed on the increased need for regulatory oversight, she re-emphasized the need to ensure that experimental human models for clinical trials of vaccines and therapeutics are conducted efficiently in compliance with internationally acceptable standards. She concluded that while effective regulation of medical products provides guarantee on the quality, safety and efficacy of products circulating in various markets and prevents proliferation of substandard and falsified (SF) products, African government's noble role to protect the health of their people towards the attainment of the highest possible physical and mental wellbeing is now opportune by its COVID-19 response to address the existing regulatory capacity challenges that African countries are facing.

The presentation from the African Development Bank Group was delivered by Dr. Babatunde Omilola, Manager for Public Health, Security and Nutrition. The presentation focused on financing instruments required to support African manufacturers in order to catalyse manufacturing capabilities.

He stated that the COVID-19 pandemic is already having catastrophic impact on African countries in the areas of health, humanitarian and general economy. The continent is estimated to lose about 5-10% of its GDP as commodity prices and revenues from tourism, trade and remittances continues to shrink; hence African countries need to look inward and rely on their local manufacturers to bridge the supply gap.

Local manufacturers in Africa produce about 25 to 30% of pharmaceuticals and less than 10% of medical supplies that are on the African market. Practically, this is not enough to meet the growing demand of medical supplies in the wake of this outbreak. This is why the Bank is stepping in to roll up financing instruments aimed at boosting local production of medical supplies in response to the outbreak on the continent.

These series of webinars are designed to be a combination of presentations addressing Africa's urgent need to combat COVID-19. The success of these webinars will be predicated on using a multisectoral approach coupled with the leadership and coordinated approach from AUDA-NEPAD.

BACKGROUND AND OVERVIEW



In 2012 the 19th African Union Assembly Decision {Assembly AU/Dec.442(XIX)} endorsed the Pharmaceutical Manufacturing Plan for Africa (PMPA) Business plan which provides a package of technical and policy solutions to the challenges hampering Africa's progress to creating a viable pharmaceutical industry that can provide in a sustainable manner the much-needed essential medical products to improve public health outcomes on the continent.

In 2019 African leaders adopted the treaty for the establishment of the African Medicines Agency (AMA) as the single medicines regulatory agency in Africa whose major role would be complement national medicines regulatory authorities' capacity especially when confronted with the need to fast track the approval of medical products used in emergencies such the current COVID-19 pandemic.

The continent is experiencing shortages in supply of medical products used in the response to COVID-19. These includes Personal Protective Equipment (PPE) that is, gloves, gowns, surgical and respirator masks among others. There is also a critical shortage of the diagnostic capability, both Point of Care serology tests for screening and real- time RT-PCR for diagnosis. Africa also has a limited supply of mechanical ventilators and many essential medicines needed to deal with the pandemic and its complications.

COVID-19 has led to the shutdown of the global supply chain; hence India, has banned the exportation of all these priority medicines to Africa. Likewise, many European countries and Russia, have formally prohibited the exportation of many medical technologies and priority medicines in order to cater to nationalistic concerns.

To this end, Africa needs local solutions otherwise COVID-19 will overwhelm Africa's health systems. The shutdown of the global supply chain should look inward and embrace local manufacture of pharmaceutical products in order to make sure African have access to essential medicines and in turn make the African pharmaceutical sector sustainable.

WEBINAR 7-POINT RECOMMENDATIONS

Recommendations endorsed by Participants at the First Africa Pharma Conference 2019 to advance LPP in Africa in line with the PMPA.

1. WHO to identify the priority essential medical products needed to address the demand;
2. AUDA-NEPAD in collaboration with member states and RECs as well as relevant partners to drive a continental / regional mechanism for procurement of essential medical products and identify credible local manufacturers from whom to procure;
3. AUDA-NEPAD in collaboration with relevant stakeholders to define the appropriate supply management mechanism that would increase the viability of local pharmaceutical production;
4. Africa CDC in collaboration with the African Society of Laboratory Sciences to develop a continental strategy for strengthening laboratory capacity to respond to COVID-19 in the immediate, and long term be able to meet the continent's need;
5. AMRH Secretariat to fast-track the adoption and implementation of harmonised guidelines for the clinal development, manufacture, marketing and distribution of needed essential medical products and supplies;
6. AfDB and Afrexim in collaboration with relevant stakeholders to urgently define and accelerate its strategy for access to affordable financing, detailing how to access it, and how it supports the development and growth of the African pharmaceutical industry;
7. AUDA-NEPAD with the support of the Federation of African Pharmaceutical Manufacturers and other relevant partners assess current status and develop a strategy to boost the current capacity of the local pharmaceutical industry to supply the much-needed essential medical products. This might involve generally increasing the industrial capacity or re-purposing existing production lines to meet the demand for priority products.

WEBINAR IN NUMBERS

OVERALL

565
Registered

7
Speakers

COUNTRY PARTICIPANTS

32
African
Countries

7
Other
Countries

DELEGATE ROLES

144
Local Pharma & Medical Supplies

45
Multilaterals & Development Agencies

25
Academics & Researchers

24
Government officials

15
NGOs and Civil Societies

12
Investors & DFIs

5
Media & Press

KEYNOTE/WELCOME ADDRESS



Dr Ibrahim Assane Mayaki, CEO of AUDA-NEPAD

The CEO of AUDA-NEPAD Dr. Ibrahim Assane Mayaki gave the keynote address at the webinar. Here is a transcript of his opening remarks:

I am pleased to officially welcome you all to our first series of webinars aimed at leveraging Africa's Industrial Capacity to Produce Critical Pharmaceutical and Medical Supplies to combat COVID-19 while continuing our trajectory of promoting the growth of Africa's pharmaceutical industry.

These webinars will facilitate concrete actions by African governments, regional economic communities and private sector players on the continent to develop and use Africa's pharmaceutical sector as a catalyst to contribute to the prevention, medication, best practises and solutions to combat COVID-19 in Africa.

It is my hope that by the end of this webinar we will have deeper understanding of:

1. The priority products needed on the continent to deal with COVID-19;
2. The need to adopt a harmonised and coordinated approach to identify the continental demands and to plan appropriate steps to meet the demand;
3. What local pharmaceutical capabilities exist on the continent to match the demand and how this can be rapidly scaled up;
4. The capacity of laboratory systems on the continent and how these can be supported to better respond to COVID-19 and future pandemics;
5. The existing regulatory frameworks to fast-track regulatory approvals of the clinical development, manufacture, distribution and sale of medical products required to respond to this pandemic while at the same time ensuring compliance to internationally acceptable quality standards;
6. The need to address the procurement and supply chain management which have substantively been affected by the lockdown in many countries;
7. The role of our development financing institutions in boosting Africa's pharmaceutical manufacturing capacity to supply the much-needed medical products efficiently.

Once again, I welcome you all and wish you successful deliberations.

Thank you!

THE PRESENTATIONS

PRESENTATION 1 - PRIORITY PRODUCTS NEEDED IN AFRICA TO DEAL WITH COVID-19

Speaker: Dr Matshidiso Moeti - WHO Regional Office for Africa



Dr. Matshidiso Moeti, Regional Director: WHO

Problem Statement

Dr. Matshidiso Moeti started her presentation by highlighting the top priority products needed to fight the COVID-19 pandemic. Top of the list are:

1. Personal Protective Equipment (PPE) for health workers and
2. Diagnostic supplies and equipment for COVID-19

Solution

Firstly, the WHO sees this very challenging time as an opportunity to strengthen Africa's pharmaceutical manufacturing capability through:

1. Political Commitment to support local production
2. African countries signing the treaty for the African Medicines Agency
3. Strengthening national regulatory systems
4. Increasing availability of expertise and
5. Need for policies promoting use of local goods

The second approach to addressing the availability and supply of priority products is by monitoring the COVID-19 supply chain through a

1. Global and regional approach to procurement. UN agencies coordinating large-scale procurement to ensure the process is coherent, efficient and that countries are not competing against each other
2. Sub-regional: technical working groups on logistics and access (WFP), procurement and supply monitoring (UNICEF), health logistics (WHO) with the following key areas for action:

- Continental coordination to ensure sub- regional coherence
- National supply and logistics committees to monitor availability and forecast needs

Thirdly, Dr. Moeti highlighted that Smart Local Production will boost the capacity of big manufacturing sites by

1. Reaching out to manufacturing sites to scale production e.g. Textile, Carpentry facilities
2. Re-purposing of sites to manufacture the critical supplies needed e.g. oxygen supply, ventilators, hand sanitizer etc



Lastly, African countries must start preparation to manufacture COVID-19 diagnostics and vaccines

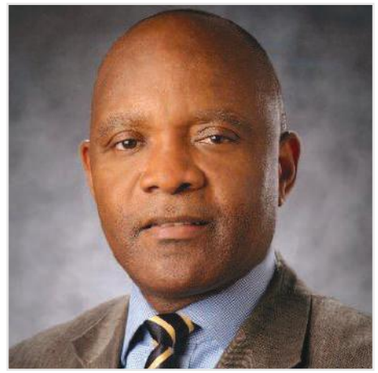
Approach (Practical Steps)

Dr Matshidiso Moeti ended her presentation by highlighting the following key call to actions:

1. Work together to create robust industries in Africa and for Africa
2. Empower local manufacturers to improve access to needed COVID-19 products
3. Advance research and development
4. Expand the availability of skilled human resources
5. Grow the knowledge economy on the continent

PRESENTATION 2 - PROCUREMENT AND SUPPLY CHAIN MANAGEMENT MECHANISMS FOR COVID-19 PRODUCTS

Speaker: Dr. John Nkengasong - Director at African Centres for Disease Control and Prevention (represented by Dr. Ahmed Ogwell, Deputy Director at Africa CDC)



Dr. John Nkengasong, Director: African Centres for Disease Control and Prevention.

Problem Statement

Dr Ahmed started his presentation by highlighting the key drivers of disruption to procurement and supply chain of critical medical supplies needed to respond to the COVID-19 pandemic namely:

1. The epicentre of the epidemic outbreak was in China. This significantly affected manufacturing across China which meant most of the import to Africa was severely affected by the shutdown of factories in China.
2. Countries that had decent manufacturing capability were also affected by the Coronavirus outbreak meaning they placed a restriction on export of medical supplies
3. Air travel has been severely disrupted globally which makes it difficult to move supplies around at a speed at which they are needed

Solution

Right from the beginning of COVID-19's outbreak in China, the Africa CDC and the African Union moved swiftly to convene a meeting of African's ministers of Health which held on Feb 22, 2020. At this meeting, a continental strategy to address the COVID-19 pandemic was adopted with the following key pillars:

1. Set up the Africa Task Force on COVID-19 which has since been in operation
2. Set up of six (6) African Technical Working Group one of which will address Supply Chain Management

At the policy level, the Bureau of the African Union (i.e. heads of state from the 5 regions of the AU) has now met twice to endorse the continental strategy and has instructed the AUC and Africa CDC to ensure the Task Force and Working Groups are delivering on the adopted strategy.

The 5 regional Bureau discussed the need to support member states in the areas of health products needed to respond to COVID-19 such as laboratory test kits, Personal Protective Equipment (PPE), Therapeutics etc. and also to start exploring how to address the issue of very minimum non-core production.

The Bureau set up 3 ministerial coordinating committees in Health, Transport, Finance each of these are incorporating regional economic blocs providing guidance to the African taskforce on COVID-19 and ACDC are implementing guidance provided by these coordinating committees



At Africa CDC level, a few things have been done to address the disruption in procurement and supply chain management:

1. Estimated the need of priority items that are urgently required and currently seeking funding from member states. As outbreak evolve, budget will be adjusted to make sure it is targeting the most urgent needs.
2. Market intelligence for large scale production which are mostly in a few countries in Asia, China. The intelligence is able to help Africa CDC identify companies that can manufacture specific bulk items required
3. Whole procurement and distribution to member states e.g. lab test kits – efficient distribution
4. In process of ensuring test kits received from Germany are getting across to member states despite heavy reduction in travel by air across Africa
5. Within the AU, Africa CDC has been working closely with agencies and organ such as the AUDA-NEPAD on how to ensure the regulatory space for products manufactured in Africa will be solid, quality is good, sustain quality beyond COVID-19, process for approvals are going to be efficient and fast so that what is being produced gets to market, if some things produced by company x, they can be easily accessed by country y and address immediate needs during the pandemic. Working also with Transport ministers to open up air corridors for both human resources and the critical supplies needed
6. Discussion with UNECA, Afrexim, UNDP, WHO, Global Fund so that supplies wherever they are can be accessed by Africa as efficiently as possible.



Approach (Practical Steps)

Dr. Ahmed Ogwell ended his presentation by highlighting the practical steps being taken to improve Procurement and supply chain management

1. Short term – there's a need to ensure that all who are involved in COVID-19 work together to have visibility of what is available in the market. Procurement should be based on need so that there are no cases of hoarding.
2. Medium term – repurpose production capability lying

idle. Some countries are already taking a lead in this such as seen in Kenya, Egypt, South Africa, Ghana, Uganda etc.

3. Long term – continue working to ensure local production increases for COVID-19 medical supplies and not just PPEs but must extend to therapeutics, 90% of which comes from outside Africa. We need to start seeing where we can start producing locally.

PRESENTATION 3 - LOCAL MANUFACTURING CAPABILITIES IN AFRICA TO MATCH THE DEMAND FOR COVID-19 PRODUCTS

Speaker: Dr. Skhumbuzo Ngozwana - President & Chief Executive Officer at Kiara Health



Dr. Skhumbuzo Ngozwana President & Chief executive officer: Kiara Health

Problem Statement

The CEO of Kiara Health Dr. Skhumbuzo Ngozwana started his presentation by quoting from Michel Sidibe's address to the African heads of State and Government on June 6, 2012 when he said: "In the future, regional and global power and national stability will be determined not by who controls arms, but by who controls access to medicines". Dr. Skhumbuzo framed his presentation as a national and continental security issue. He stated that "perhaps, the biggest threat to security of supply of medicines and pharmaceutical products in Africa is from pandemics such as COVID-19, Ebola, MERS, SARS, and the emergence of drug resistant strains of organisms". Dr. Skhumbuzo further said such challenge will emerge as a strain on global supply chain and due to Africa's limited financial resources or smaller volume purchases and perceived lesser strategic importance to supplier countries, Africa will inevitably be at the back of the queue for any product supplies.

Dr. Skhumbuzo posited that Africa needs local solutions where we can, when we can, and whilst we can; otherwise COVID-19 will overwhelm Africa's health systems. The shutdown of the global supply chain should teach Africa a painful lesson that we cannot rely solely imported pharmaceutical products. The hard evidence suggests that Africans must embrace local manufacture of pharmaceutical products in order to make the African pharmaceutical sustainable.

Solution

The Federation of African Pharmaceutical Manufacturers Associations (FAPMA) has conducted a regional survey across Africa and the conclusion is that there is sufficient local capacity within Africa to respond to the production of covid-19 priority products.

1. Multiple Manufacturers across East, West and Southern Africa has installed capacity in the tens of billions (tablets / capsules); and different production technologies for multiple critical Ems. There is also the willingness to share technology across the continent in order to increase production for critical products such as: Paracetamol, Azithromycin, Hydroxychloroquine, Chloroquine, Oseltamivir, Lopinavir / ritonavir, Valacyclovir and Hand sanitizers / Disinfectants.
2. African manufacturers in East, West and Southern Africa are already manufacturing Personal

Protective Equipment (PPE) with capacity constraints because until now their production has been country focused. In order for these manufacturers to service the entire continent, they will need to scale-up rapidly. This will only happen with the right financial support. Nevertheless, African manufacturers are ready to supply the needed PPE to combat COVID-19, products such as: masks (surgical / N95), disposable gowns, facemask with eye shield, Gloves and overshoes.



3. Multiple African companies with the capacity to manufacture SARS and Cov-19 Rapid Diagnostic (POC) kits exists and this is an opportunity to support these companies to scale their production of antigen, antibody, and RT-qPCR primers. This pandemic also presents us the opportunity for immediate Tech Transfer to various African producers following validation of product from a pedigreed International Supplier (crucial as we need mass screening & cannot afford RT-PCR which requires infrastructure, trained people etc, and is costly.
4. South Africa has started the national ventilator project started and production starts at the end April. This project will manufacture 10,000 ventilators by June 2020.

Approach (Practical Steps)

1. African manufacturers face a grave challenge in raising capital to increase their capacity and capability buy raw materials for their products. Most pharmaceutical companies in Africa operate with tight cash flows (pre-payments) and lack of liquidity. They also content with delays in government payments and the fluctuation of foreign exchange. Procurement agencies are often slow, Lethargic and at times unresponsive. This must become more efficient in order to respond effectively to the need to increase availability of priority products and medicines



2. The COVID-19 pandemic has also made access to raw materials really difficult because prices have increased dramatically, coupled with huge global demand, this translates severe delays in supply chain; hence any hitch in the procurement process is punished by going back to the end of the queue. At times 100% pre-payment is requested due to logistical constraints.
3. This pandemic can be Africa's opportunity to build - in

the middle of the storm. The absence of supply from India and China should be used to support local manufacturers in Africa to step up major production lines.

4. This is the opportunity to fast track AMA through central evaluation for products to be supplied continentally. Procurement agencies should develop policies to enhance the purchase of ALL local production capacity. And prioritise policies that support external procurement only if there are no local suppliers to manufacture them.
5. Finally, this is Africa's opportunity to prepare for the next pandemic (and there will be others). Africa must build local capacity now. Institutions on the continent such as AUDA-NEPAD, AfDB, Afreximbank, UNECA and others must create urgent financial instruments to support local pharmaceutical production (LPP).

PRESENTATION 4 - LABORATORY CAPACITY TO COMBAT COVID-19 IN AFRICA

Speaker: Dr. Nqobile Ndlovu - African Society for Laboratory Medicine



Mr Nqobile Ndlovu, CEO: African Society for Laboratory Medicine

Problem Statement

Dr Ndlovu noted, as also consistently echoed by the World Health Organisation, that this is all about testing, hence we need to consider the following urgently:

1. Scaling up testing on the continent
2. Ensuring continuous and uninterrupted testing supplies
3. Developing local capacity to manufacture these kits
4. Regulatory mechanisms during emergence situations

While advocating and reiterating the Africa CDC testing strategy, which is driven off the possibility of community transmission or not, he stressed the need to increase testing on the continent while considering different approaches (centralised, decentralised, country specific) and different tests (PCR, Nucleic et al).

Africa CDC testing strategy is driven off community transmission and noted below:

1. If no known community transmission:
   a. Anyone with fever and acute respiratory symptoms who have been in a place in the last 14 days
   b. Where COVID-19 is transmitting, and who is currently in a location without local transmission.
   c. All symptomatic contacts of a confirmed or probable case of COVID-19.
   d. All cases of SARI and selected ILI samples reported through National Influenza Sentinel Surveillance.
   e. Healthcare workers with symptoms consistent with COVID-19 disease regardless of exposure
2. If known community transmission:
   a. All cases of SARI and ILI reported through the Influenza Sentinel Surveillance System to identify undetected transmission areas.
   b. Severe acute respiratory infections presenting to hospitals.
   c. Healthcare workers with symptoms consistent with COVID-19 disease regardless of exposure.

Solution



The question that needs answering then is how much testing is happening? Number of samples tested for COVID 19 as of April 3rd, 2020 stands at ~65,000 +. This must be encouraged and other

forms of testing must be considered. Laboratory-wise, trainings have been ongoing to ensure the full continent has access to diagnostic capabilities for COVID-19 by Africa CDC, WAHO and WHO. So far for Molecular (PCR based) testing platforms, we have:

1. >50 trained lab personnel
2. Remaining: Lesotho, Eswatini, Sao Tome and Principe and Comoros
3. 1,220,000 tests distributed (PM Abiy and Jack Ma Foundation initiative donation)

He, however noted that rapid scale up can be accomplished in Africa by using the large global footprint of nucleic acid testing instruments. These companies provide high capacity manufacturing and logistics expertise that can be leveraged to rapidly expand testing programs simultaneously across many countries. The companies are:

1. Abbott Laboratories (USA)
2. Roche (Switzerland)
3. Hologic (USA)
4. Cepheid (USA)
5. Thermo Fisher (USA)



Approach to testing is also of critical importance with options ranging from centralised, decentralised and point of care testing. For each, its critical to note the following:

Centralised

1. Most countries have started off with centralised testing
2. Testing happening in National Reference Labs
3. A few countries still referring to other countries NRLs
4. Requires a strong specimen referral system

Decentralised

- Testing possible with new technologies



True point of care (FDA approved)

- Still in the pipeline

While noting few countries like:

- South Africa
- Senegal
- Nigeria

with In-house developed COVID testing.

He concluded by suggesting future embrace of molecular SARS-CoV-2 testing using available EQA schemes and Gene sequencing capabilities noting that it would require:

1. Establishing sequencing capabilities in 12 reference centers
   a. Equipment placement,
   b. online installation
   c. training, reagent supply
   d. Sequencing data has been out for 35 cases in Africa
2. Understanding transmission patterns

PRESENTATION 5 - HARMONISED REGULATORY FRAMEWORK FOR THE EXPEDITED APPROVAL OF MEDICAL PRODUCTS TO COMBAT COVID-19

Speaker: Margaret-Ndomondo Sigonda - Head of Health Programs at AUDA-NEPAD



Margaret-Ndomondo Sigonda, Head of Health Programs: AUDA-NEPAD

Problem Statement

Margaret reemphasized the grave danger the COVID-19 pandemic poses to the African populations, not only in its use as Guinea pigs for clinical trials of vaccines and therapies, but importantly in two other critical areas namely:

1. The quality and safety of medical products is at stake due to unscrupulous business community taking advantage of the dire need of the African population to have access to COVID-19 medical products, and
2. Scientists and researchers experience delays in approval of protocols for clinical trials for COVID-19 medical products which will jeopardise patients' needs.

She noted that while effective regulation of medical products provides guarantee on the quality, safety and efficacy of products circulating in various markets and prevents proliferation of substandard and falsified (SF) products, African government's noble role to protect the health of their people towards the attainment of the highest possible physical and mental wellbeing is now opportune by its COVID-19 response to address the existing regulatory capacity challenges that African countries are facing.

Solution

More broadly then, AUDA-NEPAD in collaboration with AMRH Partners is advocating for implementation and/or ratification of the four key frameworks to assure quality, safety and efficacy of medical products:

1. PMPA, the AMRH Initiative, the AU Model Law on Medical Products Regulation (Model Law) and the treaty for the establishment of the AMA.
2. AU Member States are encouraged to adopt the guidelines for conducting clinical trials which were adopted by AVAREF Assembly and the African Medicines Regulators Conference, in 2017.
3. Joint review of clinical trials for COVID-19 therapies and vaccines is critical for faster and quality approval process
4. AU Member States are encouraged to adopt AMRH
5. African Union Member States are encouraged to uphold the highest levels of ethical and scientific standards when testing for the safety and efficacy of medical products including those aimed at

curbing the current COVID-19 pandemic.



6. More specifically for COVID-19 Approach, African Vaccines Regulatory Forum (AVAREF) and the African Medical Devices Forum (AMDF) meetings were urgently convened and highlights of their actions are summarised below

AVAREF:

a. AVAREF Technical Coordinating Committee (TCC) and the Steering Committee (SC) had a meeting on 1st April 2020 to discuss pertinent issues on how regulators and ethics committee members can better prepare and respond on COVID 19.

b. Agreed on joint review of COVID-19 clinical trials conducted in Africa.

c. Aim to address inefficiencies and delays in providing a final response to the sponsor resulting from sequential application to NRA and Ethics Committee without oversight of each other's inputs.

d. Guidelines for clinical trials adopted by AVAREF and the AMRC Assembly to be used as basis for review.

e. Safety surveillance to be conducted on COVID-19 medical products undergoing clinical trials

f. AVAREF Joint review Process successfully applied to important vaccines against meningitis, malaria, rotavirus, pneumococcal pneumonia and Ebola and has been extended to other therapeutic interventions.

g. The process retains local country insights so that participating agencies do not compromise protection of its citizens by a top-down approach.



h. Through this approach, AVAREF will make available an online platform (SharePoint) for joint reviews of clinical trial applications for preventive, diagnostic and therapeutic interventions related to the COVID-19 pandemic. Participating countries (national regulatory agencies, national ethics committees and targeted ethics review boards) will post their queries online for real-time response from sponsors/applicants.

i. Through virtual meetings, participating countries will conduct joint reviews of clinical trial applications on COVID-19 and also discuss pertinent issues on how regulators and ethics committee members can better prepare and respond to the COVID-19 pandemic.

African Medical Devices Forum (AMDF):

a. The Africa Medical Devices Forum leadership (South Africa-Chair & Kenya-Vice Chair) and AMRH Joint Secretariat (AUDA-NEPAD & WHO) convened first meeting on 31st March to deliberate on COVID-19 response and agreed to establish a Task Force to provide the needed expertise to guide the review and approval process by NRAs.



b. Four Working Groups have been established working on the following areas:

i. Working Group 1: To develop and update list of tests including names of the test and source

ii. Working Group 2: To Develop and update list of medical devices and other products for surveillance, prevention control and case management.

iii. Working Group 3: To propose mechanism (s) to receive information on substandard and falsified tests and other devices and dissemination of such information to regulators.

iv. Working Group 4: To develop guidance document to NRAs on management of IVDs and medical devices donations for Covid-19.

c. The four working groups are expected to conclude their assignments on 13 April 2020, the outcome of which will assist AUDA-NEPAD to guide AUC and AU Member States on approval of importations, procurement and donations for COVID-19 medical products and related supplies.

d. Experts include regulators, laboratory specialists, virologists, and partners organization such as Africa-CDC, African Society for Laboratory Medicines (ASLM), Kenya Medical Research Institute (KEMRI), just to mention a few

Margaret concluded by stating AMRH's achievement so far and noted that solutions above would be implemented by Leveraging on AMRH's achievement. Achievements like > 85% of Sub-Saharan Africa covered with medicines registration harmonization (MRH) Projects at different level, AVAREF alignment with AMRH on clinical trials ethics and regulatory oversight , domestication the AU Model Law on Medical Products Regulation (17 Countries so far), Creation Regional centres of regulatory excellence (11 of such exists at the moment) and an indicators monitoring framework that includes 9 critical categories and 27 indicators.

PRESENTATION 6 - FINANCING INSTRUMENTS TO SUPPORT AFRICAN MANUFACTURERS TO CATALYSE MANUFACTURING CAPABILITIES

Speaker: Dr. Omilola, Babatunde Olumide - Manager, Public Health, Security and Nutrition Division African Development Bank



Omilola, Babatunde Olumide, Manager: African Development Bank

Problem Statement

Dr. Omilola emphasized the weak industrial base of the continent, noting that though the value of the pharmaceutical industry rose from USD 5.5 billion in 2007 to USD 28.56 billion in 2017, its local production of medicine remains weak and limited with local manufacturers producing less than 10% of its own medical supplies hence not meeting its own growing demand of medical supplies in the wake of this outbreak.

Solution

Given the severity of this pandemic and the World Health Organization's (WHO) call on the international community including Development Finance institutions to support Africa in containing, mitigating and properly responding to COVID-19, the Bank is stepping in to roll up financing instruments aimed at boosting local production of medical supplies on the continent.

The Bank's overall response mechanism to this pandemic is consolidated into three separate strategies

1. Ensure the supply of emergency materials-- Immediate term response (April – June 2020)
2. Boost local production of essential supplies- Short-term response (June to December 2020)
3. Develop Africa Health Defence System- Medium to long term, High 5 #5 Strategy (2020-2025)

With his focus on 2.) above, and considering how the ongoing crisis has exposed the continent's fragile health systems, a system totally dependent on imports, he noted the tremendous opportunity to correct the course and emphasized the Bank's move beyond the immediate emergency operation to incentivizing Africa's manufacturing SMEs and Pharmaceutical companies to boost Africa's medical supply chains.

This approach, according to him, will three different dimensions.

- Firstly: The Bank will support ten eligible and viable local SME manufacturers in each region (North, South, East, Central, West Africa and Nigeria) to swiftly transform their manufacturing capabilities to produce simple products (e.g. medical masks, alcohol-based sanitizers). The support will be through financing, creation of enabling environments, and coordinating off-take agreements with governments. Through an effective "One Bank" approach, Sectors will work closely with Country offices and Regional Hubs in developing these fast-tracked non-sovereign operations (NSOs).
- Secondly: The Bank will work with existing Private Equity (PE) clients to channel up to 25% of the already committed ADB's financing into viable healthcare and pharmaceutical companies. The Bank has active financing in private equity funds that are investing nearly UA 20 million in 16 Pharmaceutical companies across all regions of the continent. The Bank will negotiate with Fund Managers the financial implications of increasing private equity funding into these viable companies. The financial gap will be covered from CRF resources earmarked for NSOs, and
- Thirdly: The Bank will negotiate with Financial Intermediaries (FIs) to enhance their on-lending from ADB's committed Lines of Credit (LoC), trade finance and guarantees to small and medium sized pharmaceutical and medical supplies companies.



In addition to incentivising African manufacturing SMEs, the bank will also:

1. Channel existing Financial instruments to boost Africa's medical Supply chain, specifically:
   a. Under the CRF, UA 1.0 billion of ADB non-sovereign resources available in 2020 will be dedicated to fighting the COVID-19 crisis by assisting existing private sector clients through reprofiling their debts and loans, providing emergency liquidity facilities, trade finance and guarantees
   b. In addition, UA 0.5 billion is available to support other non-Sovereign projects not directly linked to the CRF. However, most of these resources (UA 430 million) has been earmarked to a prioritized set of non-sovereign operations that were pre-planned for approvals in 2020.
   c. Seek to mobilize additional financing to boost SMEs production of medical supplies in the short term. The Bank would also encourage RMCs to channel some of the sovereign funds for budget support to support their SMEs in the pharmaceutical sector.
2. Operationalise other innovative approaches devised by the bank to support African pharmaceutical companies. Approaches like;



a. Supporting the consolidation of pharmaceutical firms through the establishment and financing of four African Regional Health Hubs (AHHs)

b. Facilitating four continental Distribution Notes (DNs) for the production and distribution of medicines and other medical products with the capacity and capability to meet a large portion of the continent's demand. The four RPCs will be located in North Africa (Egypt); Southern Africa (South Africa); East Africa (Kenya); and West Africa (Nigeria), where a large concentration of manufacturing activity exists, and



c. Facilitating access to low interest loans to:

   i. pharmaceutical manufacturers, and

   ii. to the wider pharmaceutical ecosystem through the financing of SME and pharmaceutical companies toward improvement of their facilities to achieve international standards of good manufacturing practices (GMP), for building capacity and for working .

CLOSING REMARKS

Presenting the closing remarks, Dr. Janet Byaruhanga the senior program officer, public health at AUDA-NEPAD said: On behalf of Dr. Ibrahim A. Mayaki and the organisers of this first series of AUDA-NEPAD webinars aimed at leveraging Africa's industrial capacity to produce critical pharmaceutical and medical supplies needed to effectively respond COVID-19 and future pandemics, permit me to thank all our distinguished speakers for the wonderful presentations.



To the participants from across the continent and beyond, it has been a pleasure having you. The questions you raised and contributions as well as recommendations are much appreciated.

Now that we have come to the end of this first webinar, we trust that were able to deepen our understanding of the current demand, procurement and supply chain, laboratory capacity, local manufacturing capability, regulatory framework and financial instruments that have been proposed to facilitate Africa's response to COVID-19 pandemic.

We will be sharing with you all the report of the proceedings and outcome of this webinar and look forward to having you on our 2nd series on 28th April 2020.

Thank you again and goodbye!

PARTNER APPRECIATION

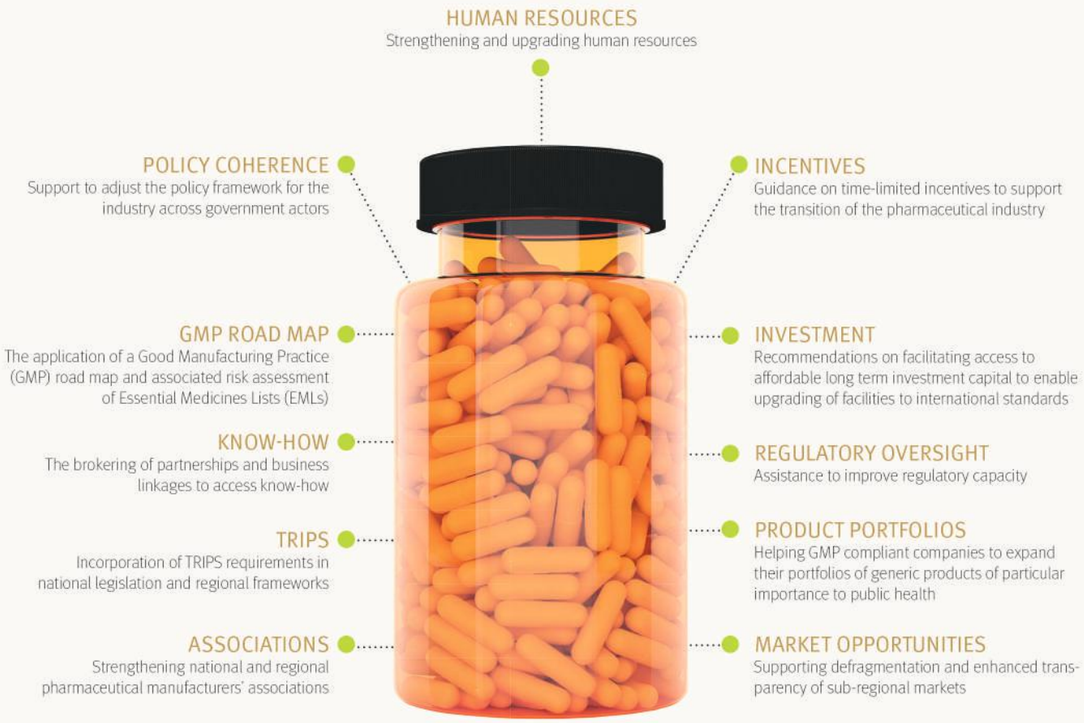
Thank You!

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WHAT?

a comprehensive package of solutions

The complex nature of the pharmaceutical sector requires a comprehensive response in terms of technical support. The Business Plan for the accelerated implementation of the PMPA therefore proposes a package of generic solutions that can be tailored to specific country-level and sub-regional contexts, addressing dimensions such as:



creating synergy



'The task of ensuring reliable and sustainable manufacturing of medicines and other health technologies is a complex undertaking that requires highly accountable and strategic partnerships. [...] The AUC's PMPA Business Plan, as well as its Roadmap on Shared Responsibility and Solidarity, provide excellent platforms around which international partners [...] can contribute'[1]

[1]Commodities for better health in Africa - time to invest locally. Michel Sidibé, Li Yong and Margaret Chan. Bulletin of the World Health Organization 2014;92:387-387A - doi: http://dx.doi.org/10.2471/BLT.14.140566