

AUDA-NEPAD COVID-19 RESPONSE WEBINAR SERIES

ROBUST REGULATORY SYSTEMS: A CRITICAL ENABLER OF
LOCAL PHARMACEUTICAL DEVELOPMENT IN AFRICA



HOSTED BY:



DFSAfrica

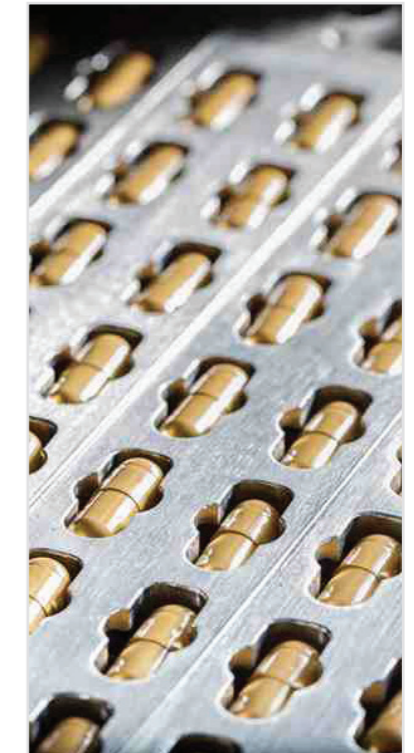
POST WEBINAR REPORT
9TH JUNE 2020

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EXECUTIVE SUMMARY

The AUDA-NEPAD COVID-19 response webinars are designed to facilitate conversations on galvanising African manufacturers to supply pharmaceutical and medical products required to combat the COVID-19 pandemic. The webinar presentations focused on how technology transfer can advance local production pharmaceutical products to improve access of quality-assured medical products in the time of COVID-19.

In her welcome remarks, **Dr. Janet Byaruhanga, Senior Programme Officer, Public Health at AUDA-NEPAD** stated that robust regulatory systems are critical not only to local production of pharmaceuticals but to the entire pharmaceutical value chain. Effective regulation ensures that markets and the health system are protected from untoward effects of substandard and falsified medical products.



This serves to boost both investors' confidence in such markets and the confidence of citizens (especially health workers) in locally produced medical products.

The first keynote presentation was delivered by **Dr. Emily Kaine, Senior Vice President at the United States Pharmacopeia (USP)**. Dr. Kaine emphasized the critical role regulators play in public health and local pharmaceuticals production. She opined that across the product lifecycle good regulatory practice advances public health and helps strengthen the pharmaceutical sector and Mexico's COFEPRIS provides a brief case study on the benefits of regulatory reform. These reforms improved patient access and fostered pharmaceutical sector growth. She concluded her presentation by stating that regulators can increase support to local pharmaceutical production through governance, registration and inspection and harmonization.

Dr. David Mukanga, Senior Program Officer Regulatory Affairs – Africa Systems at the Bill and Melinda Gates Foundation delivered the second keynote presentation and started his presentation by defining a regulatory system as that specialized part of the health system codified in law to provide oversight for the development, manufacture, storage, distribution (including import export) and use of all medical products, as well as the external actors and networks that facilitate the actions of the legally mandated regulatory institutions. He focused his presentation on how regulatory systems can be a critical enabler of local pharmaceutical development in Africa by citing case studies such as the African Medicines Regulatory Harmonization (AMRH) initiative experience which provided harmonization of technical requirements and processes across the region and the Brazil experience where local manufacturers share of generic drug market increased and prices dropped due to regulatory requirement mandating the use of International Non-proprietary Names (INN) over brand names. He concluded his presentation by saying regulatory agencies while keeping their oversight role, must work hand in hand with manufacturers, academia, health providers to advance innovation, research and development, and improvement in quality systems.

The third keynote presentation was delivered by **Mr. Joshua Setipa, Managing Director, United Nations Technology Bank**. Dr. Setipa provided information and insight into the recently launched Tech Access Partnership (TAP), a COVID-19 Tech Sharing Platform whose mission is to address the shortages by connecting experienced innovators and emerging manufacturers in developing countries to share key data, knowledge, and other relevant support through a coordinated network. TAP aims to bring together partners across sectors to facilitate technology transfer in developing countries which will boost innovation, contribute to inclusive economic growth and create more resilient health systems and supply chains. TAP going forward is preparing countries for this crisis and the next.



The presentations were followed by contributions and discussions from our distinguished panellists.

Mrs. Margareth Ndomondo-Sigonda, Head of Health Programs at the African Union Development Agency (AUDA-NEPAD) highlighted progress made since the establishment of the AMRH initiative in creating an enabling policy and legal environment (adoption and domestication of the AU Model law on medical products regulation), capacity building in regulatory affairs through the regional centres of regulatory excellence-RCOREs and creating the foundation for AMA (through regional harmonisation programmes spear headed by the RECs). She explained importance of and creating autonomous agencies across the continent an effort that AMA and the AU model law call for. She highlighted the various investments that have gone into developing a robust regulatory system and concluded her remarks by saying 'its high time we documented best practises as this is something that we haven't done as a continent'. In addition she re-iterated that collaboration is the way to go. *'The academia, industry and regulators must come together to produce products that are developed on the continent to achieve a changing landscape of local production on the continent'*.



In his response, **Dr. Kofi Francis Aboagye-Nyame Director - Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program** emphasised the need for regulatory and governance authorities to take a system approach that covers various sectors of the economy and the whole pharmaceutical value chain. Just having a unitary focus within a regulator, or strengthening individual component within the regulatory authority is not sufficient and there's need to take a broader look at other sectors and at how regulatory systems and governance are improving health outcomes for Africans. He concluded by calling upon African governments to increase and/or harness existing political will to ensure an integrated approach is taken strengthen regulatory systems.

Dr. William Wekwete Head-Evaluations and Registration for Medicines Control Authority in Zimbabwe focused his response on recommending the use of International Non-proprietary Names (INN) as adopted in SADC countries where products are named by their INN and not their trade names and considering Bio-Equivalence (BE) requirements as implemented by Brazil where local generics companies use their BE data to make the case that their quality is just as good as the innovator. He emphasizing the importance of adopting harmonised regulatory systems if Africa's to take its systems more robust and meaningful to the local production sector. He shared some of the achievements of the AMRH initiative particularly in the SADC region of which MCAZ is part.



Mr. Sinhue Noronha CEO of Africure Pharmaceuticals Limited based in Mauritius with manufacturing plants in Cameroon, Côte d'Ivoire, Namibia, Botswana, India, and Ethiopia responded by saying a robust, efficient and uniform regulatory system is what will drive investors to invest in the Pharmaceutical space of course it is also a function of government intent and support from various quality development and Financial development institutions.

BACKGROUND AND OVERVIEW



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.

The 7-point recommendations from the inaugural webinar as stated below, serve as the framework for subsequent webinars organised under specific themes:



WEBINAR 7-POINT RECOMMENDATIONS

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 clinical 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.

KEYNOTE/WELCOME ADDRESS



Dr. Janet Byaruhanga - Senior Programme Officer, Public Health at AUDA-NEPAD

The Senior Programme Officer, Public Health at AUDA-NEPAD, Dr. Janet Byaruhanga, delivered the welcome address at the webinar. Here is a transcript of her opening remarks:

Distinguished speakers and all participants.

Robust regulatory systems are critical not only to local production of pharmaceuticals but to the entire Pharma value chain. Effective regulation ensures that markets and the health system is protected from the untoward effects of substandard and falsified medical products.

This serves to boost both investors' confidence in such markets and the confidence of citizens (especially health workers) in locally produced medicines and products.

Robust regulatory systems enhance access to real time and quality information that can guide policy interventions and capital investments. Indeed, everybody wins from the citizens who get access to quality medicines to the investor who gets due protection within the sector.

To help us dissect the topic of today's webinar "Robust Regulatory systems - a critical enabler of local pharmaceutical development in Africa", we are joined by distinguished experts and senior executives representing a wide range of stakeholder organisations namely USP, BMGF, UN Technology Bank, Africure Pharma, MTaPS Program of USAID and our very own AUDA-NEPAD.

Now allow me to hand to our first keynote speaker, Dr. Emily Kaine, Senior Vice President Global Health at United States Pharmacopeia (USP).



THE PRESENTATIONS

PRESENTATION 1 - ROLE OF STRONG REGULATORY SYSTEMS IN PHARMACEUTICAL SECTOR GROWTH

Speaker: Dr. Emily Kaine - Senior Vice President, United States Pharmacopeia (USP)



Dr. Emily Kaine - Senior Vice President, United States Pharmacopeia (USP)

Problem Statement

While admitting that the full picture of the maturity of the regulatory landscape across the 54 NMRAs is not completely known, Dr. Kaine noted that although the vast majority of the NMRAs have minimal or no capacity measured by the WHO Global Benchmarking Tool, there has been significant improvements for example she reported that NMRAs in Tanzania and Ghana had attained as GBT maturity level 3.

Another achievement of the African Medicines Regulatory Harmonization that she mentioned was domestication of the AU Model law on medical products regulation which represented a major stride as underpinning for effective regulation; She called for further action in this area to make progress.

Finally she highlighted that the establishment of Regional Centers of Regulatory Excellence (RCOREs) by AUDA-NEPAD AMRH in 2014 is providing an opportunity to advance workforce development across regulatory science areas and Joint dossier review activities across RECs show promise, including:

- Reduce marketing authorization timelines (30-40%) in East African Community (EAC) and the Southern African Development Community (SADC) member states
- More than 100 products recommended for registration in the Zazibona Scheme in the SADC region, and 13 in the EAC region following joint assessments

Solution

Dr. Emily reiterated the role regulators play in advancing public health and support pharma sector growth noting that WHA Resolution 67.20 recognized the critical role regulators play in public health and local production.

She noted that:

- Effective regulatory systems contribute to better public health outcomes,

- Regulators are an essential part of the health workforce,
- Inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products.
- Effective regulatory system can support expansion of local or regional production of quality medicines



Approach (Practical steps)

She suggested that since good regulatory practice advances public health and helps strengthen the pharma sector across the product lifecycle, the overarching principle of innovation, increasing access and improving decision making process should be embraced.

Good regulatory practices like:

- Transparent and consistent rule making and processes
- Consistent high-quality bar based on international standards
- Risk-based review pathways framed in public health need/ priority
- Regulatory reliance
- Rewarding "built in" quality practices, with high up-front quality bar
- Robust, risk-based quality/ pharmacovigilance systems

Would ensure that we have improved business and health implications by:

- Fostering foreign and domestic investments
- De-risking long-term investments in quality
- Increasing efficiency savings for both regulator and manufacturer
- Ensuring timely access to medicines and market
- Providing public confidence to facilitate adoption/ uptake

Dr. Kaine concluded by noting that regulators can advance regulation and increase support to local pharmaceutical production by focusing on few key areas along Governance, Registration and Inspection and Harmonization. *A few thoughts raised are summarized below:*



Along Governance:

- Domesticate AU Model Law on medical products regulation
- Deploy understandable, adaptable guidelines for manufacturers based on international standards
- Publicly publish guidelines, procedures, NMRA decisions and reports
- Hold regular meetings and discussion forums with manufacturers and other stakeholders


Along Registration and Inspection:

- Invest in clearing backlogs and implement risk-based review and inspection approaches
- Adopt international standards such as common technical document to facilitate convergence and predictability
- Waive registration fee (if possible) for medicines that are continuously in short supply.
- Implement reliance schemes

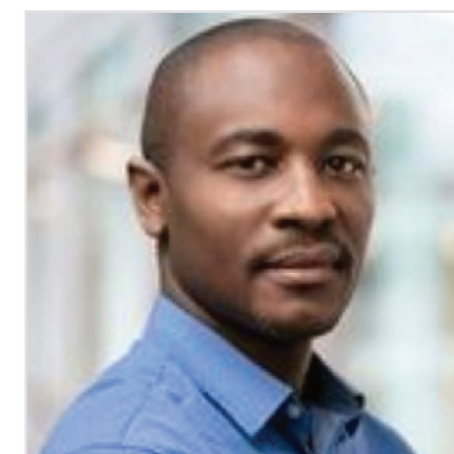
Along Harmonization:

- Accelerate networking, regulatory reliance and mutual recognition to create larger potential markets and remove hurdles to market access, building on existing harmonization initiatives.
- Create common database of API and raw material sources accessible to African manufacturers



PRESENTATION 2 - ROBUST REGULATORY SYSTEMS: A CRITICAL ENABLER OF LOCAL PHARMACEUTICAL DEVELOPMENT IN AFRICA

Speaker: Dr. David Mukanga - Senior Program Officer Regulatory Affairs - Africa Systems, Bill and Melinda Gates Foundation



Dr. David Mukanga - Senior Program Officer Regulatory Affairs – Africa Systems, Bill and Melinda Gates Foundation

Problem Statement

Dr Mukanga defined a regulatory system as a “system of all organizations, people and actions whose primary intend is to ensure access to essential medicines and other health products of assured quality, safety and efficacy or performance, hence more than the pyramid or the institutional arrangements of public institutions that deliver regulatory services but include private providers such as manufacturers or distributors, quoting “The Global Fund, 2019”.

He further stated that it can also be defined as a Regulatory system which is that specialized part of the health system codified in law to provide oversight for the development, manufacture, storage, distribution (including import export) and use of all medical products, as well as the external actors and networks that facilitate the actions of the legally mandated regulatory institutions hence an effective, efficient, predictable and transparent approach is critically important in ensuring the quality, safety and efficacy of health products in an increasingly complex global environment

He, however noted that, regulatory agency is not the only player in the regulatory system, and cannot deliver on the access goal on their own – manufacturer, distributor, local outlets, patients/ caregivers are all needed hence regulatory agencies while keeping their oversight role, must work hand in hand with manufacturers, academia, health providers to advance innovation, research and development, and improvement in quality systems

He concluded his introduction by noting that Access is not just availability but includes affordability, physically accessible, acceptable and an informed provider/user and this is the problem statement for the present NMRA on the continent and where more work is needed.

Solution

Dr Mukanga reiterated that the main goals of Regulatory systems should be to improve:

- Access to medicines of assured quality, safety and efficacy by patients

- Standards for quality, safe, efficacy
- The provision of a well-regulated markets which ensures good companies flourish
- The use of generic names as this can have a huge impact on competitiveness of the local industry, and lower prices
- The drive for innovation by encouraging and driving scientific advice sessions to align on development programs; policies on CTs in country or region; policy coherence on what needs to be produced locally overtime
- Proactive linkages with other key actors –
 - HTA, procurement agencies to help drive quality considerations
 - Providers to understand product performance, define unmet need



He also noted that initiatives like the AMRH should increase and be improved on as it provides:

- Benefits of harmonization of technical requirements and processes across the region
- Regional work-sharing, and opportunities to leverage these to cover regional markets
 - Promoting reliance, efficiency and predictability
 - Cutting regulatory and overall timelines
 - Next step is to link these to procurement - regional PQ listing
- Capacity building of regulators and industry
 - Practical talent building being the natural next step

He concluded by citing the progress made in Brazil and Mexico in reforming their approach to pharmaceutical regulation.

He summarised the major changes in Brazil as thus:

- INN was more pronounced than a brand name so as to lower costs
 - Executive issued a presidential decree (793/1993) introducing how generic drugs would be marketed which matters a great deal for company marketing strategies and costs. It was then agreed that:



- In the label of innovator products, the trademark would be displayed in a higher font size and the INN would come right below, with a reduction of 50% compared to the brand name.
- On the other hand, all products registered as generic drug could only be commercialised by its INN
- The font size of brand name could not exceed 1/3 of the font size of the INN;
- Drug retailers should present a list of generic medicine names; and
- All drugs prescribed and procured by the National Health System should use the generic name



- In 1996, under the administration of Fernando Henrique Cardoso, that Congress approved the IP law, assuring patent protection of pharmaceutical products and processes (Law 92879/1996) with the of an increase in the local manufacturers share of generic drug market and drop in prices.
- An increased use of Bioequivalence

Major Changes of equal success in Mexico is summarised below:

- Elimination of Requirement for in-Country Manufacturing
- Clinical trials - By requiring a percentage of the test population in multicentre trials be Mexican, COFEPRIS could discard the previous requirement for a certification of marketing in another country prior to acceptance of a marketing application in Mexico. This facilitated quicker submissions of marketing applications with better information about use of the product in the Mexican context
- Use of an online checklist of the dossier requirements to mitigate the submission of incomplete dossiers
- Reliance on information and reports from MAs issued by reference regulatory agencies for both medicines and medical devices
- Prior to 2011, companies requesting marketing authorization of medicines were required to build and operate a manufacturing plant in Mexico. However, in March 2011 this requirement was repealed, resulting in 614 products registrations, which would not have been authorized if the



in-country manufacturing site requirement was still in place

- Clinical trial reform - an estimated USD 100 million in new technological investments occurred in 1 year. In 2013, the Mexican pharmaceutical industry registered 86,783 direct jobs
- COFEPRIS accepts certificates of compliance with GMP issued by Australia, Brazil, Canada, Europe, Japan, and the US. These redundant inspections alone has saved COFEPRIS 200 million USD



PRESENTATION 3 - TECH ACCESS PARTNERSHIP: A COVID-19 TECH SHARING PLATFORM

Speaker: Mr. Joshua Setipa - United Nations Technology Bank for Least Developed Countries



Mr. Joshua Setipa - United Nations Technology Bank for Least Developed Countries

Problem Statement

Mr Setipa introduced his presentation by stating what the mission of the Tech Access Partnership is, noting that it was created to address shortages of COVID 19 products (ranging from personal protective gears, medical devices like ventilators to diagnostic and testing materials) by connecting experienced innovators and emerging manufacturers in developing countries to share key data, knowledge, and other relevant support through a coordinated network.

He buttressed this by noting that there are fewer than 2000 working ventilators in 42 African countries with 10 countries not having anything at all.

Solution

The Tech Access Partnership will provide three key areas of support:

- Product Information: TAP will offer a digital warehouse of manufacturing and design specifications, technical knowledge and other information required to scale up production.
- Technical guidance: TAP will help manufacturers troubleshoot issues they may encounter as they seek to ramp up production, including by providing information on market dynamics and regulatory hurdles.
- Partnerships: TAP will facilitate partnerships by matching companies based on expertise, needs and capacity.

TAP aims to bring together partners like Private sector participants, Governments, Development partners and civil society across sectors to facilitate technology transfer in developing countries

He concluded by noting that, this in the long term in addition to helping countries respond and recover from the pandemic, will:

- Boost innovation
- Contribute to inclusive economic growth
- Create more resilient health systems and supply chains going forward, preparing countries for this crisis and the next.

CONTRIBUTIONS FROM PANELISTS

Mrs. Margaret-Ndomondo Sigonda, Head of Health Programs at the African Union Development Agency (AUDA-NEPAD)

Mrs. Sigonda started her contribution by agreeing with Dr. David Mukanga's emphasis on policy coherence. She reiterated that it is true that when it comes to having a robust regulatory system, we need to ensure it's an encompassing process and not just the regulatory agency per se but how the regulator is bringing various stakeholders into the picture. The public, industry and other partners must be involved as we have seen in the Brazil and Mexico examples.

While there has been regulatory harmonisation activities in Africa prior to the launch of AMRH in 2009, the AMRH has been able to bring together partners and regulators in the RECs in a more structured way and mobilising the needed resources be it financing, technical, political advocacy that has contributed to the development of the Africa Pharma sector.

She opined that what is key is which direction we should be going as a continent. It is clear that there is agreement that:

1. Harmonisation of technical requirements of product is key and that has happened through the RECs
2. We need to have robust regulatory agencies that are governed by comprehensive laws and that is the reason we've been able to have the AU Model Law. The AU Model Law is a legislative framework aimed at guiding AU Member States and Regional Economic Communities (RECs) in harmonising medical products regulatory systems. Strengthens national Laws on medical product regulation and promotes autonomous National Regulatory Authorities (NRAs). AU Member States are at liberty to domesticate and adapt the AU Model Law to ensure alignment with their Constitutional principles and legal systems.
3. A lot of regulators are seeing the value of working together through the regional platforms and it is through that we have been able to see that capacity is improving. For example in East Africa communities, we see a change from having a few autonomous agencies to now having 4 out of 6 NMRAS having autonomous agencies. This is equally happening in the SADC and ECOWAS region.

Mrs. Sigonda emphasized the need for Africa to now be able to link the investment that has gone into regulatory systems strengthening and harmonisation and translate into investment in pharmaceutical sector so we get to a point where we can capture information that shows the positive impact on local pharmaceutical production.

Two points to highlight where we are heading.

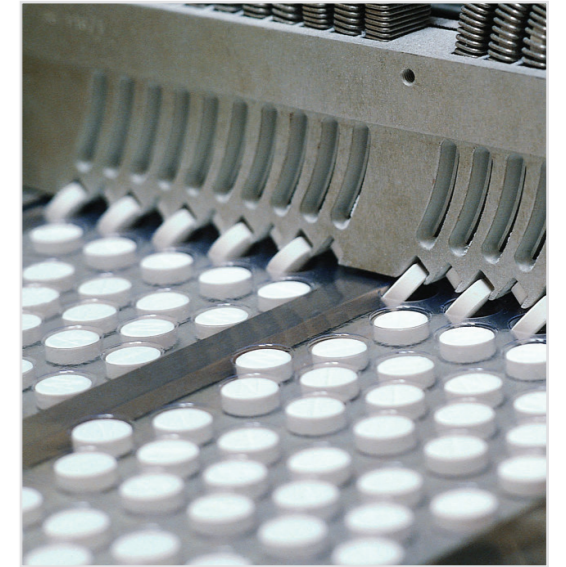
1. Advent of the African Continental Free Trade Area (AfCFTA) brings a lot of opportunities to



Mrs. Margaret-Ndomondo Sigonda - Head of Health Programs at the African Union Development Agency (AUDA-NEPAD)

take advantage of investments that has gone into the regulatory space e.g. a number of initiatives happening on the continent such as Pooled procurement to take advantage of economies of scale.

2. The African Medicines Agency (AMA) which supports the varying regulatory capacities of its member states and the set-up a comprehensive, regional system of regulatory supervision that serves to harmonize regulations across national boundaries, make efficient use of its limited resources, and deepen its capacity building. AMA amongst other things has facilitated the ability of 12 countries to participate in pooled procurement. The SADC region has now created opportunities for local manufacturers to participate in the procurement process.



On the issue of regulatory capacity development on the continent within the regulatory space, Mrs. Sigonda mentioned that this encompasses legal framework, financial resources and human resources. At the moment, 17 countries have domesticated the AU model law. This has led to growth in autonomous agencies that will be able to coordinate regulatory activity in those countries and will ensure we don't have fragmented processes.

In terms of human resources, we have invested in the setup of regulatory centres of excellence, building capacity in pharmacovigilance, clinical trials and product assessments. All of these are a solid foundation taking us to where countries can be galvanised in a more structured way by using AU as a platform to advance these initiatives that are already bearing fruitful results.

On how we can work together, she cited an example of AMRH as a partnership that has successfully brought together partners from Governments, Agencies, RECs, Development partners where every partner can contribute their comparative advantage. Currently the AMRH platform created by AUDA-NEPAD has more than 30 partners which has resulted in better coordination of efforts, less duplication of resources, a more collective way of looking at things and better assessment of decisions together. At AUDA-NEPAD, we have created a platform that brings together various partners and this has been replicated in other sectors such as Agriculture, Infrastructure and now extending to local pharmaceutical production.

She concluded her remarks and contributions by thanking all speakers and offering 2 points to ensure Africa takes advantage of the investments that has so far gone into developing regulatory capability:

1. Document best practises and produce data on local pharmaceutical production capability that exists on the continent
2. Collaboration is the way to go. Research, Academic and Industry must come together to produce products that are developed on the continent to achieve a changing landscape of local production on the continent



Dr. Kofi Francis Aboagye-Nyame Director - Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program

The MTaPs program is a USAID funded program and our main goal is to strengthen the pharmaceutical system to ensure access to and rational use of medicines. Mr. Kofi Francis Aboagye-Nyame emphasised the fact that we cannot have the regulatory system exist in isolation. It really exist within the pharmaceutical system and if we look at the issue from a systems approach, the governance structures that are needed must have links to other sectors of the economy such as trade, education sector etc. All these are needed for the regulatory system to be effective. Just having a unitary focus within a regulator, or strengthening individual component within the regulator is not sufficient, we need to ensure these links to everything else.

In Emily's presentation, she mentioned that a good regulator promotes confidence within the system. This has impact on pricing, on financing implications, on how we are ensuring access to new chemical entities, what is the marketing authorisation doing, access to new commodities amongst other benefits of taking a system wide approach. We can't do this alone within our countries or within one medicine regulatory authority. The whole continent must understand the importance of working together to have a common goal of enhancing regulatory capacity within the continent to improve pharmaceutical production on the continent.

We all have been talking about the Pharmaceutical Manufacturing Plan for Africa (PMPA), the real question is how to set up a regulatory system that is harmonised in a way that there will be confidence in the market.

One of the key consideration for the way forward is building on political will of member states. A few questions need to be addressed:

1. How are we on the African continent, within our Regional Economic Communities (RECs) depending and trusting each other in order to put in place and put in effect decisions that will allow us to get this work across. Focus should not just be in regulating products but in how these initiatives and systems are improving health outcomes.
2. How are we ensuring incentives are applied in a fair and equitable way to promote utilisation of these services, how it promotes rational use of these medicines as no point producing products if it will not lead to improved health outcomes?
3. How are we supporting the AU? What kind of support are governments giving, what kind of support are



Dr. Kofi Francis Aboagye-Nyame Director - Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program

donors giving? There's need for all the investments in capacity building to result in actions which will only happen sustainably if there's political will and the governance structures are put in place.

In concluding his remarks, Dr. Aboagye-Nyame said the MTaPs program will continue to work with AUDA-NEPAD and other partners to ensure that regulatory systems are thorough and connects to all other part of the system to ensure it's connected to healthcare goals of each country.

Dr. William Wekwete Head - Evaluations and Registration for Medicines Control Authority in Zimbabwe.

TAP is a welcomed development as it supports technology transfer. At the moment we are grappling with the enforcement of standards. Right now in Zimbabwe, the Pharmaceutical association is supporting its members to be able to access technology transfer that enables local production of products in essential medicines list.

Also touching on Dr. David Mukanga's presentation on the use of International Non-proprietary Names (INN), I think that is highly recommended approach that has been adopted in SADC where we prefer products to be referred to by their INN and not their trade names. The issue of Bio-Equivalence (BE) is happening where we have manufacturers who have been producing simple products and want to expand into making products like anti-hypertensive which need BE. The example of Brazil is quite apt and in the end those manufacturers who manage to do BE will be able to show their products are comparable in the interchange with innovators.

I would like to add that regulators must follow good practises, ensure consistency, transparency and economise on resources without compromising on quality of products.

There's a lot of work gone into regulatory framework in Africa. UNIDO mapping their needs. WHO tech capacity to review dossiers have increased. In conclusion, AUDA-NEPAD has laid the foundation and we have something to build on.



Dr. William Wekwete Head - Evaluations and Registration for Medicines Control Authority in Zimbabwe.

Mr. Sinhue Noronha - CEO, Africure Pharmaceuticals Limited.

We are the Africure Group based in Mauritius and focused on creating manufacturing assets and capabilities in Sub-Saharan Africa. We have set up Oral Solid Dosage (OSD) plants in Cameroon, Coted'voire, Namibia Botswana and India, and have a plant being set up at Ethiopia.

We believe that the way forward in African Health care is to manufacture pharmaceuticals locally by the local Africans so as to create Self Dependency and Self-sufficiency. We understand well the complexities of manufacturing in Africa and believe that with the appropriate inputs and support Africa can produce all that it needs.

A robust, efficient and uniform regulatory system is what will drive investors to invest in the Pharmaceutical space of course it is also a function of government intent and support from various quality development and Financial development institutions.

Today we have heard from the distinguished speakers of the various initiatives that are in place to meet this objective of strengthening the regulatory processes and are encouraged that we are in the right space.

We must express that in some places we have suffered delayed support due to various bureaucratic challenges but have not lost faith that with time governments will understand the need to strongly support local manufacturing by reducing bureaucratic bottle necks.



Mr. Sinhue Noronha CEO of Africure Pharmaceuticals Limited.

CLOSING REMARKS

Presenting the closing remarks, Mr. Olakunle Olaniyi-Edwards the Executive Director DFS Africa said: On behalf of all our partners, we are happy to deliver the 5th webinar in the AUDA-NEPAD COVID-19 response series.

COVID-19 is the challenge of our generation and as a generation of Africans we are determined to meet the challenges of our time on our own terms through our deliberate actions, we will defeat the pandemic. We hope our audience has been adequately informed on how a robust regulatory system can help to increase access to affordable and quality medicines. A robust regulatory system will not only ensure access to medicine, it will increase markets, increase the level of innovation, attract investors and ultimately improve health outcomes for all Africans.

Please permit me to thank all our distinguished speakers for their wonderful presentations and responses. 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.

In the coming days we will be sending you a recording of this webinar and a post-webinar report that succinctly captures today's event. We look forward to having you on 14th July for the 6th webinar in our COVID-19 response series where we will be discussing **"Opportunities for improved market access for local pharmaceutical manufacturers in Africa – Implications of the African Continental Free Trade Agreement (AfCFTA)"**.

Thank you again and goodbye!



Mr. Olakunle Olaniyi-Edwards - Executive Director, DFS Africa

WEBINAR IN NUMBERS

OVERALL



473

Registered Delegates



7

Speakers

COUNTRY PARTICIPANTS



36

African Countries



12

Other Countries



4

Continents Represented

DELEGATE ROLES



280

Local Pharma & Medical Supplies



108

Members of the Public



27

Government officials



18

Academics & Researchers



15

Multilaterals & Development Agencies



14

NGOs and Civil Societies



8

Investors & DFIs



3

Media & Press

PARTNER APPRECIATION



Thank You!



AFRICAN EXPORT-IMPORT BANK
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THE MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

These logos belong to the partners who support AUDA-NEPAD in the implementation of PMPA

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

¹Commodities 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>