

AUDA-NEPAD COVID-19 RESPONSE WEBINAR SERIES

HOW TECHNOLOGY TRANSFER CAN ADVANCE LOCAL PRODUCTION TO IMPROVE ACCESS OF QUALITY-ASSURED MEDICAL PRODUCTS IN THE TIME OF COVID-19



HOSTED BY:



 **DFSAfrica**

POST WEBINAR REPORT

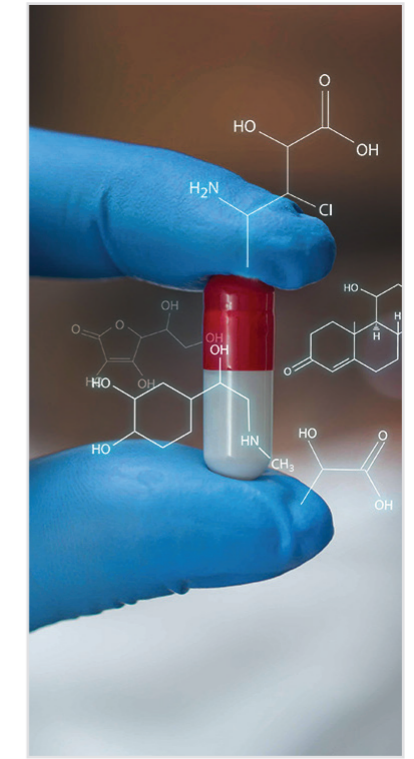
26TH MAY 2020

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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 of pharmaceutical products to improve access of quality-assured medical products in the time of COVID-19.



The opening address by Dr. Janet Byaruhanga, a Senior Programme Officer, Public Health at AUDA-NEPAD stated that technology transfer does not occur by accident. *'It must result from the deliberate effort of various stakeholders in taking something from the research laboratory, protecting it through the IP system, licencing a company to produce it, obtaining regulatory approval to get it into the market place and making it accessible to all who need it'*.

Furthermore, she stated that Africa's governments should invest in creating an enabling ecosystem, leveraging partners and stakeholders support for effective technology transfer. It is our hope that all that research that has been published by universities within and beyond the borders of the African continent do not remain in journals but should translate into products that can bring about improvements in the socioeconomic wellbeing of African communities.

The keynote speaker Dr. Emily Kaine, Senior Vice President at the United States Pharmacopeia stated that across the main drivers of "competitiveness"; health and primary education, macroeconomic environment, infrastructure, innovation, institutions, business sophistication, market size, technological readiness, financial market development, labour market efficiency, goods market efficiency, higher education and training, African markets are still relatively disadvantaged.

She reiterated that technology transfer will be one of the levers through which African products and markets would gain competitiveness. She further defined the crux of technology transfer as the transfer of technical information, tacit know-how and performance skills, technical materials or equipment, jointly or as individual elements, with the intent of enabling the technological or manufacturing capacity of the recipients. Dr. Kaine posited that technology transfer should be considered as a possible solution in accelerating development of Africa's pharmaceutical production base and Africa must leverage on its substantial potential – both as a producer and consumer, to drive socio-economic development and growth.

Dr. Kaine admonished the stakeholder groups present, that the aim of "tech transfer" can/ should be more expansive, going beyond a sender/ receiver transaction, resulting in diffusion

of capabilities. Furthermore, factors related to innovative and absorptive capacity would frame the likelihood of successful technology diffusion and must be considered when fashioning strategies that would help with technology transfer.

Ms Cecilia brought the attention of attendees to the Tech Access Partnership (TAP) launched on 12th May as a joint effort by the UN Technology Bank, WHO, UNDP & UNCTAD to establish a global technology transfer platform to scale up local production of life-saving health technologies for COVID-19. Speed, reliability as well as enabling policy, legal and regulatory environment as critical enablers of effective tech transfer aimed at improving local production.



Dr Victor Konde focused his response on the need for 'National intent'. What is the national ambition? Do the countries want to build an industrial base? What type of markets are we trying to create? All these questions and more need to be answered by national policy makers and governments. He called for a holistic approach involving both the public and private sector stakeholders as well as a need to develop and implement a generic curriculum for technology transfer for pharmaceuticals.

Dr. Skhumbuzo Ngozwana in his response emphasized on the power of technology transfer and how intent rather than having sufficient absorptive capacity should be the driving force for technology transfer in Africa. He cited countries such as India, Bangladesh, Tunisia, Algeria, who grew their local pharmaceutical production through technology transfer even though they all had little absorptive capability at the beginning. Technology transfer give the opportunity to lower cost and to increase competitiveness.

Dr. Frederick Meadows stressed the importance of absorptive capacity as an important ingredient for sustainable technology transfer. He highlighted the key drivers for timely technology transfer noting the importance of sender/receive alignment in critical areas such as skill set, regulatory environment e.g, ISO guidelines, WHO Prequalification that provide guarantees to access to markets etc.

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. Hello and welcome to the 4th meeting of the AUDA-NEPAD COVID-19 response webinar series on galvanizing African industrial capacity to supply pharmaceuticals and medical products;

On behalf of the leadership of AUDA-NEPAD, I am honoured to welcome our

distinguished speakers and all participants joining us from across the continent and beyond. Your attendance in large numbers, I am told we have over 650 registered participants. This indeed indicates your individual and organisations' commitment to contribute to supporting Africa's efforts to contain the COVID-19 pandemic and reduce its impact on our people; We thank you!

Today's webinar will focus on technology transfer can advance local production to improve access of quality-assured medical products in times like these.

Technology transfer does not occur by accident, it a deliberate effort of various stakeholders taking something from the research laboratory, protecting it through the IP system, licencing a company to produce it, obtaining regulatory approval to get it into the market place and making it accessible to all who need it.

It starts with conducting research that does not only result in the creation of a vast body of knowledge in form of publications but that gets translated into products that bring about desired social impacts.

Therefore the conversation today should be: Are Africa's governments investing enough in technology transfer, what is required to be able to transfer all that research that has been conducted in universities within and beyond the borders of this African continent into products that can bring about improvements in the socioeconomic wellbeing of communities.

I wish you fruitful discussions.

Thank you!



KEYNOTE PRESENTATION

TECHNOLOGY TRANSFER FOR LOCAL PRODUCTION

Speaker: Dr Emily Kaine | The United States Pharmacopeia



Dr Emily Kaine - The United States Pharmacopeia

Problem Statement

Dr Emily noted that across the main drivers of "competitiveness"; Health and primary education, Macroeconomic environment, Infrastructure, Innovation, Institutions, Business sophistication, Market size, Technological readiness, Financial market development, Labour market efficiency, Goods market efficiency, Higher education and training, African markets are still relatively disadvantaged.

Solution

She further highlighted that Technology Transfer, defined as the transfer of technical information, tacit know-how and performance skills, technical materials or equipment, jointly or as individual elements, with the intent of enabling the technological or manufacturing capacity of the recipients, should be considered as a possible solution in accelerating development of Africa's pharmaceutical production base and leverage on its substantial potential – both as a producer and consumer, to drive socio-economic development and growth.

The aim of "tech transfer" can and should be more expansive, going beyond a sender / receiver transaction, resulting in diffusion of capabilities.

Factors related to innovative and absorptive capacity frame likelihood of successful technology diffusion and must be considered when fashioning strategies that would help with technology transfer. Innovative capacity is a function of three things:

- Innovative input
- Scientific output
- Technological output

While Absorptive capacity have relating factors like:

- International trade
- Infrastructure
- Human capital
- Social cohesion and economic inequality
- Quality of institutions & governance systems

She concluded that the case for local manufacturing, which can be spurred by technology transfer is strong and *the urgency of the imperative is high as COVID crisis reveals fundamental global supply chain vulnerabilities.*

The three reasons below buttress her point.

- **Affordability:**
 - At scale FPP manufacture in Africa, even accounting for raw material/ API import, could result in a 12% or more reduction in landed price to distributor versus FPP import¹
 - Further upside from opportunity to “leapfrog” through adoption of advanced manufacturing technologies: Using Ethiopia as an example, McKinsey and company analysis revealed that improved chemical-synthesis processes could reduce costs by approximately 5 to 35 percent, and continuous production could cut costs by another 10 to 25 percent
- **Market responsiveness and security:**
 - Local pharmaceuticals are more incentivized to bring newer/ more innovative generics to their markets, compared with global players who may lack incentives to navigate local regulatory requirements
 - Greater health security (as evidenced by COVID crisis): Access to locally-produced medicines ameliorates need to compete with more powerful/ wealthy markets for finite global essential medical commodity resource pool
- **Reduction in trade imbalance:** If Ethiopia and Nigeria were to increase their local share of production from roughly 15 to 20 percent to around 40 to 45 percent, both countries could expect to see their trade balances improve by \$150 million to \$200 million annually¹



Approach (Practical steps)

She suggested four practical steps that can be taken to accelerate technology transfer/ diffusion and local manufacturing?

Facilitate economic & technical planning

- Conduct a rapid mapping (building on many pre-existing efforts) of existing manufacturing capacity and capabilities across continent or in select markets What is “untapped” and where does absorptive capacity exist? Where is the market potential?



- Based on mapping, develop targeted plan for technology transfer, investment and more broadly stimulation of LPP which leverages favorable government investment and industrial policies to de-risk process



Create connectors

- Leverage technical and business knowledge created by mapping exercise to drive facilitated “connection” process, where a trusted broker connects investors, technology holders and potential recipients
- Identify and support additional “connectors” to facilitate objective assessments on tech “transfer readiness”
- Accelerate regulatory reliance and mutual recognition to create larger potential markets and remove hurdles to market access, building on existing economic cooperation efforts

Remove barriers

- Create common database of API and raw material sources accessible to African manufacturers

Promote diffusion

- Designate funded centers of excellence to house and amplify technical knowledge

CONTRIBUTIONS FROM PANELISTS

Ms Cecilia Oh - Program Advisor HIV, Health and Development Group, UNDP

Speaking from UNDP's regional centre in Bangkok, Ms Cecilia Oh started her contribution by stating the fact that the current public health crisis creates an opportunity for a strong and galvanising call for global cooperation and sharing of technology to provide universal and timely access to all essential health products required to respond effectively to COVID-19.

One of the issues that hasn't been discussed very much is how some technologies may be protected by Intellectual Property (IP) rights which is a major barrier to technology transfer. Ms Oh highlighted one of the resolutions from the World Health Assembly (WHA) which amongst many things is the need for equitable access and fair distribution of these essential technologies. This requires that technologies and innovations are made available in an open format so that barriers to technology transfers are removed as much as possible.

It's become very clear that we need to have open sharing so that technology would not be blocked by IP rights and technology transfer can take place effectively and speedily.

In addition to absorptive capacity of recipient of technology transfer raised by Dr. Emily Kaine, we also need to look at the fact that the speed at which technology transfer can take and often take place is important to owners of the technology and also the question of sustainability on the longer term to ensure production actually does happen.

To ensure technology transfer does actually help grow local production especially during a pandemic like COVID-19, Ms Cecilia brought the attention of attendees to the Tech Access Partnership (TAP) launched by UN Agencies on May 12 in a joint effort to scale up local production of life-saving health technologies for COVID-19. The United Nations Technology Bank, together with the UN Development Programme (UNDP), UN Conference on Trade and Development (UNCTAD), the World Health Organization (WHO) and other technical partners, launched the Tech Access Partnership (TAP) as part of a coordinated approach to strengthen developing countries' responses to COVID-19 and increase access to lifesaving health technologies. As demand for personal protective equipment, medical devices and diagnostics increases exponentially amid the global pandemic, countries with limited resources are often unable to purchase or produce the tools they need to mount effective responses to COVID-19. Lack of access to technical expertise, training and regulatory frameworks also limit



Ms Cecilia Oh - Program Advisor HIV, Health and Development Group, UNDP



local production of essential equipment in these regions, particularly for more complex products like ventilators.

She mentioned that TAP aims to address critical shortages of essential health technologies and equipment by connecting manufacturers with critical expertise and emerging manufacturers in developing countries to share the information, technical expertise and resources necessary to scale up production of these tools. The Partnership will also support countries to develop affordable technologies and equipment that meet quality and safety standards.

Ms Cecilia Oh concluded her contribution by highlighting the following key points

- There's a need for greater cooperation on Quality Assurance and Regulatory approval. This is already helped by initiatives such as the AMRH. In the current pandemic, one of the things that can also be done is to provide platforms for regulatory approval and registration pathways for all essential products needed to respond to COVID-19.
- While national intent to grow the pharmaceutical industry is important, there is also a need for overarching enabling policy and legal environment in the country where local production takes place. These policies should ensure that there are no barriers to effective technology transfer and that incentives are put in place including procurement policies that will make technology transfer sustainable.
- Voluntary licensing is an important step especially with the example of Gilead's Remdesivir. The TAP wants to go further to ensure that as far as possible, technology transfer is available in an open source format as there are usually concerns with voluntary licensing such as specific terms and conditions and geographic restrictions that could limit the ability of some countries to access tech transfer.



Dr Victor Konde - Head of New Technologies and Innovation Section, Special Initiatives Division, United Nations Economic Commission for Africa (UNECA)

Technology Transfer entered internal discourse way back in the 1970s. Since then there's been new fields of studies which has also presented new challenges now for technology transfer.

Dr Konde started his contribution by noting that many years ago, the world tried to negotiate an international code for technology transfer. Technology Transfer was defined as systematic knowledge for the manufacture of a product for the application of a process or delivery of a service. The next challenge was differentiating between transfer of information and transfer of knowledge. When do we actually say that technology transfer has taken place. Is it when a country such as Ethiopia has built up a decent capacity to produce some vaccines or should we extend it to Article 6.2 of the TRIPs agreement which looked at technology transfer in the context of enabling the country to build a sound industrial base. The WTO wants technology transfer to go beyond developed countries sending models of what can be produced but do the companies across Africa have the machines to produce these models or have access to the materials needed to produce?

What can African countries do? While Africa has been into pharmaceutical for so long as far back as the top Egyptian universities there hasn't been much progress in growing the industry. Dr. Konde highlighted some key questions and views that could ensure that technology transfer put's the continent's pharmaceutical industry on a path to sustainable growth:

1. What is the national ambition? Do the countries want to build an industrial base? What type of markets are we trying to create? Do you want a closed market like the Cubans have or an open market like the Koreans? Are we trying to build absorptive capacity at a national level? Does your country want to grow the sector to a level it can export or is producing for the country sufficient? All these questions and more need to be answered by national policy makers and governments.
2. Configuration of a national economy is important. Many of our countries have attracted firms that can provide technology transfer and also invested in production however the government has an agreement with India and China for another 3 years so the companies are stuck with drugs produced. The market needs to be configured to support technology transfer.

Dr Konde concluded his response by highlighting ways in which African countries can be better positioned for technology transfer:

1. National intent. This is important as there's a difference between what a company can do and what the nation decides. For example, South Africa as a country has a national intent to build the Pharmaceutical sector as one of the leading sectors in its economy.



Dr Victor Konde - Head of New Technologies and Innovation Section, Special Initiatives Division, United Nations Economic Commission for Africa (UNECA)



2. A pandemic such as COVID-19 is a time to build national resilience and capability to be part of countries that undertake research into vaccines.
3. IP barriers can be addressed by injection of financing into the value chain.
4. Knowledge is key. Can we develop programs that universities can offer to students that will grow their knowledge of the industry and ensure we increase absorptive capacity? This will help create a network within the youth population. Students should not be locked in a laboratory but also exposed to work experience in Pharmaceutical companies.
5. Government support to get the pharmaceutical companies big enough to list in the financial markets.



Dr. Skhumbuzo Ngozwana - CEO, Kiara Health and Member of the Board the Federation of African Pharmaceutical Manufacturers Associations (FAPMA)

Dr. Skhumbuzo Ngozwana started his contribution by referring to Dr. Emily Kaine's point that "technology transfer is not just between the sender and receiver, it's got to be diffused to a larger group of stakeholders". He noted that India was set on a path to self-sufficiency in the manufacturing of antibiotics and other injectables. Hindustan Antibiotics was started with the help of UNICEF and WHO in 1954 and pioneered Penicillin manufacturing in India, and Indian Drugs and Pharmaceuticals Ltd started with the help of the USSR in 1961 and pioneered other bulk drugs in India.

Out of IDPL people like Dr Anji Reddy, who learnt about API manufacture there, went and set up Dr Reddys laboratories. From this one company (a top 10 generic player globally and key API manufacturer) further break-aways led to the formation of Hetero (a top 3 ARV API and Formulation supplier globally), Suven Nishtaa, Divis Laboratories etc. This is the power of technology transfer even though there wasn't apparent absorptive capacity.

In view of this successful case study of technology transfer in India, we shouldn't look at technology transfer in absorptive capacity alone but should also add intent. Most African countries won't be able to start if we look at absorptive capacity alone.

The second example is Aspen Pharmacare, a South African company which was bought in 1997 when on the brink of bankruptcy. Aspen's revenue grew from \$82m in 2000 and after a couple of technology transfers to revenue of about \$2.5 billion in 2017. Technology transfer gave them injectable facilities with cash investment and made ASPEN a global leader in injectables and Number 6 in the global generics space with current revenue of over \$4 billion.

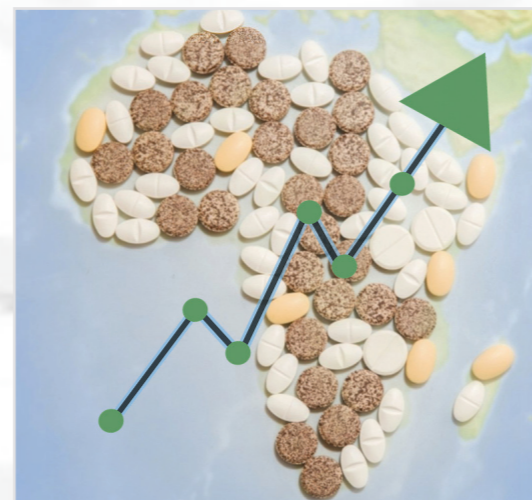
We must never forget that technology transfer is one of the most effective weapons that companies that want to enter difficult markets use. In a post-COVID world where travel is likely to remain muted for a long term, this is the opportunity for technology transfer. This is the opportunity to assist these companies to enter markets that they will have to forgo otherwise.

Thirdly, Dr. Ngozwana noted that technology transfer gives us the opportunity to lower cost and increase competitiveness. We need to start looking at companies in India, Bangladesh, Tunisia where companies have now grown on the back of technology transfer to supply into the US and other markets.

In conclusion, Dr. Ngozwana emphasized the need for the following:



Dr. Skhumbuzo Ngozwana - CEO, Kiara Health and Member of the Board the Federation of African Pharmaceutical Manufacturers Associations (FAPMA)



1. National governments must look at countries that have successfully transitioned. These countries took a deliberate decision to support local pharmaceutical companies. This allowed their local companies to flourish. Algeria has a very simple rule that if a product is manufactured by at least 5 companies and they produce sufficient quantity to meet local demand, importation of those drugs is banned. There are currently 280 on that list. Other foreign companies then have to find a way to work with Algeria which mostly have to now be in technology transfer.
2. In Ethiopia, a portion of government tenders are carved out for local manufacturers. This helps grow the market. This is the time to look further into the horizon and take advantage of the AfCFTA which allows Africa to create bigger markets for our companies.
3. Add industrial applicability to students' curriculum



No doubt that technology transfer is the way to go if we want to manufacture locally. Lilly's technology transfer with ASPEN is a textbook case in how it should be done.

Dr. Frederick Meadows – Senior Technical Advisor, Product Supply Management & CMC at United States Pharmacopeia (USP)

Dr. Meadows shared his experience as someone with more 20 years' experience in Research & Development all the way to commercialising products. He noted that technology transfer has always been on the list of the top of things that cause companies to do business and he cited the key drivers for successful and timely technology transfer.

He noted that when companies decide to perform technology transfer, largely the company has a lot of investment in terms of the people they are investing in, lots of Subject Matter Experts (SMEs) are involved to ensure the success of the transfer but also want to know that there is absorptive capacity to make sure that once transfer has taken place, it is sustainable. This is important as there are timelines to adhere to in terms of the company's investment so usually want to make it a predictive process so they can move on to another project.

In terms of COVID-19, within a few weeks, there's already talk of technology transfer for Remdesivir. This means there must have been a deep understanding from Gilead about where they will transfer to based on absorptive capability which all make a difference in facilitating conversations between the sender and the receiver. Other factors to consider are skill sets and lower cost environment so that success is more predictable.

Dr. Meadows reasoned that there are not a lot of failures in technology transfer mostly because the heavy lifting had already been done as companies tend to already decide who they want to share with based on the points noted above.

He concluded by highlighting the key drivers for timely technology transfers:

1. Pre-planning process is necessary to make this happen. Before the Gilead transfer was announced, there would have been a look at facilities of the receiver, regulatory authorities and there has to be some type of medium that these two entities are communicating which could be ISO, registration capabilities etc to facilitate such a fast transfer.
2. Moving forward if on one hand we have the receiving end and the sender, the same process has to be incubated on the other side of the fence. If both sides look very much the same then technology transfer can happen much faster. So there there must be efforts to speak in the 'same language' such as in the Gilead example, ISO 17025 certification, speaking the ICH language etc and because of that the technology transfer can happen much more quickly.



Dr. Frederick Meadows – Senior Technical Advisor, Product Supply Management & CMC at United States Pharmacopeia (USP)



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 4th webinar in the AUDA-NEPAD COVID-19 response.

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 technology transfer can help to accelerate implementation of the PMPA which helps to grow local production. More success stories of technology transfer put the continent in a better position to fight the current COVID-19 pandemic and any future pandemics.

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 9th June 2020 for the 5th webinar in our COVID-19 response series where we will be discussing **“Robust regulatory systems: A critical enabler of local pharmaceutical development in Africa”**

Thank you again and goodbye!



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



WEBINAR IN NUMBERS

OVERALL



642

Registered Delegates



6

Speakers

COUNTRY PARTICIPANTS



36

African Countries



14

Other Countries



4

Continents Represented

DELEGATE ROLES



302

Local Pharma & Medical Supplies



135

Members of the Public



74

NGOs and Civil Societies



48

Academics & Researchers



35

Government officials



28

Multilaterals & Development Agencies



12

Investors & DFIs



8

Media & Press

PARTNER APPRECIATION



Thank You!



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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>