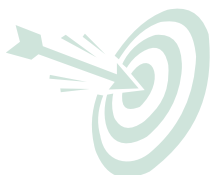


Africa Centres for Disease Control and Prevention

Medical PPE production in Africa: promoting local manufacturers to support the COVID-19 response



A workshop report



Contents

Context	1
Introduction	2
Overview	4
Expected outcomes of the meeting	4
Participants.....	4
Session 1: Opening ceremony.....	4
General session.....	4
Section 2: Description of PPE and standards testing frameworks	6
Section 3: Quality Assurance Systems, SMEs, and theregulatory capacity of PPE	7
Section 4: Coordination, provision, and procurement of PPE	10
Conclusion	12



Context

The global pandemic has highlighted fragility in international supply chains and the dependency of many African countries on imported personal protective equipment (PPE). Market pressures have also increased prices for imported supplies and put additional pressure on areas with limited resources for procurement. There is an urgent operational need to develop the domestic capacity to supply PPE from within the African continent. There is huge variation in Member States industrial manufacturing capacity and the regulatory and testing capacity of government agencies at present. Growing number of companies, including micro- and small-medium enterprises, have responded by repurposing, albeit temporarily, to manufacture an assortment of PPEs. This workshop aims to bring together government representatives, industry, and subject matter experts on material testing and standards to promote the development of domestic production of safe and effective PPE made in Africa.





Introduction

To support Member States to respond to COVID-19, African Health Ministers at the Emergency Ministerial meeting for COVID-19 on 22 February 2020 endorsed the establishment of the Africa Taskforce for Novel Coronavirus (AFTCOR) as a continental mechanism to ensure effective coordination, preparedness, and response to COVID-19. The infection prevention and control (IPC) and supply chain technical working group (TWG) operates within this mechanism to provide guidance and technical support to Member States preparedness, response to and control of COVID-19. One of the exercises of the TWG have been jointly engaged was to map the producers of PPE on the continent. During this process, a number of issues were highlighted, such as:

1. Currently, there is no domestic capacity to meet all PPE requirements in any Member State.
2. New manufacturers are coming onto the market quickly in response to local needs.
3. Existing manufacturers of PPE have limited routes to market through large scale procurement mechanisms.
4. Not all countries and national standards organisations have the skills to be able to accredit new producers.
5. There is very limited post market surveillance of PPE standards, for both imported and locally produced PPE at the present time.
6. There is limited laboratory testing capacity for new manufacturers to test and accredit PPE on the continent.

There is work also being done at the continental level through the African Medical Devices Forum (AMDF) to advise National Regulatory

Agencies (NRAs) to develop guidelines and apply regulatory testing for medical devices including PPE where none existed before. There is great heterogeneity within and between national regulatory mechanisms, some Member States have government agencies with clear remits but not all.

Pivoting from a supply chain based on international producers to a mixed supply chain, including locally manufactured PPE, will involve a rapid scale up of not only industrial and logistical capacity but also many regulatory functions, which may not have been performed previously.

A key need for stakeholders is to understand better the nature of the requirements to produce safe and effective medical grade PPE. There are various elements of PPE required for COVID-19 response. Some of these items are simpler to produce, they require materials that are more readily available, and the design and components are quicker to scale up. Scrub suits and face shields are among these items. Medical face masks and N95 respirators, however, require very specific materials and production methods. The testing regimen for these is more complex and expensive for manufacturers or governments to set up.





Workshop overview

Participants

The core audience were government representatives from Member States who have an interest in developing local production of PPE; industry representatives whether they are currently producing PPE or are interested into moving into this field; innovators and young start-up businesses; and those responsible for large scale procurement of PPE.

Session 1: Opening ceremony

The opening ceremony speaker was introduced by Dr Yewande Alimi. Dr John Nkengasong, the Director of Africa CDC, gave the opening remarks and was the moderator. He welcomed everyone to the workshop and discussed how the COVID-19 pandemic has revealed vulnerabilities and deficiencies in health systems, particularly on the African continent. He emphasized that this period should cause us to think strategically on how to best address the pandemic including instituting prevention measures as the primary approach, as well as building resilient health systems. He stressed the timeliness of the event and stated rather remarkably, in setting the stage for the workshop, that “Africa, a continent of 1.2 billion people, cannot continue to import over 95% of its PPE requirements, or be dependent on others for medications or vaccines.” He further stressed the role that adequate PPE supplies played in protecting vulnerable healthcare workers (HCWs) from contracting SARS CoV-2 infection and asked for a 1-minute silence to pay respects to HCWs whom have died from the virus. Finally, he emphasized that Africa’s industries should be supported, including financially, to mass produce PPE and this was to be the focus of the workshop.

Next, Dr Tochi Okwor, co-chair of AFTCOR IPC TWG and speaking on behalf of Nigeria’s CDC director, Dr Chikwe Ihekweazu, stated that there

was no better time than now to make the continent self-sufficient with its health needs, particularly PPE. She highlighted the objectives of the workshop as focusing on highlighting barriers, solutions, and finding ways to support development of capacity to develop medical grade PPE. She was hopeful that innovators and technical experts would convene as a direct result of the workshop to discuss how these goals would be achieved. She also hoped that best practices would be shared between stakeholders, including regulatory agencies. Altogether, these activities would leave to achieving pandemic preparedness on the continent.

His Excellency, Otunba Adeniyi Adebayo, Nigeria's Minister of Industry, Trade and Investment, represented by his permanent secretary, Dr Sani-Gwarzo, officially opened the workshop and commended the Africa union's role in promoting sustainable development across the continent, as well as WHO and United Nations entities that provided support to the continent during the global pandemic. He felt that the occasion of the pandemic lends itself to achieving self-determination, freedom, and collective prosperity. He stressed that with the right resources, support, and enabling environment, continent-based entrepreneurs could successfully rise to the challenge of meeting Africa's PPE needs. He mentioned that initiatives such as the Africa Continental Free Trade Area (AfCFTA), to start in Jan 2021, would hopefully move the continent to move away from being import dependent to becoming an industrialized community that is able to meet its own manufacturing needs. He encouraged public-private partnerships to achieve this goal.

Lastly, the Secretary general of the AfCFTA, His Excellency, Mr. Wamkele Mene, highlighted how the pandemic has distorted supply chains and systems and has exposed the weaknesses of the continent particularly its dependence on importation for critical healthcare supplies. He said that the continent should identify ways to leverage industrial capacity to position Africa to be self-sufficient and accelerate productive capacity with establishment of value chains. He raised many pertinent issues including that revisiting and reviewing intellectual rights and patents, in the context of the continent's unique needs, and how making them flexible, will allow for generic products to service Africa's need. In closing, he wished the workshop attendees a successful deliberation.

Session 2: Description of PPE and standards testing frameworks

This was the first technical session of the workshop and provided insight into different types and classifications of PPE, materials used in manufacturing (with durability and reusability emphasized as desirable characteristics), and regulatory standards segregated by PPE type.

The initial presentation was delivered by Dr Ying Ling, Clinical Engineer Consultant at the Operations Support and Logistics (OSL), WHO headquarters. She provided an overall description of PPE components, materials, and functional requirements of clinical PPE. This provided an essential common framework to support the discussions about some of the more specific issues that were brought up later in the workshop.

The next speaker was Ms Alison Syrett, a representative of SIGMA PPE testing and compliance, a private business that provides testing services for manufacturers who produce clinical PPE. She shared her expertise on the range of international standards and testing frameworks that are employed across different global regions and the implications of adopting or adapting these on the African continent.

Finally, Dr Paulyne Wairimu spoke, who is both Head of Medical Devices and IVDs Pharmacy and Poisons Board in Kenya, and Vice-Chair for the African Medical Devices Forum. She brought the session to a close by giving us the perspective of NRAs assessing and enforcing standards. She gave valuable insights into the Kenyan experience, including both challenges and successes in ensuring standards of PPE production and supply are maintained.

The general session concluded with a short question and answer period questions posed by the participants and addressed to the presenters using the Zoom Q&A box. This afforded the participants the chance to interact with the presenters and also allowed them to leave feedback in the Zoom chat box, gathered after the session was concluded.



Session 3: Quality assurance systems, SMEs, and the regulatory capacity of PPE

In her opening remarks for the session, the Director of African Union Trade and Industry stated that COVID-19 has highlighted the gaps in the supply chains on the continent, hence, the department would closely monitor this. The Department of Trade will try to help the private sector and public institutions in the production of PPEs to make the continent more sufficient in PPE. Further, they have tried to organize the private sector with the pan African manufacturing association with the chamber of manufactures associations on the continent. Africa needs to manufacture not only PPE but medicines as well. The director stated that PPEs can easily be made in Africa and therefore, there is not a need to import 90% of PPEs.

The first presenter in this session was from UNICEF. Mr Ehab Atia discussed the technical requirements and quality assurance for PPE procurement in UNICEF. He discussed the conformity with quality management systems in UNICEF requiring manufacturers to conform to ISO 9001:2015 quality management system or ISO 13485:2016. UNICEF can also assign an offer based on a conditional acceptance of the ISO he stated. He further mentioned that the product standards are done in consultations with other UN agencies and organizations such as UC, US CDC, and MSF. He stressed the importance of requesting relevant documents to ensure that the offered products are fit for its intended use and complies with relevant standards for performance and safety. Technical specifications define the minimum requirements for the product to ensure good quality, safety, and efficiency. The products will be authorized by at least one of the management committee members of the International Medical Device Regulators Forum (IMDRF). If the procurement is not conducted in accordance with documented best practices, the products may result in an increased risk of infections. To avoid this, the products shall conform to the design, functionality, and claimed intended use by manufacturer and technical specifications as stated by UNICEF. Next, the presenter took the participants through the documents requested during procurement. This was followed by the technical evaluation of the information provided. In terms of the

detection of fake or invalid certificates, he mentioned that UNICEF applies a stringent due diligence investigational exercise to ascertain that documents presented by suppliers are authentic.

The second presenter from UNICEF, Mr Steward took the participants through the pre-delivery inspection (PDI). PDI is carried out at the supplier's premises and a successful outcome is a requirement prior to the shipping of goods. Challenges of the PDI is external access to proficient testing labs, a longer turnaround time, and lack of implementation of post market surveillance.

The third presenter looked at SMES in PPE production from Nigeria. The CEO of Transgreen Nigeria, Mr Cyprian Orakpo, said that the COVID-19 outbreak changed the face of the world and those leaving in it. He discussed the local situation in Nigeria, the absence of the local manufacturing capacity in most African countries, and the nonexistence of PPE manufacturing in Nigeria prior to COVID-19. He stated the challenges of importation with the export ban by advanced economies, high prices of PPE, and unregistered products on the market. He posed a question, "Why was there the absence of manufacturing of PPE on the continent prior to COVID-19?" As a result of these challenges, local manufacturers decided to address them. The Nigerian government organized a meeting where the promotion of manufacturing of PPE was encouraged. This was done to have local solutions to the local problems. The company was producing DVDs initially and converted part of the company to produce masks. The Transgreen O-Care medical mask was launched in three months. The company obtained financing from Standard Chartered Bank in Nigeria to obtain machines for mask production. At present, the company is able to produce 240,000 masks per day but scalable to reach 300,000 masks in a day. Some of the challenges faced at the beginning of production included: unregulated manufacturing of PPE, unregistered and unregulated importers, high mask illiteracy, and lack of knowledge on the sterilization of PPE. The lack of access to financing, high cost of funds, importation of raw materials from Asia, high-tariff rates, and lack of availability of foreign exchange, also posed problems. He described several solutions to some of the challenges, which included: strong regulation agencies, a PPE literacy campaign, and provision of special funds in local and foreign

currencies. He emphasized the importance of inter and intra African trade on PPEs and that a sustainability plan is needed to ensure local manufacturing companies remain viable post COVID-19.

The fourth presenter, an SME from Ethiopia, was Ms Kamila Hamza from the Hawassa Company. She started with a description of the Hawassa Industrial Park (HIP): its location, customers, and the workforce. At full capacity, the HIP can employ 60,000 people and can generate over 1 billion dollars in annual exports. Most of the disruption across the industry was due to COVID-19 and retail and apparel industries where the worst impacted. When the global apparel demand shrunk, an increased PPE demand surfaced (due to COVID-19) and thus, drove companies in the HIP to pivot into PPE production. The increased demand for PPE in Ethiopia coupled with support from Ethiopian airlines to bring in raw materials, duty free import, and VAT free local sales of PPE policy by the Ethiopian government, gave a huge opportunity for companies to venture into PPE production. Through repurposing into PPEs, they ensured that the skills were being retained for sustainable production of PPE on the continent. She said that WHO identified 19 essential supplies being produced by the companies within the HIP and described the respective companies within the HIP. The best practices within the HIP included: a harmonized and collaborative community, continued support from the investor's association, proactive support from the Ethiopian government, and relevant regulatory bodies and supply of products to the ministry of health. The challenges faced by the HIP: finding a market for already adjusted PPE capacity at national and international level, a lack of awareness of COVID-19 in general, a lack of understanding of PPE as a product, insufficient public procurement tenders and the mixed views globally about government policies, and personal behaviors of the general public that are required to fight COVID-19 together.

The last presentation was from Mr Amit Raga, the South African Bureau of standards (SABS), in the department of trade. The mandate of SABS includes standardization, certification and testing, regulation, and accreditation. He explained the PPE hierarchy of controls, elimination, substitution, engineering controls, and administrative controls of PPE. For PPE, information and training is essential. Certification is a

conformity assessment process whereby an independent neutral body confirms that a product or service complies with relevant specification or standards. Companies need to voluntarily request a conformity assessment body to test their product against a relevant standard. Beneficially, SABS assures quality of critical products, improves procurement and provides assurance, improves supply chain management, enhances legal compliance, reduces lost revenue, and improves the integrity of tender documentation ad requirements. The presentation was concluded by describing the post market surveillance. A short Q&A session was conducted to conclude this session.

Session 4: Coordination, provision and procurement of PPE



This session was moderated by Dr Yewande Alimi. During the last session, Mr Paul Tanui from AUDA-NEPAD spoke on, “the coordination of PPE regulation on the continent.” He introduced AUDA-NEPAD as a development agency of the AU located in South Africa and was providing support to many technical working groups of Africa CDCs’ COVID-19 taskforce leading the pandemic response. He discussed the African Medical Devices forum and Africa Medical Regulatory Harmonization (AMRH) program’s efforts with the ultimate goal of establishing a continent-wide regulatory agency (Africa Medicines Agency [AMA]) in the next 5 years. AMRH had engaged 55 national medicines regulatory agencies across the continent but found inconsistency, lack of capacity, and variability in their approach to medicines and devices regulation. Therefore, the vision was to strengthen institutional regulatory capacity and programs, to have a single set of guidelines, transparency with regulatory processes with clear timelines, resource pooling including twinning programs, and leading to earlier approval of medical products (including medicines, blood products, diagnostics, vaccines, and devices). He highlighted the AMDF’s objectives to create a model and framework for regulatory oversight and harmonize technical guidelines for continental partners hopes it would spurn the creation of AMA that would implement harmonized regulatory framework for regulation of medical devices and in vitro diagnostics, as well as support training and capacity development.

Dr Ossy Kasilo from the WHO regional office for Africa, discussed the joint WHO-UNIDO effort to enhance PPE provision across the continent. She highlighted the objectives and outcomes of the effort to include improving the ability of countries in Africa to protect healthcare and other vulnerable workers from acquiring COVID-19 through the following outputs: to develop, update, and apply guidelines for the manufacture, use, and disposal of PPE; enhance manufacture of locally made and quality assured PPE; and support training on best practices with the use of PPE and post marketing surveillance. In the short term, these will result in improved pandemic preparedness for COVID-19 and in the long term, future pandemics. There are specific projects in five selected African countries—Egypt, Ethiopia, Kenya, Senegal, and South Africa. Altogether, these efforts provided synergy and support to achieve sustainable development goals on the continent.

Lastly, Ms Chidinma Ifepe, a developer of the online resource Africa Medical Supplies platform, introduced the nonprofit platform to the group as a digital marketplace that enabled access to critical medical supplies to African governments (with the support of the AU). She highlighted how it can be accessed and utilized by interested parties and stakeholders and that it was restricted to AU Member States. The platform included access to PPE, clinical management devices and diagnostic kits, and was recently expanded to allow for procurement of drugs and vaccines. By providing access to global manufacturers, allowing volume aggregation and payment facilitation, it provides an efficient platform to procuring supplies across the continent with fast delivery timelines. Unfortunately, her presentation emphasized the lack of African-based manufacturers onboarded with the platform at the current time. Ultimately, the platform would ensure that the continents needs are fully met.



Conclusions

In his closing remarks, Dr Onyema Ogbuagu (Associate Professor of Infectious Diseases at Yale University, USA) and Chair of the IPC logistics sub-working group of the AFTCOR IPC TWG, on behalf of the TWG members, thanked the organizers, speakers, and participants for their attendance.

He highlighted common themes that arose throughout the workshop: the need for uniform continental standards for PPE materials and devices (including domestication of international standards, the need for greater collaboration between national regulatory agencies in order to share best practices, resources and harmonize standards), provide opportunities for post marketing surveillance and flagging of substandard PPE as well as identifying ways to enforce PPE standards and control messaging around appropriate products to be procured and utilized, and the need to protect intellectual property rights and patents. In addition, mobilization of resources and availability and logistics of procurement of raw materials for PPE manufacturing were identified as key bottle neck impacting scaling up production.

Lastly, Dr Ogbuagu offered next steps to build on the successes of the meeting including opportunities for initiating a forum for PPE manufacturers on national, regional, and continental levels to support collaboration and cooperation between groups; emphasized the AMHR's efforts to serve as a forum for collaboration between NRAs; developing a publicly accessible interactive map and database of IPC manufacturers and NRAs across the continent; and finally, the need to explore opportunities to promote and support continent-based PPE manufacturers through the existing AMSP platform but also to compete globally. He stressed that these and many other efforts would be critical to sustainability of ramping up PPE manufacturing efforts and better pandemic preparedness for the future.



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