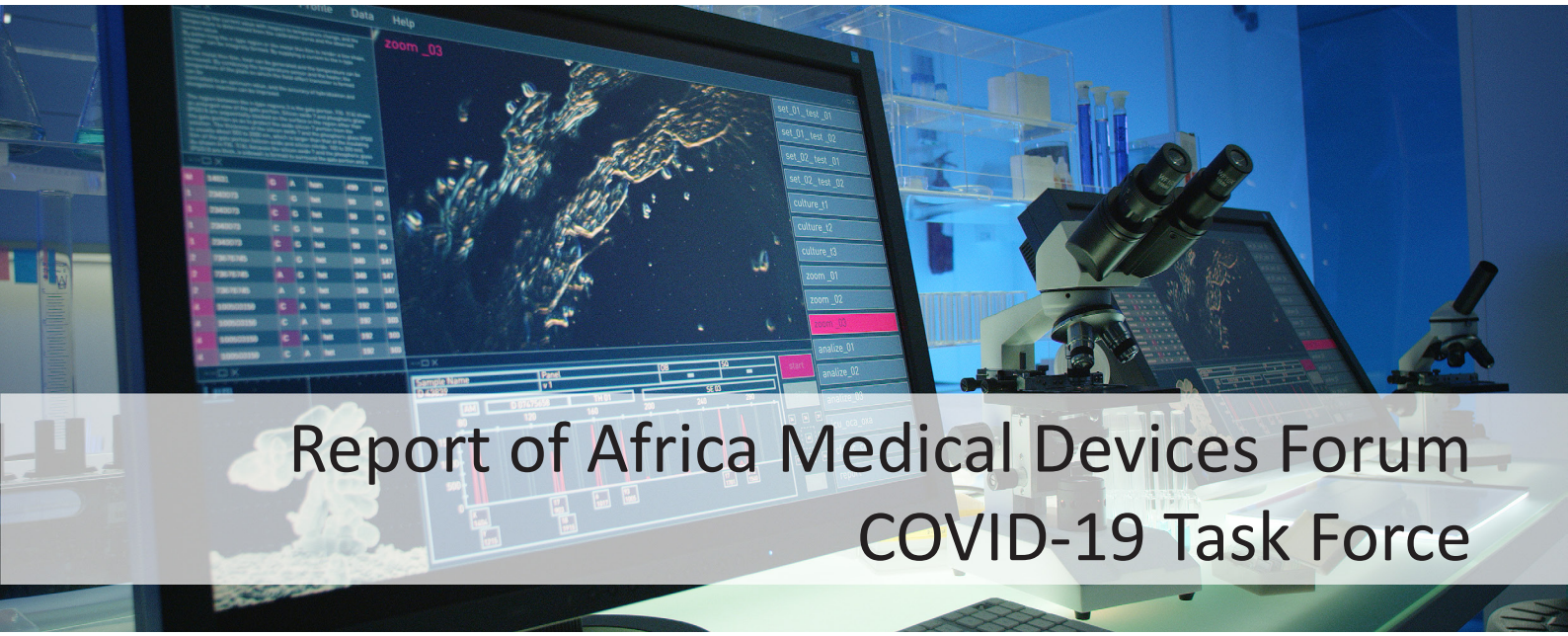
Africa Medical Devices Forum (AMDF) – Technical Committee under the African Medicines Regulatory Harmonization (AMRH) Initiative



Report of Africa Medical Devices Forum COVID-19 Task Force

APRIL 2020

1. Introduction

In recognizing the challenges that African Union Member States are facing in accessing information on recommendedin vitro diagnostics, other medical devices and personal protective equipment (PPEs) for surveilance and management of COVID-19, Africa Medical Devices Forum (AMDF) Technical Committee leadership and AMRH joint secretariat (WHO and AUDA NEPAD) conducted a meeting on 31 March 2020. The aim of the meeting was to discuss and provide recommendations on how to address the challenges in Africa. During the meeting it was agreed to establish COVID-19 Task Force that can provide technical advice and provide recommendations to the AMDF Technical Committee and subsequently to the AMRH Steering Committee (SC) including National Regulatory Authorities (NRAs). On 2nd April 2020, AMDF established a COVID-19 Task Force comprised of experts from National Regulatory Authorities (NRAs), Laboratories, Research Institutions, African Society for Laboratory Medicines (ASLM), African Centres for Disease Control (Africa CDC) and WHO experts. Within the Task Force four (4) separate working groups were established to address the following four key areas: -

i. Prepare list of commercial COVID-19 in vitro diagnostics tests which have been assessed using various regulatory approaches to confirm acceptable quality, safety and performance.

ii. Prepare list of selected medical devices and protective, preventive equipment used in COVID-19 management.

iii. Propose mechanism(s) to receive information on substandard and falsified diagnostic tests and other medical devices and dissemination of such information to regulators on the continent.

iv. Prepare a guidance document on management of IVDs and medical devices donations for COVID-19.

The working groups conducted virtual meetings between 6 and 14 April 2020 and provided feedback to the AMDF Task Force on 14 April 2020.

2. Working group 1: List of COVID -19 diagnostic and surveillance tests

Globally there are two types of in vitro diagnostic tests which can be used for diagnosis and surveillance of COVID-19. Nucleic Acid Tests (NAT) COVID-19 assay, detect viral genetic material (RNA) and can be used to establish and confirm COVID-19 infection as they become positive very early in infection. The second type of assays are rapid diagnostic tests (RTD) which detects COVID-19 antigen and/or antibody which appear during the later stage of infection. Currently, WHO recommend the use of Nucleic Acid Tests (NAT) COVID-19 assay to establish and confirm COVID-19 infection. Working group 1 was given the task of developing a list of COVID-19 diagnostic and surveillance tests to enable African Regulators and Health workers to make informed decisions when procuring such tests. Based on the WHO recommendation the working group decided to make a list made of NAT assays which have been assessed and listed based on established Emergency Use Assessment (EUAL), procedure in the following jurisdictions.

i. WHO Prequalification In vitro Diagnostic EUAL procedure.
ii. Assays which have received regulatory approval by National Regulatory Authorities or Reference or Research Laboratory in various African countries and Saudi FDA.
iii. Assays which have received regulatory approval by individual International Medical Device Regulators Forum (IMDRF) member states.

In order to assist the users, efforts were made to obtain at minimum name of the assay, name of the manufacturer, type of the assay, the product codes/catalogue number of the listed products and link to the instruction for use.

The final list consists of assays which have been assessed and listed by WHO; assays which have received regulatory Emergency Use approval by National Regulatory Authorities including South Africa Health Products Regulatory Authority, Pharmacy and Poisons Board Kenya, Nigeria's National Agency for Food and Drug Administration and Control, Saudi Arabia Food & Drugs Authority, United States Food and Drug Administration, Health Canada, Therapeutic Goods Administration (Australia), Singapore FDA and Japan. The list of the tests is shown in ***Annex 1.***

3. Working group 2: List of medical devices and other products for surveillance, prevention control and case management of COVID-19.

In global response to COVID-19 pandemic the World Health Organization has published a recommended list of medical devices and personal protective equipment (PPEs) that are critical in supporting other medical and non-medical interventions embarked by the member states. The items are essential in protection of health workers working in the front line in the fight of the pandemic as well as tretment of patients requiring hospitalization as a result of infections from the causative virus.

Working Group 2 was tasked to prepare List of medical devices and other products for surveillance, prevention control and case management which have been approved by various jurisdictions. It was envisaged that the lists will be useful in informing the NRAs of the respective countries on which devices to approve for use under emergency use in response to COVID-19 pandemic. In addition, the WG was asked to prepare a list of local (African) manufacturer which have the licensed by National Regulatory Authorities.

The outputs of WG2 included a list of 374 brands of medical devices and PPEs authorized by National Regulatory Authorities in Ghana, Nigeria, Kenya and Tanzania as recommended by the WHO model regulatory framework for medical devices. The list also consists of names and contact addresses of domestic manufacturers of medical devices and PPEs licensed in Tanzania and Kenya and 99 ventilators and masks authorized in USA and Canada ***(Annex 2)***.

4. Working group 3: Substandard/ Falsified Medical Devices including IVDs

Currently, there is established and anecdotal evidence of presence of Substandard/Falsified Medical Devices including IVDs for COVID-19. As a result, WG3 was tasked to establish a mechanism to receive feedback on substandard and falsified IVDs, medical devices and PPEs to support NRAs. This was done by first transforming the WHO IVD complaint form which has been used extensively by WHO but include all medical devices.

To effectively use the reporting form, it was agreed to prepare a standard procedure on how to use the reporting medical devices reporting form. Lastly, it was agreed to translate the form and the standard operating procedure into French, Portuguese and Arabic languages. Saudi Arabia volunteered to share a post market surveillance form for targeted to COVID-19.

The outputs were AMRF reporting form for complaints for medical devices including in vitro diagnostics and Standard operating procedure for handling reports of substandard/ falsified medical devices including in vitro diagnostics ***(Annex 4)***. It was recommended to post the Adverse reporting form and standard operating procedure on the WHO-AMDF MedNet, WHO website and NRA websites, share Field Safety Notices. In addition, use of WHO product alert system and encourage heads of agencies to nominate focal point for medical devices. Lastly to prioritize market surveillance of certain COVID-19 medical devices identification of focal point for S/F devices for each country

5. Working group 4: Guidance on assessment of medical devices including diagnostic tests donations for in-country use during emergencies

In response to the COVID-19 Pandemic outbreak African countries have witnessed donations of medical devices including IVDs. Donations however, present common challenges that have previously been reported; which include donation of expired or near to expiry products, lack of proper documentation in-terms of source of the product, lack of evidence to support safety, quality and performance, non-functional, outmoded. Other challenges include outdated and or damaged products, and lack of information about the products (manual and instructions for use). In-Vitro Diagnostics (IVDs) present unique challenge when it comes to donations. This is in the backdrop of there being no existing policy guide documents that would address unique challenges that diagnostics pose. In response to the COVID-19 Pandemic outbreak, the Africa Medical Devices Forum sort to develop guidance to national regulatory authorities (NRA's) on how to quickly verify the quality, safety and performance of donated medical devices including In-Vitro Diagnostics.

WG4 was given the task to prepare a guidance on assessment of donated medical devices including diagnostic tests for in-country use during emergencies. This was accomplished through review of guidance documents including several WHO guidelines about donations relevant to developing countries. The main output of the group is an AMDF Guidance on assessment of medical devices including diagnostic tests donations for in-country use during emergencies ***(Annex 4)***.

6. Deliberations

The above listed outputs were extensively discussed during the AMDF Technical Committee feedback meeting held on 14 April 2020. The following deliberations were drawn:

i. Members of the Task Force and other stakeholders voiced their appreciation for the great work which has been accomplished in a very short period.

ii. WHO has committed to further support the work being done by AMDF COVID-19 Task Force.

iii. AMRH Steering Committee is requested to expedite approval of the developed guidance documents so that they can be shared immediately by countries.

iv. The group was challenged to keep the momentum, finalize the documents and share extensively through the existing platforms such as AMDF MEDNET, AUDA-NEPAD website and NRA websites.

v. With the support from WHO, developed guidance documents will be translated into French, Portuguese and Arabic languages to facilitate effective implementation of the documents.

7. Recommendations

The technical committee recommended the following:

i. The list should be updated regularly to include new assay (s) assessesed and listed by different jurisdictions. The updated list may include RDTs once they are recommended for diagnosis of COVID-19 by WHO. Links to the publication of lists on the WHO website and the websites of other NRAs will also be made available as a mechanism to ensure access to the most current information.

ii. The Task Force will follow up on the performance evaluation protocol for RDTs which is being developed by the National Laboratories in South Africa and/or WHO.

iii. Encourage African countries to start planning processes for validation/verification of COVID-19 RDTs.

iv. AMRH SC was advised to encourage African countries to use the developed guidance documents.

8. List of annexes

i. **Annex 1:** List of COVID-19 NAT diagnostic tests assessed and approved by various jurisdictions.

ii. **Annex 2:** List of 374 medical devices and PPEs authorized by National Regulatory Authorities of Ghana, Nigeria, Kenya and Tanzania, List of domestic manufacturers of medical devices and PPEs licensed in Tanzania and Kenya. List of 99 ventilators and masks authorized in two IMDRF member countries (USA and Canada).

iii. **Annex 3:** AMRF reporting form for complaints for medical devices including in vitro diagnostics and standard operating procedure for handling reports of substandard/ falsified medical devices including in vitro diagnostics.

iv. **Annex 4:** AMDF Guidance on assessment of medical devices including diagnostic tests donations for in-country use during emergencies.

9. Members of various working groups

Working Group 1:
Anafi Mataka (Chair, African Society for Laboratory Medicine), Andrea Keyter (Africa Medical Devices Forum, South Africa Health Products Regulatory Authority), Agnes Kijo (Secretariat, World Health Organization), Paul Tanui (Secretariat - African Union Development Agency, New Partnership for Africa's Development), Sunday Kisoma (Tanzania Medicines and Medical Devices Authority), Donewell Bangure (Africa Centres for Disease Control and Prevention), Adrian Puren (National Institute for Communicable Diseases, South Africa), Paulyne Wairimu (Pharmacy and Poisons Board, Kenya), Irena Prat (World Health Organization HQ), Rosemary Audu (Nigerian Institute of Medical Research, Nigeria), Willy Urassa (Advisor), Razan J. Asally (Saudi Food and Drug Authority), Mohammed Y. Majrashi (Saudi Food and Drug Authority), Fajer K. Alkusair (Saudi Food and Drug Authority).

Working Group 2:
Sunday Kisoma (Chair TMDA, Tanzania), Andrea Keyter (AMDF, SAPHRA, South Africa), Agnes Kijo (Secretariat WHO), Adriana Velazquez (Secretariat WHO), Bolanle Ikusagba (NAFDAC, Nigeria), Akua Martey (Ghana), Razan Asally (Saudi FDA), Fajer K. Alkusair (Saudi FDA), Andrea Keyter (SAPRHA), Mohammed Majrashi (Saudi FDA), Willy Urassa (Advisor).

Working Group 3
Anita Sands (Chair WHO), Akua Amartey (Ghana), Paulyne Wairimu (Kenya), Bangure Donewell (African CDC), Wilberforce Gachoki (Kenya), Willy Urassa (Advisor), Mohamed Majrashi (Saudi Arabia), Razan Asally (Saudi Arabia), Fajer K. Alkusair (Saudi Arabia), Agnes Kijo (Secretariat WHO), Paul Tanui (Secretariat AUDA-NEPAD.

Working Group 4
Paulyne Wairimu (Vice Chair PPB Kenya), Agnes Kijo (Secretariat WHO), Paul Tanui (Secretariat AUDA-NEPAD), Anafi Mataka (ASLM), Bolanle Ikusagba (NAFDAC, Nigeria), Akua Amartey (Ghana, FDA), Langar Houda (WHO EMRO), Rarazan Asally (Saudi FDA), Fajer K. Alkusair (Saudi FDA), Mohammed Majrashi (Saudi FDA), Willy Urassa (Advisor), Adriana Velazquez Berumen (WHO-HQ).

Other experts who supported the Task Force include; Samvel Azatyan (WHO HQ), Hiiti Sillo (WHO HQ), Stanislav Kniazkov (WHO AFRO), Houda Langar (WHO-EMRO), Moji Christianah Adeyeye, (Steering Committee Chair, AMRH), Margareth Ndomondo-Sigonda (AUDA-NEPAD) and David Mukanga (Chair, AMRH Partnership Platform).