African Union

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

World Health Organization

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

20 - 24 APRIL 2020

1. Introduction

In recognizing the challenges that member states in the African region are facing in accessing the recommended, in vitro diagnostics, other medical devices and PPEs, African Medical Devices Forum (AMDF) leadership WHO continued to support virtual meeting of AMDF COVID-19 Working Groups between 20 and 24 April 2020. The objective was to further consolidate and update the outputs which were achieved during earlier meetings held between 6 and 14 April 2020. Below is the summary of the proceedings and outputs.

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

The group updated the COVID-19 Nucleic Acid tests to include assays which were recently listed for Emergency Use by WHO Diagnostics Prequalification and United States Food and Drug Administration (US FDA) ***(Annex 1)***. Following previous recommendation, a list of COVID-19 serology assay which have been listed by United States Food and Drug Administration, Therapeutic Goods Administration (Australia), Singapore FDA and Nigeria Agency for Food and Drug Administration (NAFDAC) has been compilled ***(Annex 2)***. WHO does not recommend used of serology for diagnosis of COVID-19. Therefore, these assays are only indicated for identification of individuals who have been infected by the virus causing COVID-19. Lastly, the group has been working on developing performance specification, and varification protocol for COVID-19 serology assays. This is work in progress.

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.

During the past one week the WG-2 continued discussions. The list of approved medical devices and PPEs was updated to include technical specifications and links to standards/specifications ***(Annex 3)***. In addition, Technical specifications for face masks which was kindly provided by Saudi FDA were adopted. The specifications include; General requirements; Recognized standards and Labelling requirements. The WG is proposing to further update the lists of local manufacturers of PPE, masks and ventilators to include product codes in order to clearly identify the products. In addition, the group will review of technical specifications submitted by the Saudi FDA for possible adaption especially the guidance requirements for ventilators, tubing connectors and accessories.

Other items will include obtaining feedback from IMDRF on comprehensive list of authorized devices and PPEs, discussions on specifications of the home-made masks and gathering information on the assessments which have been done on recent N95 Ventilators donated by Jack Ma.

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

WG3 was tasked to establish a mechanism to receive feedback on substandard and falsified IVDs, medical devices and PPEs to support NRAs. The AMDF reporting form for complaints for medical devices including in vitro diagnostics was approved by AMRH Steering Committee and posted on the AMDF MEDNET so that all NRA can assess and use the form. The standard operating procedure for handling reports of substandard/ falsified medical devices including in vitro diagnostics was further improved and now is ready to be submitted for approval by the AMRH Steering Committee ***(Annex 4)***. Plans to translate the two documents into French, Portuguese and Arabic languages are ongoing.

Efforts are ongoing to identify focal points for reporting of Substandard Falsified medical devices. Members have been identified by list drawn by NRA through AUD-NEPAD, WHO AMDF MedNet contacts persons and recent participants in WHO NRA survey. Once the list has been compiled, meeting will be conducted to introduce the form and the SOP.

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. To further expand the target audience, the WG has developed and finalized a short guidance on the role of the National Procurement Agencies on ensuring the quality and safety of donated medical devices including diagnostics. ***(Annex 5)***.

6. Deliberations

The above listed outputs were discussed in the Task force meeting held on 24 April 2020. The following are the deliberations:

- Members of the task force voiced their appreciation for the great work which has been accomplished in a very short period.
- The group was challenged to keep the momentum, finalize the documents.
- The list should be updated regularly to include new assay assessesed and listed by different jurisdictions.

- The task force will encourage African countries to use the developed guidance documents.
- Ensure that the Task force outputs is shared extensively including using AMDF MEDNET and NRA websites.

7. List of annexes

i. Updated list of COVID -19 NAT diagnostic tests assessed and approved by various jurisdictions
ii. List of COVID -19 serology tests assessed and approved by various jurisdictions.
iii. Update list of approved medical devices and PPEs updated to include technical specifications and links to standards/specifications.
iv. Standard operating procedure for handling reports of substandard/ falsified medical devices including in vitro diagnostics.
v. AMDF Guidance on assessment of medical devices including diagnostic tests donations for in-country use during emergencies.

8. 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), Irena Prat (World Health Organization HQ), Willy Urassa (Advisor), Razan J. Asally (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), Willy Urassa (Advisor)

Working Group 3
Anita Sands (Chair WHO), Akua Amartey (Ghana), Bangure Donewell (African CDC), Willy Urassa (Advisor) and Agnes Kijo (Secretariat WHO).

Working Group 4
Anafi Mataka (ASLM), Bolanle Igusabha (NAFDAC, Nigeria), Akua Amartey (Ghana, FDA), Langar Houda (WHO EMRO), Willy Urassa (Advisor), Adriana Velazquez Berumen (WHO-HQ), Agnes Kijo(Secretariat WHO) and Paul Tanui (Secretariat AUDA-NEPAD),

Other members
- AZATYAN, Samvel (WHO HQ Secretariat)
- SILLO, Hiiti Baran (WHO HQ Secretariat)
- KNIAZKOV, Stanislav (WHO AFRO)
- NIKIEMA, Jean Baptiste (WHO AFRO)
- Margareth Ndomondo-Sigonda (AUDA-NEPAD)