CRITERIA FOR INCLUSION OF IN-VITRO DIAGNOSTICS AND MEDICAL DEVICES IN THE MEDICAL DEVICES FORUM (AMDF) LIST UNDER THE AFRICAN MEDICINES REGULATORY HARMONIZATION (AMRH) INITIATIVE

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1. Introduction

In recognizing the challenges that African Union Member States are facing in accessing information on recommended in 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 the 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 considering limited regulatory capacity to approve COVID-19 related commodities. 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 Technical Committee 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.

Out of the four (4) working groups which were established within the Task Force; two (2) focused on the development of the following lists:

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

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

Considering the emergency with Covid -19 pandemic and the fact that there was no guidance document for approval of medical devices and In vitro diagnostics through the AMRH programme, AMDF Task Force decided to establish criteria for listing products for emergency purposes. Criteria for listing Covid-19 diagnostic tests and medical devices, PPEs have been highlighted in section 2 and 3.

2. 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 immunoassays including rapid diagnostic tests (RTD) and Enzyme Immunoassays (EIA) 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.

Based on WHO recommendation the following criteria were accepted as a basis for listing Covid 19 diagnostics tests to enable African Regulators to make informed decisions when approving such tests for use:-

i. Assays listed through the WHO Prequalification In vitro Diagnostic EUAL procedure.

ii. Assays which have received regulatory approval by individual International Medical Device Regulators Forum (IMDRF) member states.

iii. Assays which have received regulatory approval by National Regulatory Authorities or National Public or Research Laboratories in African countries and Saudi FDA.

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.

3. 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.

3.1 Criteria that were used to list medical devices, PPEs are as follows:

i. List of medical devices and other products for surveillance, prevention control and case management which have been approved by various jurisdictions especially in Africa.

ii. Devices and PPES that have been approved by NRAs with regulatory oversight for medical devices.

In addition, a list of domestic manufacturers licensed by National Regulatory Authorities was also developed.

The criteria developed by the AMDF are intended to be used only during this time when AMDF Technical committee is organizing its sub-working groups to enable development of specific guidelines that will be used by the technical committee for use during emergencies but also other guidances that would allow systematic quality assurance of medical devices and diagnostics through the AMDF premarket sub working group.