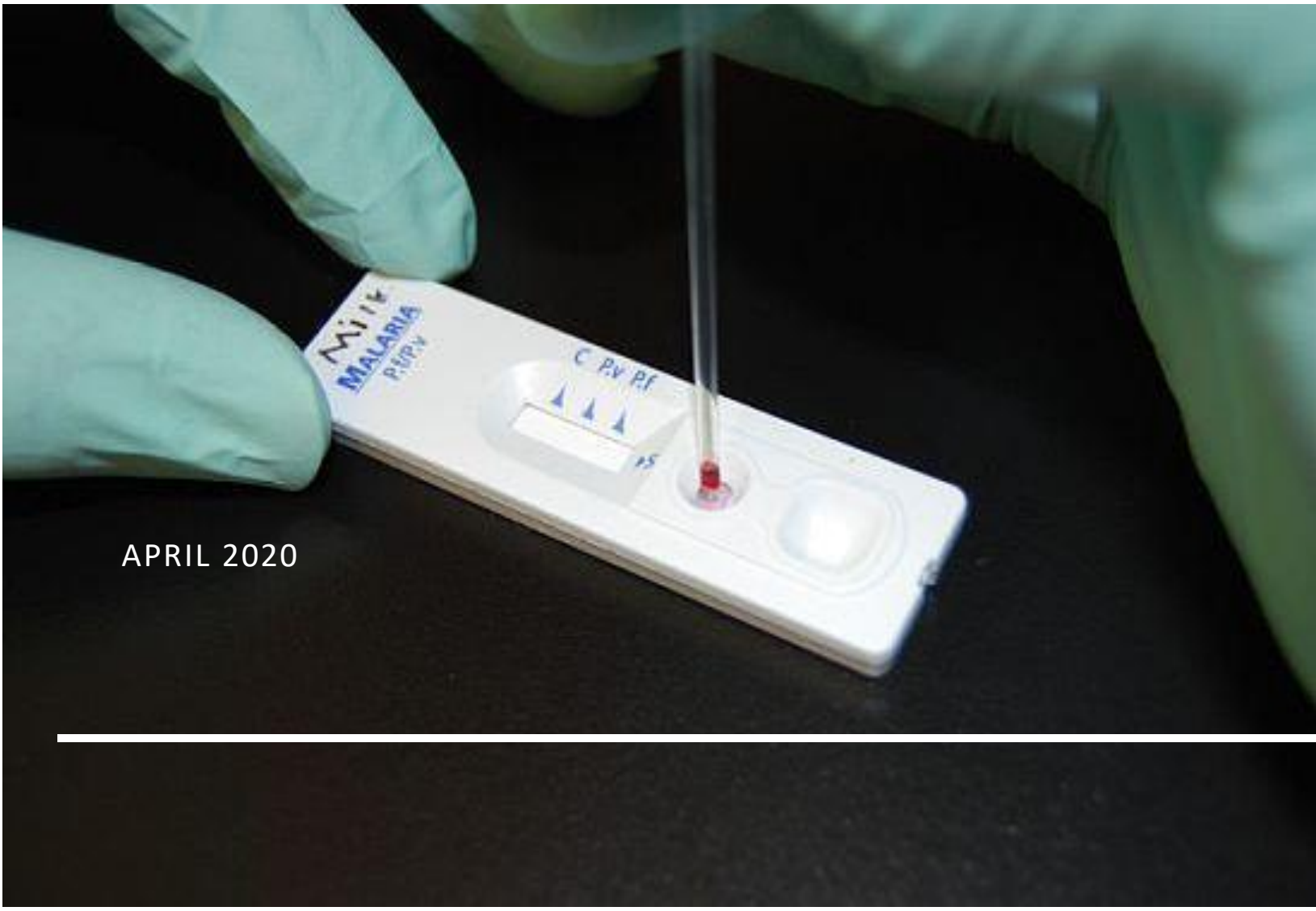
AFRICA MEDICAL DEVICES FORUM (AMDF) – TECHNICAL COMMITTEE UNDER THE AFRICAN MEDICINES REGULATORY HARMONIZATION (AMRH) INITIATIVE

GUIDANCE ON ASSESSMENT OF MEDICAL DEVICES INCLUDING DIAGNOSTIC TESTS DONATIONS FOR IN-COUNTRY USE DURING EMERGENCIES



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1.0 Introduction

This guidance document has been developed by the Africa Medical Devices Forum (AMDF) with the aim of providing guidance to the National Regulatory Authorities (NRAs) on how to quickly verify quality, safety and performance aspects of donated medical devices including in vitro diagnostics during Covid-19 Pandemic and future emergencies.

When there is war, disease outbreak such as Covid-19, earthquake, hurricane or accidents which involves a significant number of causalities, there may be a need of humanitarian support including donations. Donations can range from very simple items such as bedsheets to very complex products such as medical devices including In-vitro diagnostics (IVDs). Appropriate and well planned, donations can provide valued support to the health care services to governments facing ever increasing burden of financing the health needs of the country with limited resources and especially during emergency. In the past, many countries have benefited from various donations that have complemented national systems for health care provision. However, donations may also have unwanted effects on existing institutional arrangements in the country's financing, procurement and supply chain management systems and have very serious health consequences to the intended use and intended users if their safety, quality and performance is not guaranteed.

Some of the common challenges that have been reported for donated products 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of source of the product, lack of evidence to support safety, quality and performance, non-functional, outmoded, outdated and or damaged products, and lack of information about the products (manual and instructions for use). Other challenges include pressure to accept donations especially during emergencies, lack of expertise to assess performance of the donated products and lack of guidance to donors on specific requirements about donations.

It is expected that this guidance document will enable regulators to make informed decisions in deciding which donated products that can be considered for use during emergencies. In-Vitro Diagnostics (IVDs) present the 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 this regard, it is important to note that the World Health Organization has no written recommendations for donations of in vitro diagnostics.

2.0 Scope

The guidance is intended for all donated medical devices including in vitro diagnostics.

3.0 Key considerations

Several considerations must be considered when receiving donated medical devices including IVDs. They include:

3.1 Four core principles of the WHO guidelines for accepting donations of health technologies include:

- Donated medical devices should have maximum benefit to the recipient.
- Donated medical devices should respect for wishes and authority of the recipient.
- There should be no double standards in quality, safety and performance.

- There should be effective communication between the donor and the recipient.

3.2 For donated In-vitro diagnostics the handling, supply chain process and as-well as instructions for use must be provided.

3.3 When in-vitro diagnostic requires a specific instrument as in closed systems, the donor or recipient should ensure availability before accepting the donation.

3.4 Medical devices intended to be donated must be collected from reputable and known sources for ease traceability.

3.5 Donated kits or reagents should have at least two thirds of prescribed shelf life

3.6 If the medical equipment has been used before, it must be reconditioned, tested and all essential parts, accessories and working materials included before shipment including relevant supporting documents to indicate that the device is in good working condition. For software operated medical devices, the software shall be either preloaded and/or accompanied by the software package. In case of electrical equipment, the electrical needs of the equipment shall be set to the standard voltage of 220V/50Hz to 240V/50Hz. For X-ray emitting equipment it shall be calibrated and inspected by a qualified person and evidence of such certification provided.

3.7 Donated medical devices must be robust and fully operational as a full system or as a separate subsystem and meet safety and performance specifications provided by the manufacturer.

3.8 Information provided on the label, user manual and other documents must be written in a language understood by the recipient country.

3.9 Medical devices intended to be donated must be packed and transported in recommended conditions to maintain integrity of the products.

3.10 Expired, damaged and out-of-date medical devices for which spare parts and consumables are no longer available and/or equipment which is no longer supported by the manufacturer shall not be accepted. Expired medical devices must be returned to the donor at their own cost**.**

4.0 Assessment of medical devices

National Regulatory Authority has the responsibility to ensure quality, safety and performance of medical devices and in vitro diagnostic tests that have been donated. Therefore, the following can be done to verify suitability of the donated medical devices:

4.1 Check availability of the following documents; packing list, certificate of analysis for all products and especially for sterile medical devices, certificate of refurbishment for used medical devices (issued by manufacturer of certified company), physical damage and expiry date (s). The certificate of refurbishment stating the following:

4.1.1 tested, labeled and packed; and

4.1.2 replaced or repaired and the repair service that were performed on the medical device and the source of the repair parts and provide an acceptance report for these parts;

4.1.3 If calibrated it shall state and verify the operation of the medical device, performance standard

used to calibrate it; and disinfected or decontaminated.

4.2 Labelling of the donated medical device

4.2.1 Depending on its nature and type, the labelling of donated medical device should have the following minimum information:

4.2.1.1 the name of the medical device;

4.2.1.2 model number or serial number;

4.2.1.3 manufacturing and expiry date (where applicable)

4.2.1.4 life span or expectancy;

4.2.1.5 name and address of the manufacturer;

4.2.1.6 handling and storage requirement (s);

4.2.1.7 technical direction for use;

4.2.1.8 an indication, if applicable, that the medical device is intended to be

4.2.1.9 The words “used only for clinical or performance investigations” before being supplied;

4.2.1.10 for a sterile medical device, the word “Sterile” and where appropriate, description of methods of re-sterilization;

4.2.1.11 if the device is a refurbished, an indication of the device as refurbished device;

4.2.1.12 if the device is intended for presentation or demonstration purposes only, it must be labeled as “for presentation or demonstration purposes only, not for use on human”;

4.2.1.13 if the device emits radiation for medical purpose, details of its nature, type and where appropriate, the intensity and distribution of the radiation

4.2.1.14 if the device is to be installed with or connected to other medical device or equipment, or with dedicated software, to operate as required for its intended use, sufficient details of its characteristics to identify the correct device or equipment to use to obtain a safe combination;

4.3 Labelling information of the medical device can be provided on the medical device itself, packaging used for the medical device, on an insert supplied with the medical device or in a printed document or using other appropriate media.

4.4 Each donated medical device shall have accompanying user manual with detailed information on handling, installation, operation, maintenance, trouble shooting, precautions and other important information.

5.0 The performance of the IVDs must undergo verification studies at the National reference laboratory based on international standards including appropriate Clinical Laboratory Standard International (CLSI) standard(s)[2], use of appropriate local clinical samples and reference method(s). Other quality assurance measures including running of internal quality controls and participation in established external quality

assessment scheme during routine testing. Post market surveillance must be conducted by the relevant authorities to monitor the performance of the assay.

6.0 Acceptance criteria

Based on existing donation policy, the recipient countries shall establish risk-based acceptance criteria based on the above considerations for all donated medical devices.

7.0 Reporting

The recipient must report to the Authority including defects, adverse effects, problems related to quality and safety and other reportable cases related to the donated device during use.

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