iAHO Integrated African Health Observatory

World Health Organization African Region

75 HEALTH FOR ALL

Analytical Fact Sheet

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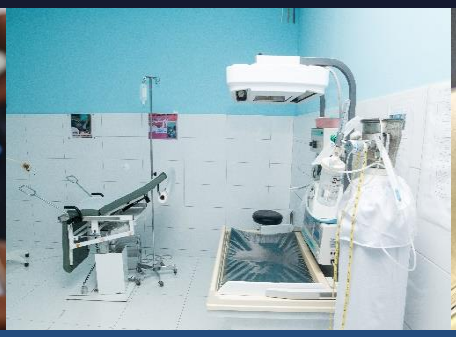
MIM Team



Critical call: Strengthening regulation of medical devices and in vitro diagnostics in Africa

Rationale

A well-functioning health system depends on access to safe, effective and quality-assured medical products, including medical devices, without financial hardship. Medical devices are essential to perform common medical procedures - from bandaging a sprained ankle, to diagnosing HIV/AIDS, COVID-19, to delivering oxygen, to performing surgery as example. Today, there are an estimated 2 million different types of medical devices on the world market, categorized into more than 22,000 generic device groups. Substandard and counterfeit medical devices can harm patients and fail to diagnose and treat the disease for which they are intended. According to WHO, Africa alone accounts for 42% of detected cases of substandard and counterfeit medical products worldwide. Recognizing the need to strengthen the regulation and quality assurance of medical products, Member States have adopted a series of World Health Assembly (WHA) resolutions on health technologies, including the WHA 67.20 on regulatory system strengthening for medical products as a key pillar to better health outcomes. This factsheet provides key information on the regulatory situation for medical devices including In vitro diagnostic in the African Region. Data are from the World Health Organization.

Key messages

- Thirty-four countries (85%) have regulatory authorities for medical devices and in vitro diagnostics as well as a single authority responsible for the regulation of medical devices and IVDs.
- Twenty-one countries (52.5%) reported that they do not have a published national law establishing a regulatory framework for medical devices.
- Nine (22.5%) National Regulatory Authority (NRAs) have all the recommended documents in the regulatory hierarchy, i.e. legislation, regulations/schedules and guidelines.
- Seventeen (42.5%) countries are not aware of the existence of the WHO Global Model Regulatory Framework for Medical Devices.
- Three NRAs (7.5%) reported that they implement all requirements for premarket of medical devices, from of the WHO Global Model.
- Twenty-seven NRAs (67.5%) reported that they implement all requirements for placing devices on the market.
- Eleven NRAs (27.5%) reported having the full set of elements for post-market surveillance and vigilance systems.

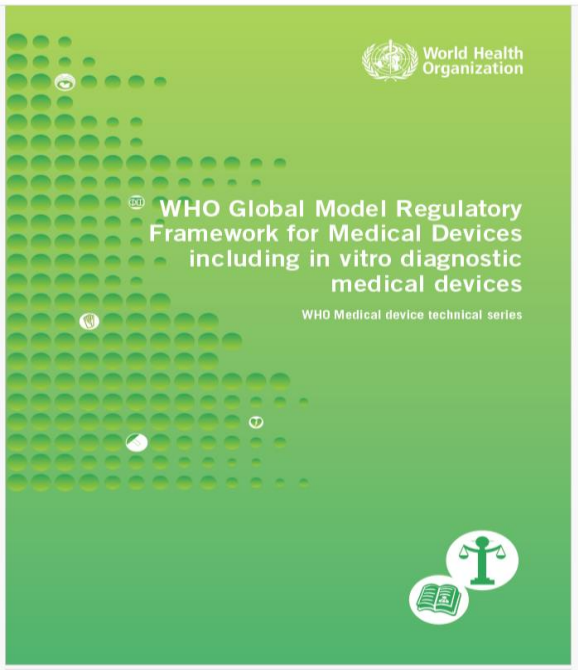
I. Definition of medical device and in vitro diagnostics (IVDs)

The Global Harmonization Task Force (GHTF) has developed a definition of medical device and in vitro diagnostic (IVD). Major jurisdictions have accepted the principles of this definition. In the interest of international regulatory convergence, it is recommended that its widespread use be encouraged.

Medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease.
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury.
- investigation, replacement, modification or support of the anatomy or of a physiological process.
- supporting or sustaining life.
- control of conception.
- disinfection of medical devices.
- providing information by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.



In vitro diagnostic (IVD) means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

II. Medical devices classification

It is widely accepted that medical devices can be divided into groups or classes, typically four, A, B, C and D. The risk class of a medical device is determined by factors such as the degree of invasiveness and duration of use in the body and the technical, scientific and medical expertise of the intended user (lay or health care professional). The Regulation specifies how a manufacturer should demonstrate compliance with the safety, performance and quality requirements. Regulatory oversight by the authority should increase in proportion to the potential of a medical device to cause harm to a patient or user.

Table 1: Examples of medical devices by risk class

Class	Risk	Examples
A	Low	Syringes, examination gloves, patient hoists, stethoscopes, wheelchairs, in vitro diagnostic instruments, microbiological culture media.
B	Low–moderate	Surgical gloves, infusion sets, pregnancy tests.
C	Moderate–high	Condoms (unless with spermicide (class D)), infusion pumps, neonatal incubators, therapeutic and diagnostic X-ray, lung ventilators, hemodialyzers, anesthesia equipment, self-test glucose strips, in vitro diagnostics for the diagnosis of Neisseria gonorrhea.
D	High	Implantable cardioverter defibrillators, pacemakers, breast implants, angioplasty balloon catheters, spinal needle, in vitro diagnostics for the diagnosis of HIV, hepatitis C or hepatitis B.

III. Survey on the state of the regulatory framework for medical devices, including in vitro diagnostics, and the methodology used

Objective

Identify the gaps and challenges faced by national regulatory authorities to inform and guide evidence-based decision-making in countries and at the regional level including regional economic comities, health systems strengthening partners, to take critical, coordinated steps towards and to collectively forge a path to improving medical devices access in the region

Methodology

The survey was developed in November 2019 using a WHO extranet DataCol, by the former WHO, Regulatory Systems Strengthening (RSS), Regulatory Networks and Harmonization (RNH), based on the recommendations of the WHO Global Model Regulatory Framework (GMRF). The survey was sent online to thirty-five (35) national regulatory authorities (NRAs) in November 2019, with an extended deadline for responses until the end of March 2020. A total of 26 NRAs responded to this survey with only five responses from French speaking countries. In July 2023 the same survey was sent in to the twenty-two (22) NRAs from French- and Portuguese-speaking countries of the region with a deadline for response of 15 August 2023. 19 countries responded, most of them on time. Responses from both surveys were analyzed using the Excel data analysis sheet and percentages were rounded to the nearest decimal place. 5 countries (Burkina Faso, Burundi, Gabon, Mali, Senegal) replied to both questionnaires (2020 and 2023).

IV. Main results of the survey

4.1 Countries responding to the survey questionnaire

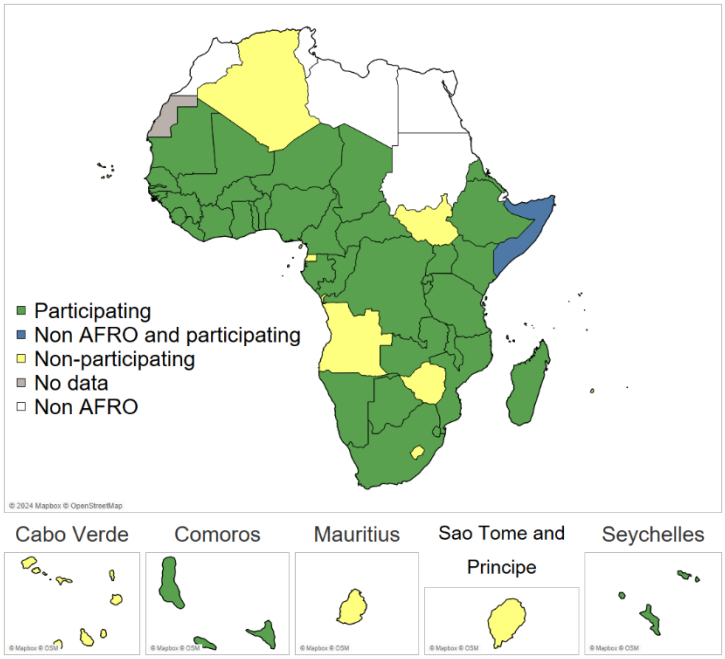


Figure 1: Countries which participated in surveys on regulation of medical devices in the WHO African Region, 2020–2023 *(source: WHO)*

- A total of forty (40) NRAs responded to the questionnaire in the two surveys conducted in 2020 and 2023. Tanzania and Zanzibar were counted as two countries and Somalia, which is not part of AFRO, was included in the survey. The countries that responded are shown in green on the map below (Figure 1).
- Countries that did not respond are shown in yellow in Figure 1 (Lesotho, Zimbabwe, Angola, Equatorial Guinea, South Sudan, Cabo Verde, Sao Tome and Principe, Algeria and Mauritius).

4.2 Legal Requirements, Definitions, Classification, Essential Principles of Safety and Performance

4.2.1 Regulatory requirements - legislation published for the regulation of medical devices and in vitro diagnostics

- Nine NRAs (22.5%) have all the recommended documents in the regulatory hierarchy, i.e. legislation, regulations/plans and guidelines (DRC, Ethiopia, Ghana, Niger, Nigeria, Senegal, Uganda, South Africa, Tanzania).
- Twenty-one NRAs (52,5%) reported having an incomplete set of recommended documents and 10 didn't have any such documents.

4.2.2 Existence of an authority for the regulation of medical devices and in vitro diagnostics

- Thirty-four countries (85%) have authorities for the regulation of medical devices and in vitro diagnostics and as the sole agency responsible for regulation of medical devices and IVDs.
- Only Mauritania, Namibia and Seychelles reported that they did not have authorities for medical devices and in vitro diagnostics.
- Many countries such as Benin, Burkina Faso, Burundi, Guinea, Mali and Eswatini reported having multiple institutions regulating these products.

4.2.3 Definition and classification of medical devices and In vitro diagnostics

- Twenty NRAs (50%) reported having adopted definitions and risk-based classification of medical devices and IVDs based on the IMDRF (GHTF) guidelines.
- Countries such as Central African Republic, Chad, Comoros, Democratic Republic of Congo, Guinea and Guinea Bissau, Madagascar, Mauritania do not have an alternative classification system.

4.2.4 Participation in regional or global harmonization initiatives

- Twelve NRAs (30%) did not participate in any regional or global harmonization initiative (Eritrea, Eswatini, Liberia, Rwanda, Seychelles, Somalia, Uganda and Malawi, Mauritania, Congo, Chad, Cameroon).
- For the 28 countries (70%) participating in regional or global harmonization initiatives, the most common harmonization initiatives are the West African Economic and Monetary Union (UEMOA) and the Economic Community of West African States (ECOWAS), the African Medicines Regulatory Harmonization (AMRH) initiative, in particular the African Medical Devices Forum (AMDF), and the Asian Harmonization Working Party (AHWP).
- Others indicated their participation in other mechanisms, such as the WHO Collaborative Registration Procedure.

4.2.5 Participation in reliance and recognition mechanism

- The WHO-GMRF advocates for reliance. It is an act whereby the regulatory authority of a jurisdiction considers and gives significant weight to the assessments made by another regulatory authority or reference institution such as WHO prequalification and/or World Listed Authorities, in making its own decisions. The mechanism aims to speed up regulatory approvals and scaling-up access to medical devices and IVDs.
- Analysis of the data received shows that twelve NRAs (30%) have included this provision in their law and are implementing this approach. These NRAs are from Benin, Democratic Republic of Congo, Eswatini, Ethiopia, Ghana, Guinea, Kenya, Malawi, Nigeria, Senegal, South Africa and Tanzania.
- Five NRAs from Gabon, Gambia, Sierra Leone, Somalia and Zanzibar implement reliance mechanisms without such a provision in their law.

4.3 Basic level controls and enforcement

This section was intended to determine the extent to which NRAs are implementing the basic level controls and enforcement in all its three main pillars i.e. Pre-market, placing on market and post market.

4.3.1 Premarket

- Three NRAs (7.5%) indicated that they are implementing all the recommended elements from WHO global model for premarket requirements (Nigeria, Senegal et Tanzania).
- Eighteen NRAs (45%) reported having a national law setting out a regulatory framework for medical devices in the country

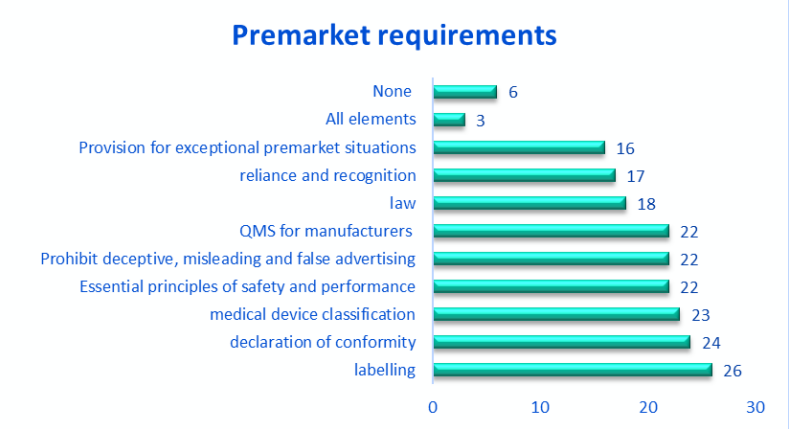


Figure 2: Distribution of NRAs by pre-marketing requirement, in the African Region, 2020-2023 *(source: WHO)*

4.3.2 Placing on market

- Twenty-seven NRAs (67.5%) indicated that they are implementing all requirement for placing market (Benin, Burundi, Cameroon, CAR, Cote d'Ivoire, DRC, Eritrea, Ethiopia, Gabon, Gambia, Guinea, Guinea Bissau, Kenya, Liberia, Mali, Mozambique, Niger, Nigeria, Rwanda, Senegal, Sierra-Leone, South Africa, Togo, Uganda, Tanzania, Zambia, Zanzibar).
- Thirty-two NRAs (80%) indicated having requirements for registration of establishments, thirty (75%) for listing and notification, and twenty-eight NRAs (70%) for import controls.

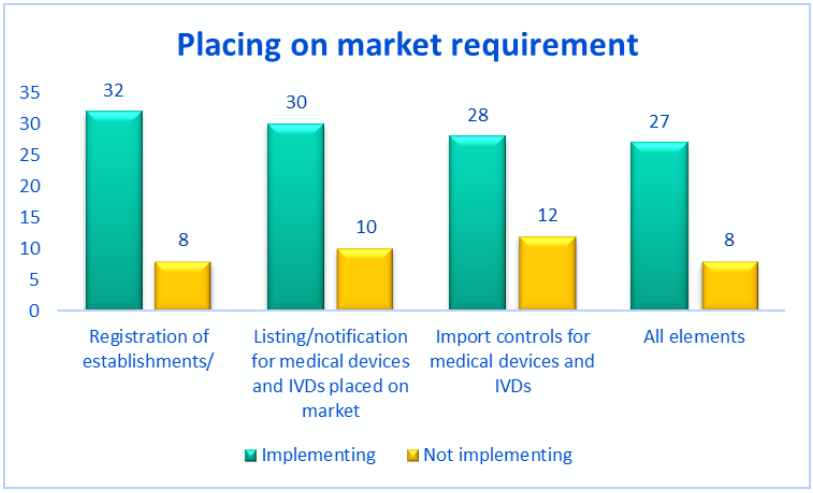


Figure 3: Distribution of NRAs by placing on market requirement, in the African region, 2020-2023 *(source: WHO)*

4.3.3 Post market surveillance and vigilance

- Eleven NRAs (27.5%) reported having the full set of elements for post market surveillance and vigilance system (Cameroon, Chad, Cote d'Ivoire, Eritrea, Ghana, Guinée, Namibia, Rwanda, Senegal, South Africa, Tanzania).
- Twelve NRAs (30%) reported not having post-market surveillance systems and vigilance.
- Twenty-six countries (65%) have a system of serious adverse event reporting and twenty (50%) a system of alerts.

Figure 4: Distribution of NRAs by post market surveillance and vigilance, in the African region, 2020-2023 *(source: WHO)*

4.3.4 Implementation of basic level of control

- According to the survey responses, five NRAs have reached the basic level of controls for medical devices and IVDs which is approximately 12.5% of NRAs that responded to the questionnaire (Ghana, Nigeria, Senegal, South Africa, Tanzania)

4.4 Gap analysis of existing controls

- Gap analysis of existing controls for medical devices and IVDs has been done by six countries which accounts only to 15% of the participating countries (Burkina Faso, DRC, Kenya, Mozambique, Niger, and Uganda).
- The common challenges identified were:
  1- absence of laws and with regulatory texts not detailed for the regulation of medical devices, including IVDs.
  2- Absence of Infrastructures/laboratory for quality control of medical devices.
  3- Insufficient in competencies and quantity in human resources.
  4- Lack of coordination of activities between the different entities in charge of regulating medical devices.

4.5 Regulatory authority fees on services for medical devices and IVDs

- Twenty-eight NRAs (70%) have indicated having in place requirements for regulatory fees (Benin, Botswana, Burundi, Burkina Faso, Cameroon, CAR, Cote d'Ivoire, Eritrea, Eswatini, Ethiopia, Gabon, Guinea, Gambia, Kenya, Madagascar, Mozambique, Namibia, Nigeria, Niger, Rwanda, Sierra Leone, Somalia, South Africa, Tanzania, Togo, Uganda, Zambia, Zimbabwe).

4.6 Awareness of the WHO Global Model Regulatory Framework for Medical Devices including In Vitro Diagnostic Medical Devices

- Countries unaware of the existence of the document are 17 (42.5%) including Benin, Botswana, Cameroon, CAR, Chad, Comoros, Congo republic, DRC, Eswatini, Liberia, Malawi, Mozambique, Rwanda, Uganda, Seychelles, Togo, Sierra Leone.
- NRAs that are aware of the WHO Global Model Regulatory Framework for Medical Devices, including in vitro diagnostic, have been informed about the document through WHO organized programs, meetings and workshops.

V. Recommendations

To Member States

- Adopt the WHO global model regulatory framework recommendations to address the key elements of medical devices and in vitro diagnostic regulation in a phased approach based on the availability of resources.
- Assess the maturity of the national regulatory authorities using WHO global Benchmarking tool (GBT) for medical devices and develop and implement Institutional development plans (IDP)to attain a stable and functional regulatory system.
- Leverage reliance mechanism to accelerate decision making in regulatory activities, rationalize resources and harmonize practice in the region.

To WHO

- Organize awareness-raising activities with African national regulatory authorities through their Regional Economic Communities (RECs) on GMRF to promote and advocate to prioritize effort to scaling up the regulation of medical devices and in vitro diagnostics in the region.
- Provide technical support to countries to assess the maturity of their national regulatory authorities and to establish Countries Interest Parties (CIP) to accelerate the implementation of their IDPs.
- Strengthen capacity building of national regulatory authorities with the Development of training materials, including e-learning platforms, promotion of establishment of collaborative center and Centre of excellence for regulatory experts to build their capacity in this area, including on dossier assessment, import controls and post-marketing surveillance, quality control.
- Assist countries and Regional Economic Communities (RECs) in the development of regulatory requirements and guidance to address all key elements of the WHO Core Controls and subsequent extended levels of control for medical devices.

References

1. WHO medical devices website. **https://www.who.int/health-topics/medical-devices#tab=tab_1**
2. WHO Global model regulatory framework for medical devices including in vitro diagnostic medical devices. 2017. **https://www.who.int/publications/i/item/9789241512350**
3. Report of the survey on the status of regulatory framework for medical devices including in vitro diagnostic medical devices in Africa, 29th June 2020

Sources

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