3.2 Regulation of medical devices

3.2.1. Introduction

Regulation of medical devices is a means of reducing potential health risks as much as possible and enabling patient access to high quality, safe and effective medical devices while restricting access to those products that are unsafe or ineffective. When appropriately implemented, regulating medical devices contributes to better public health outcomes.

WHO has a mandate, as outlined in the World Health Assembly (WHA) Resolution 60.29 on Health technologies which encourages “Member States to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and, where appropriate, to participate in international harmonization”9.

The 67th WHA in 2014 adopted Resolution 67.20 on regulatory system strengthening for medical products10. It stresses the importance of the regulations for medical devices as one of the medical products, for better public health outcome and to increase access to safe, effective and quality medical products. The complete text of the resolution is available in the 6 WHO official languages. Please refer to Fig. 3.2-1 for some important notes referring to medical devices in Resolution WHA67.20.

**WHA Resolution 67.20:**

- URGES Member States: to strengthen national regulatory systems, to engage in global, regional and subregional networks of national regulatory authorities, and to promote international cooperation, as appropriate; and
- REQUESTS the Director-General WHO: to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics; and to support the building-up of effective national and regional regulatory bodies and networks.

Fig. 3.2-1. Notes referring to medical devices in the WHA 67.20 resolution “Regulatory system strengthening for medical products”

### 3.2.2 Global facts

In contrast to the other parts of this publication, the analyses presented in this section are based on a desk survey that WHO performed on the current status of regulatory systems for medical devices in 194 WHO Member States during 2015/2016. Information on the status of a legal framework for medical devices was collected from online sources (National Regulatory Authority (NRA) websites, ministry of health websites, etc.) or by directly contacting WHO focal points or other country representatives. Exclusively officially promulgated regulations and/or guidelines by the Member States and/or their agencies were considered. Data was translated, reviewed and categorized into key elements of medical device regulation.

When information on medical devices regulations was available, it was categorized as “YES”. Any response from a country representative indicating that they did not have a legal framework for medical devices was categorized as “NO”. Information not found and any non-responses were indicated as “Non-Available”. The outcome of the desk survey is presented below.

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To begin with, the global picture of the current status of medical device regulation is visualized in Fig. 3.2-2.

Fig. 3.2-2. Global current status of medical device regulations; existence of a national legal framework for medical devices

In total, 113 out of 194 Member States scored positive on having a legal framework for medical devices, no matter how limited their regulation is. The survey found 53 countries do not have a regulation for medical devices. For 28 Member States no information was available, as shown in Fig. 3.2-3.

Fig. 3.2-3. Countries with a legal framework for medical devices (no matter how limited)

Based on the available data, the proportion of countries with a legal framework for medical devices is highest in the European region (91%) and lowest in the African region (32%), as shown in Fig. 3.2-4.

Of the low-income countries with data available, 45% have a legal framework for medical devices in place; from the high income countries 84% have such provisions (Fig. 3.2-5).
Fig. 3.2-4. Number of countries with a legal framework for medical devices by WHO region

As of 2015, at least 121 Member States have a national regulatory authority (NRA) responsible for implementing and enforcing product regulations specific to medical devices (Fig. 3.2-6). The ratios of countries with and without NRAs represented by region can be seen in Fig. 3.2-7.

Fig. 3.2-6. Existence of national regulatory authorities responsible for medical devices
Fig. 3.2-7. Existence of national regulatory authorities responsible for medical devices by WHO region

Regulatory measures should be implemented in all phases of a medical device life span. In this survey, the following key elements of regulation were analyzed:

a) “Pre-market” regulation including:
   - Definition of a medical device
   - Risk classification
   - Essential principles of safety and performance.

b) “Placing on the market” regulation including:
   - Registration of establishments
   - Listing of medical devices
   - Import controls.

c) “Post-market” regulation:
   - Adverse event reporting.

The results of the survey are presented in Fig. 3.2-8. The percentages pertain to the 113 countries that have a legal framework for medical devices. More detailed descriptions of the basic elements are given below.

Fig. 3.2-8. Basic elements regulated in countries that have a legal framework for medical devices as found by the desk survey
(a) Pre-market regulation

Basic legal provisions of pre-market regulation would include definition of a medical device, risk classification of medical devices and the essential principles of safety and performance. These provide guidance to manufacturers, importers, authorized representatives and health care professionals regarding the scope of the regulated products.

Definition of medical devices:

As found in the desk survey, at least 113 countries have a legal framework for the regulation of medical devices. Of these, 93% have a medical device definition in law or regulation⁹ (See Fig. 3.2-8). For in vitro diagnostic (IVD) medical devices the numbers are lower: only 48% of countries that regulate medical devices include an IVD definition in their legislation.

The global distribution of medical device definition in law or regulation is shown in Fig. 3.2-9. Fig. 3.2-10 shows the ratio of medical device definitions in law or regulation by World Bank income group.

Fig. 3.2.9: Existence of a medical device definition in law or regulation

![Map of global distribution of medical device definitions](image)

Fig. 3.2.10: Medical device definition in law or regulation in countries by World Bank Income group.

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One country does have a definition for medical devices, without having a legal framework.
Risk classes:
The universe of medical devices is very diverse with varying potential for harm to the patient or user. It is widely accepted that different types of medical devices are classified in groups or risk classes. Fig. 3.2-11 shows the global picture of risk classes for medical devices in countries’ legal frameworks.

Fig. 3.2-11: Existence of a medical devices risk classes in legal framework

Of the 113 countries that have a regulatory framework for medical devices in place as found by the desk survey, 73% do have a risk classes stated in their legal framework (Fig. 3.2-8). The data was further analyzed by income group (Fig. 3.2-12).

Fig. 3.2-12: Risk classes in legal framework for medical devices by World Bank income group
Essential principles of safety and performance:

Regulations should specify that a medical device be safe and effective when placed on the market. Those requirements, known as essential principles of safety and performance, have been widely adopted.

In total, 68% (78 countries of 113) of countries that were found to regulate medical devices do include essential principles as part of their regulatory requirements (see Fig. 3.2-8 and Fig. 3.2-13). The analysis by World Bank income group is illustrated in Fig. 3.2-14.

![World map showing distribution of essential principles](image)

**Fig. 3.2-13: Existence of essential principles for medical devices in the legal framework**

![Bar chart showing essential principles by World Bank income group](image)

**Fig. 3.2-14: Essential principles in countries according to World Bank income group**
(b) “Placing on the market” regulation

Basic legal provisions of “placing on the market” regulation would include registration of establishments, listing of medical devices and import controls. These elements provide an overview of what is available on the domestic market and who are the responsible actors.

Registration of establishments:

Registration of establishments includes the registration of manufacturers, authorized representatives, importers and distributors. Such registration allows the regulatory authority of a country to determine who is responsible for a product’s conformity to the regulatory requirements. When listing and registration information is publicly available, it allows medical device purchasers and users of medical devices to identify products available to them and identify the location of their manufacturers and/or distributors and/or importers.

78% of the 113 countries that have regulation of medical devices as found by the desk survey have a provision for registration of establishments (Fig. 3.2-8). The analysis by income group can be seen in Fig. 3.2-15.

![Fig. 3.2-15 Registration of establishments in countries by World Bank income group](image)

Listing of medical devices:

Listing of medical devices allows a country to determine which medical devices are introduced and by whom. In the event of a suspected problem with a medical device, it allows the regulatory authority to contact the parties responsible for that product.

Of the countries that were found to regulate medical devices by the desk survey, 86% do have a provision in their legal framework that allows for listing of medical devices (see Fig. 3.2-8). A breakdown according to World Bank income group is shown in Fig. 3.2-16.

![Fig. 3.2-16 Listing of medical devices in countries by World Bank income group](image)
Import controls:

65% the basic controls of registration and listing, import controls may be appropriate.

Two thirds of the countries that regulate medical devices as found by the desk survey have a provision for import controls in their regulatory framework (Fig. 3.2-8). A breakdown according to World Bank income group is shown in Fig. 3.2-17.

![Bar chart showing import controls by World Bank income group](image)

Fig. 3.2-17: Import controls in countries according to World Bank income group

(c) Post-market regulation

In clinical use, medical devices may not always perform as expected. Therefore it is important to analyze the medical devices after they are placed on the market. A system whereby users of medical devices may report problems, complaints or adverse events, especially when it concerns death or serious injury, may prompt the regulatory authority to take action.

Adverse event reporting:

Adverse event reporting allows the regulatory authority to take action when products do not perform as intended or when events happen that may endanger public health. Of the countries that regulate medical devices as found in the desk survey, 69% do have a provision in their legislation that enables adverse event reporting (Fig. 3.2-8). The analysis by income group can be seen in Fig. 3.2-18.

![Bar chart showing adverse event reporting by World Bank income group](image)

Fig. 3.2-18: Adverse event reporting in countries according to World Bank income group

The overall picture is that legal provisions and regulatory controls for all elements are regulated to a larger extent in high-income countries, whereas low-income countries include fewer basic elements in their legal framework for medical device regulation, as summarized in Table 3.2-1.
Table 3.2-1 Number of countries with established basic regulatory elements based on the 113 countries that have a legal framework for medical devices, analyzed by World Bank income group

<table>
<thead>
<tr>
<th>Basic Elements</th>
<th>Low income</th>
<th>Lower middle income</th>
<th>Upper middle income</th>
<th>High income</th>
<th>Total</th>
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</tr>
</tbody>
</table>

3.2.3 Further Readings

For more information about the regulation of medical devices, please refer to the following:

Documents:

Websites:
- International Medical Devices Regulatory Forum (IMDRF) http://www.imdrf.org/
- Asian Harmonization Working Party (AHWP) http://www.ahwp.info/
- WHO medical devices: www.who.int/medical_devices/