# Regulation of medical devices

## A step-by-step guide


World Health Organization

Regional Office for the Eastern Mediterranean

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# Preface

In 2012, the World Health Organization (WHO) Regional Committee for the Eastern Mediterranean Region, at its 59th session, discussed the challenges, priorities and options for future action for strengthening health systems.[1] In a resolution, the Committee urged Member States to "improve quality, safety, efficacy and rational use of health technologies, including medicines, by strengthening national regulatory authorities".[2]

The purpose of this guide is to improve access by countries to quality and safe medical devices by offering guidance on strengthening their regulatory controls. The current regional situation indicates that the performance of many national regulatory authorities is inadequate, with focus being placed mainly on the regulation of medicines and not of medical devices and blood products.

Many regulatory authorities are in quality management and in monitoring the domestic market to prevent unsafe and low quality medical products entering. The circulation and sale of counterfeit medical products, and the misuse and medical errors associated with medical products are major concerns in most countries. In addition, many of the relevant regulations are outdated, are not formally enforced or remain unimplemented. Market oversight on the private health care sector is often not included in enforcement and monitoring of approved medical products.

Since a high proportion of medical devices are imported (60%–90% in low and middle income countries)[3], the focus of regulatory measures should therefore be

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[1] Health systems strengthening in countries of the Eastern Mediterranean Region: challenges, priorities and options for future action. Cairo: World Health Organization Regional Office for the Eastern Mediterranean; 2013 (http://applications.emro.who.int/docs/RC_technical_papers_2012_Tech_Disc_1_14613_EN.pdf, accessed 28 February 2016).

[2] WHO Regional Committee for the Eastern Mediterranean resolution EM/RC59/R.3 on health systems strengthening in countries of the Eastern Mediterranean Region: challenges, priorities and options for future action. Cairo: World Health Organization Regional Office for the Eastern Mediterranean; 2012 (http://applications.emro.who.int/docs/RC_Resolutions_2012_3_14693_EN.pdf?ua=1, accessed 28 February 2016).

[3] Medical devices in contemporary health care systems and services. Cairo: World Health Organization Regional Office for the Eastern Mediterranean; 2006 (http://apps.who.int/medicinedocs/documents/s17667en/s17667en.pdf, accessed 1 March 2016)

on import controls and oversight of distribution channels. Poor regulatory practices may result in poor procurement practice. This in turn can lead to the purchase of medical devices that may do harm and that do not perform according to their intended purpose. A common principle applies to the regulation of all medical products: the balance of benefit to risk. However, the manner in which this principle is applied differs between medical products.

This guide provides decision-makers with a roadmap for implementing regulatory systems in their national settings and a step-by-step approach towards the development of national programmes for the regulation of medical devices. It can be applied by any country seeking to develop its regulatory capacity.

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