

WHO-EM/HMD/536/E

Summary report on the

Intercountry meeting on designing and implementing a regulatory programme for medical devices

Riyadh, Saudi Arabia
11–14 April 2016



World Health
Organization

Regional Office for the Eastern Mediterranean

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1. Introduction

The primary purpose of implementing regulatory systems for medical devices is to help protect and promote public health and safety. To do so, not only must the safety, quality and performance of each device be maintained throughout its lifecycle but also the organizations established in the regulated jurisdiction – such as those responsible for manufacturing, importing, distributing, representing overseas manufacturers and using medical devices – must act in an effective and responsible manner.

Unless some or all of the countries of the WHO Eastern Mediterranean Region adopt a unified approach to medical devices regulations with common controls across the Region as a whole (as in the case of the European Union), the solutions adopted will be individual to each country, with its policy-makers determining the extent and complexity of the regulatory controls that govern medical device.

In this regard, the WHO Regional Office for the Eastern Mediterranean organized a four-day intercountry meeting on designing and implementing a regulatory programme for medical devices. The main purpose of the meeting was to come up with a unified approach to medical devices regulations with common controls across the Region as a whole. The meeting was divided into an open session for regulators and national stakeholders which was held in Riyadh on 11 and 12 April, and a closed session for regulators which was held at the Saudi Food and Drug Administration on 13 and 14 April 2016.

In attendance were 30 participants from 15 countries of the Region. Participants included representatives from ministries of health or

national regulatory authorities. The meeting was facilitated by international experts and WHO staff from global, regional and country level. Its objectives were:

- to offer guidance on the design and implementation of effective and affordable national programmes for medical devices regulation;
- to share country experiences on various models used for introducing medical devices regulatory functions within existing national regulatory authorities; and
- to develop a roadmap, based on a step-wise approach, for countries at different stages of development to follow as they implement medical devices regulatory controls in their local settings.

The meeting was opened with welcome remarks from Professor Mohamed Almeshal, Chief Executive Officer of the Saudi Food and Drug Administration (SFDA). Dr Marthe Everard, Coordinator Essential Medicines and Technologies, delivered a message from Dr Ala Alwan, WHO Regional Director for the Eastern Mediterranean. After the introduction of the participants, she also introduced the meeting by presenting the objectives and expected outcomes.

The meeting agenda was arranged in such a way to follow any typical medical device life-span regulatory framework, which starts with policy development and existing resources and ends with disposal or replacement. The Regional Office has identified seven common regulatory functions to describe and assess the regulatory capacity of a national regulatory authority with regard to medical devices: 1) national regulatory system, including risk classification and quality management system; 2) inspection and enforcement, including good manufacturing practices; 3) clinical trial oversight; 4) vigilance; 5)

licensing of premises and establishments; 6) product registration and marketing authorization; and 7) post-marketing surveillance. In addition, many regulatory bodies have suggested adding two additional regulatory functions for specific devices: laboratory access and testing; and promotion, advertising and after-sales. These additional functions were discussed in a special session at the end of the second day.

2. Summary of discussions

Questions were raised about health technology regulation, assessment and management and how they should be integrated. Experts highlighted that policies should be developed in such a way to link regulation to assessment to management of medical devices such that a complete system is designed within existing national health systems. Experts indicated that this is the way forward to improve the way countries deal with medical devices.

A medical devices regulatory framework was adopted by the Asian Harmonization Working Party (AHWP) and documented in a publication entitled “AHWP Playbook”. The outline of the playbook was explained in detail. Any country may adapt the framework included in the playbook to fit their settings.

The WHO model on global medical devices regulatory framework currently under development divides the regulatory controls that should be done by any regulatory authority into basic and expanded controls. All basic controls should be adopted by any regulatory authority to be functional. Expanded controls can then be added to increase the maturity level of the authority. Medical devices regulatory programmes can be implemented in a stepwise manner based on any regulatory framework. Tools have been developed such as a decision

tree to facilitate implementation. The experience of the SFDA was presented, including the establishment of interim medical device regulations and relevant law and various steps taken by SFDA to expand their activities and regulatory functions over the period 2003–2015. In addition, the electronic data sharing system currently used by SFDA for registration, licensing, market authorization and post-market activities was demonstrated to participants.

Key updates to European Union medical devices pre-market regulatory controls will come into force in June 2016. There will be planned transition periods. Changes to the regulations mainly concern the functioning of the bodies. Cosmetic devices are now covered in the new regulations. Clinical evaluation and risk assessment have to be performed. Also the new regulations will have impact on software used in medical equipment. Qualified or responsible persons for medical devices should be involved with manufacturers. Data on sterilization and labelling have been expanded. Human factors are also included in the new directives.

Globally, 80 countries regulate medical devices and 40 are strengthening their regulations. Most countries in Africa do not regulate medical devices yet. Rigid regulatory requirements may become a barrier to access, as they are considered disincentives for manufacturers and a trend is seen that competition and innovation have decreased. Registration fees can be considerable in some jurisdictions. High fees and clinical study costs can be prohibitive for small companies. Pre-market recalls due to better evaluation and/or inspections can bring down post-market recall cases. Pre-market inspections are on the rise in all parts of the world. It was noted that an efficient registration/notification process, conformity assessment, post-market surveillance system, and on-market controls are key to overseeing and controlling what is on the market.

Questions from participants were raised around the various timelines to get a medical device approved and authorized for the local market. Experts indicated that it varies; however, they all indicated that it should be shortened to improve access to new effective technologies.

The Saudi reporting mechanism was explained in detail, especially for suspected adverse events. Under-reporting is a main issue in Saudi Arabia. There is a national centre for medical devices reporting in place. The centre is a member of Ad Hoc Working Group. Statistics on field safety notices, recalls and adverse events were provided. In addition, there are 11 port-of-entry controls currently in place in the country. The activities of enforcement and inspection were also explained.

With regard to elements of an effective post-market surveillance strategy, the importance of reporting was stressed by the presenter such that appropriate actions can be taken by the competent authorities. Reports are available on the website of the European Union regulatory authorities. Key changes in the regulatory environment for medical devices in Europe were also explained. The new directive has 10 chapters and provides the detail needed. As a new way of working, expert panels will provide advice to medical device manufacturers when they request it.

Post-market regulatory controls are all about patient safety. The prime purpose of having vigilance and post-market surveillance systems are for reporting adverse events. Stakeholders in assuring safety and performance of medical devices include manufacturers, distributors, importers and regulators, as well as end users, patients and consumers. Several examples of recalls and field safety corrective actions were significant enough to trigger improvements to the medical device regulatory processes, especially the post-market ones. Information

sharing and acceptability of information from other jurisdictions is the trend seen. A number of challenges are still faced by the industry, including traceability and device misuse or alteration. Having harmonized regulatory activities is the vision of the future to simplify processes and reporting. Trust and transparency are pillars to assure safe performance of medical devices.

During discussions, it was emphasized that reporting is the responsibility of users, vendors and manufacturers alike. It was also acknowledged that misuse and user errors are often the cause of death of patients rather than the failure of equipment.

Medical device characteristics can be classified as single use, single patient or reusable medical devices. The main reasons for reprocessing single-use devices are limited financial resources, waste minimization and economic feasibility. Reprocessing is a process of six steps: cleaning, disinfection, sterilization, functioning testing, repackaging and relabelling. Risks associated with reprocessing of single-use medical devices are various; they include product failure, ethical considerations, legal consequences, infection risks and economic burden (hidden costs and reimbursement issue for health insurance). SFDA undertook a benchmarking case study on reprocessing of single-use medical devices. A questionnaire was distributed to various levels of health facilities and the response rate was over 95%. Results showed that government and public facilities used reprocessed single-use medical devices more than private facilities, which had a negative effect on the population in the sense that it undermined the trust of public health services offered in the national health care system. The study recommended either to cease the practice of reusing single-use medical devices in Saudi Arabia, or to allow it only under strict guidelines and protocols. If the latter was the case, an advisory

committee should be established to develop these guidelines and protocols.

Participants raised questions concerning the responsibility and liability of reprocessing and reuse of single-use medical devices. It was explained that the act of reprocessing of single-use devices should be seen by the manufacturer of a “new” medical device and therefore all steps of obtaining market authorization have to be followed again. The use of third party testing is becoming more common, so the manufacturer can focus on other core issues. In fact, SFDA is contracting out laboratory testing to a third party laboratory. Testing of reusable devices comes with a range of cleaning solutions, but these may be device dependent. It is a dynamic area and a difficult environment, and a careful approach is needed. With regard to the disposal of medical devices, this issue is part of a health technology management course currently being conducted by WHO. SFDA is also developing a guideline to better address this issue.

On days 3 and 4 of the meeting, remaining participants (regulators from 15 countries) moved to the premises of SFDA. The Saudi market is the second largest market in the Middle East and Northern African region. The development of the medical devices sector in SFDA was explained in detail, including the role that many agencies and consulting firms (such as World Bank, McKinsey, etc.) played in the establishment of SFDA. The situation of the medical devices market prior to the establishment of SFDA was chaotic. The presence of the authority over the last 13 years helped in improving the quality of health care, resulting in fewer adverse events, a reduction in cases of counterfeit products, enhanced competition due to the presence of clear laws and more job opportunities for nationals.

A presentation was made on the various steps in getting a medical device on the Saudi market, including detailed explanation and demonstration of the electronic system used for registering medical devices, licensing establishments, issuing marketing authorization and importation licensing. A new application has to go through seven sections to be completed: manufacturer, general information, jurisdiction, product categories, product verification, quality system status and other national provisions. Fees to be paid depend on medical device class.

There are nine technical committees in place for the development of medical devices standards and guidelines in Saudi Arabia, established gradually since 2013. The national requirements are published online, and revised requirements will be published during 2016. SFDA's future plans include but not limited to national standards for "cupping" (a form of traditional medicine) that will be published soon. An oversight of conformity assessment bodies was provided and the process of licensing of medical device advertisements was explained with some examples.

Compliance and enforcement activities are actually parts of inspection. Details on SFDA workflow – which includes inspection, assessment and compliance – were given. SFDA's strategy against counterfeit products, which is based on protection, detection and correction, faces several challenges such as resistance to comply with the control system in place, fake documents submitted for approval, domestic production and buying over the internet.

There are 11 ports of entry in Saudi Arabia. The responsibilities of ports of entry include document verification, as well as physical checks followed by approval or rejection. Challenges are faced in the areas of coordination between bodies, overlaps with other sectors,

limited staffing, non-adherence to SFDA rules and regulations by importers, brokers, etc. The documents required at ports of entry are published on the SFDA web site. Counterfeit products can be recognized by comparing the suspected product with the genuine product. Pictures should then be sent to the concerned manufacturer. Manufacturers have web sites with search engines for verifying their products. SFDA uses a specialized company for destruction of rejected medical devices.

The main aim of the market surveillance department at SFDA is to gather and publish information and to follow up on and communicate this information to relevant persons. The challenges faced by the department include lack of collaboration from authorized representatives in submitting field security notices and recalls and slowness in taking corrective actions.

Investigation and crisis management are key components and both can be achieved through online reporting mechanisms of faulty medical devices. Social media is also used for alerting the general public. Under-reporting is one of the main challenges faced as well as lack of a database.

3. The way forward

Countries emphasized the importance of sharing experience and lessons learnt as well as exchanging information on how establish a functioning national regulatory authority. Country officials and policy-makers should be alerted to the importance of medical devices regulation in improving quality and safety of health care services. In specific, the meeting resulted in the development of a roadmap that can be used by each country in the design and implementation of a regulatory programme for medical devices. In addition, actions to be

taken by WHO to support Member States technically in developing their medical devices regulatory functions were identified. The need for a regional discussion forum on medical devices regulation to facilitate the exchange of knowledge and information was noted by all countries.

A table was distributed representing key steps to be taken by each country to improve medical devices regulation in their national settings. The 17 decisions that any country should adopt to have basic medical devices regulatory controls were examined in each of the 15 participating countries, with SFDA taken as a reference. Using this tool, countries can identify gaps, make decisions from several existing options, and finally develop a national roadmap for areas of improvement.



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