Medical device regulation: a model framework

The term “medical devices” covers a vast array of products from simple tongue depressors to magnetic resonance equipment. The intended primary mode of action of a medical device on the human body, in contrast with that of medical products, is not metabolic, immunological or pharmacological although it may be assisted in its function by such means. With around one and a half million different devices available, it is one of the fastest growing markets today. As a consequence, the regulatory approval and licensing of medical devices is becoming more and more challenging.

Ensuring the availability of quality medicines and health care products begins with effective management at national level. National medicines regulatory authorities operate with varying success in many countries and aim to achieve effective regulation of medicines. The responsibilities of regulatory authorities are broad and activities may include licensing and control of manufacture, import, export, sale, distribution, promotion and advertising; supervision and control of clinical trials; assessing safety, efficacy and quality; conducting post-marketing surveillance and monitoring adverse events; inspecting manufacturers, importers, wholesalers and dispensers at regular intervals, and providing unbiased information to professionals and the public.

Curiously, medical devices have not received the same attention as medicines despite the significant investment that their purchase may represent for health care systems and the need to ensure safety, quality standard conformity and performance. This is partly because medical devices are frequently perceived as a procurement issue as opposed to an integral part of public health policy. Few developing countries have an authority with discrete responsibility for the management of medical devices. Unfortunately, lack of effective regulation may lead to the import of substandard devices or illegal re-processing and re-packaging of products.

In 2003, WHO addressed this issue through two projects geared to strengthen the ability of national authorities to manage medical devices.

Strengthening national regulatory authorities for medical devices

The first initiative was to expand the existing WHO tool developed to assess medicines regulatory authorities to include medical devices (1). The expanded tool was used in the People’s Republic of China in September 2003 to carry out a comprehensive review of the national systems used to regulate vaccines and medicines and medical devices. This was the first time that WHO had organized such a joint assessment and the harmonized approach was appreciated by the national health authorities and local WHO staff.

In carrying out the medical device assessment, six broad areas were identified, namely:

- Medical device regulatory systems
- Marketing authorization
- Postmarketing surveillance
- Test laboratories
- Quality systems auditing
- Clinical trials.

These assessments form the basis of an institutional development plan, including training needs, and follow-up support. They are particularly useful in identifying areas for improvement. For example, it is estimated that some costly and time-consuming procedures could be avoided by the adoption of existing international standards for medical devices. The joint assessment tool and follow-up plans are now being refined and will be applied in other countries.

Harmonization of medical device regulations

The Global Harmonization Task Force (http://www.ghtf.org) was set up in 1993 by the five major global device producing and regulatory bodies — Australia, Canada, the European Union, Japan and the United States of America — with a view to harmonizing standards and regulatory practices across countries. The objective is to reduce regulatory barriers, facilitate trade and
improve access to safe, effective technologies. Much progress has been made towards this
objective over the last decade yet developing
countries, who import around 90% of the medical
devices they need, remain marginalized in this
process, largely because of lack of access to
knowledge and best practice guidelines.

The recent WHO publication Medical Device
Regulations: Global Overview and Guiding
Principles (1) aims to bridge this gap. It provides a
matrix of the entire life cycle of a medical device –
from conception to disposal – and the policies that
should be in place to manage each stage in this
life cycle. Priorities are recommended for coun-
tries with limited infrastructure or resources, with
suggestions on how to build towards a more
effective system. The major issues covered in the
publication are summarized as follows.

Safet y: The safety of the patient – and indeed of
the user and the community – is a priority for
governments in authorizing the sale of a medical
device. A medical device must provide benefit for
the patient. Potential hazards need to be weighed
against the gain. Devices are therefore classified
according to the potential risks, and the higher the
risk the more stringent the controls. All active
devices intended to administer or remove medi-
cines, body liquids or other substances to or from
the body are classified as low to moderate risk
(e.g. hypodermic syringes or anaesthesia equip-
ment). Devices incorporating a medicinal product
that is liable to act on the human body with action
ancillary to the device is in the highest risk
category (e.g. heparin-coated catheters or wound
dressings incorporating antimicrobial agents).

Stages of regulatory control: the three main
stages of regulatory control are:

• pre-market: To ensure that the product to be
sold meets standards of safety and perform-
ance;

• on-market: To ensure that the product is
accurately labelled and advertised; and

• post-marketing: To ensure the continued safety
and effectiveness of the product in use.

For pre-market regulations, governments with
limited resources are advised to take advantage
of existing approval systems and international
standards rather than setting up demanding and
costly pre-market regulations. During the introduc-
tion of the product on-market, priority should go to
ensuring a system for registering the vendor and
the device, which is essential for alerts or product
recalls during the post-marketing surveillance
phase.

International standards: all medical devices
should meet a recognized international standard
for quality and safety. An understanding of the
different standard-setting systems, the processes
used to develop standards, and their use in
conformity assessment is essential for the
establishment of medical device regulations. This
is no mean task, since there are many types of
standards that govern products, processes and
services. The WHO Medical Device Regulations
explain the purpose of prescriptive, design,
performance and management specifications and
standards of the International Standards Organi-
zation (ISO) specifically relating to medical
devices. A grasp of the difference between
voluntary or mandatory standards and current
trends in their use is all the more important since
the introduction of a new quality system for
medical devices in 2003 (2).

Priority activities: regulatory programmes can
be developed in stages according to a country’s
needs and resources. However, a core pro-
gramme, based on a clear policy and involving
the government, manufacturers, vendors, users
and the patient, should encompass:

• Essential basic legislation to empower govern-
ments to stop sale or withdraw unsafe products,
and to penalize fraudulent advertising.

• Training of customs officials using the device
acceptance criteria outlined in the national
policy to prevent substandard devices from
entering the country.

• An information network to encourage the
voluntary sharing of information, e.g. to prevent
the recurrence of an adverse event or to
investigate a potential hazard. The next step will
involve adherence to a larger, international
network for complaints and sharing of alerts.

• An inventory of devices and approved suppliers.
It is the responsibility of the vendor to keep
distribution records so that all similar products
may be identified in case of need.

• Adoption of an internationally recognized
medical device nomenclature system to enable
accurate tracking and comparison.
WHO supports the efforts of the Global Harmonization Task Force towards global convergence of regulatory requirements. WHO is also keen to develop a uniform certification process for medical devices based on the principles of the WHO Model Certification Scheme on the Quality of Pharmaceutical Products (3), as well as an international vigilance agency to increase the safety of devices in use.

Guiding principles to ensure injection device security

Injections are the most common health care procedure worldwide. Best infection control practices for intradermal, subcutaneous and intramuscular injections recommend the use of a new, single use injection device for each injection and for the reconstitution of each unit of medication. Unsafe injection practices are avoidable but continue to place patients at risk. For example, 41% of all new hepatitis C virus infections in 2000 were transmitted through the reuse of injection devices without sterilization. WHO therefore requests all donors and lenders who finance injectable products to finance appropriate quantities of single use injection devices, single dose diluents, safety boxes and the cost of sharps waste management. All organizations involved in medicine donations are also urged to follow this recommendation (4).

Conclusion

There is no medical device regulatory system template that fits all. Some countries are large manufacturers of equipment and will need to focus on good manufacturing practice and comprehensive quality controls. Others may receive regular donations of equipment that will need to fall within a clear needs assessment policy, while many countries are currently in ongoing crisis situations and need special emergency assistance.

The two approaches outlined above — creating awareness of international best practices and providing WHO technical support to national regulatory authorities — are intended to address the need for medical device regulations at the national and global level (5).

References

4. Injection safety. Guiding principles to ensure injection device security. Available from eht@who.int.
5. Department of Essential Health Technologies, World Health Organization. e-mail: eht@who.int or http://www.who.int/eht.