



AIDE-MEMOIRE

for National Medical Device Administrations

A medical device can range from a simple wooden tongue depressor or stethoscope to the most sophisticated implants or medical imaging devices. In general, a medical device is an instrument, apparatus, or machine used to prevent, diagnose or treat disease. It also serves to detect, measure, restore or modify the structure or function of the body for a given health purpose. Typically a medical device achieves its purpose without entering metabolic pathways.

Optimum safety and performance require cooperation among all involved in the life span of a medical device: the government, the manufacturer, the importer/vendor, the user and the public – each has a specific role to play in this risk management.

Many countries procure medical devices that may be sub-standard. Some manufacturers of medical devices may also be unaware of minimum standards. Governments that are unable to carry out pre-market review, either for imported devices or those manufactured locally, could assure regulatory compliance by taking advantage of the work of major device manufacturing countries. A priority in local regulatory development should be the establishment of vendor and product registrations.

Education and training of users, and the continued assessment of medical devices *in use* is as important as product control. It is critical to have access to a system for informing and collaborating with the manufacturer, vendor, all users, the public and relevant international organizations of hazards/issues related to medical devices.

Words of advice

- **Collaborate with all stakeholders to establish a clear and comprehensive national policy on medical devices**
- **Adopt recommendations on global harmonization for regulatory requirements and procedures**
- **Ensure that classified medical devices are manufactured in conformity with applicable quality system standards**
- **Link to networks that monitor medical devices and participate in post-market surveillance and medical device alert issues**



Checklist

Government

- Commitment and support
- Ensure mechanisms for recognition of and conformity assessment with national/international standards
- Develop and implement national policies
- Ensure the safety and performance of medical devices in use
- Link to international alert system
- Establish regulatory authority on medical devices for:
 - Basic acceptance criteria: requirements on safety and performance, quality systems, packaging and labelling
 - Import control
 - Local production control
 - Vendor and product registration
 - Post-market surveillance
 - User education
 - Clear policy on donations
 - Regular review of policy/standards

Manufacturers

- Comply with recommendations on global harmonization for regulatory requirements and procedures
- Undergo testing or clinical trials to substantiate intended benefit
- Ensure labelling and packaging requirements

Importer/vendor

- Ensure product complies with regulatory requirements
- Avoid making misleading claims
- Maintain device distribution records
- Provide user support
- Fulfil all after-sales obligations

User

- Secure and follow adequate training
- Monitor safety and performance of device on continuous basis
- Ensure regular calibration and maintenance
- Share information and problems
- Assure appropriate waste disposal

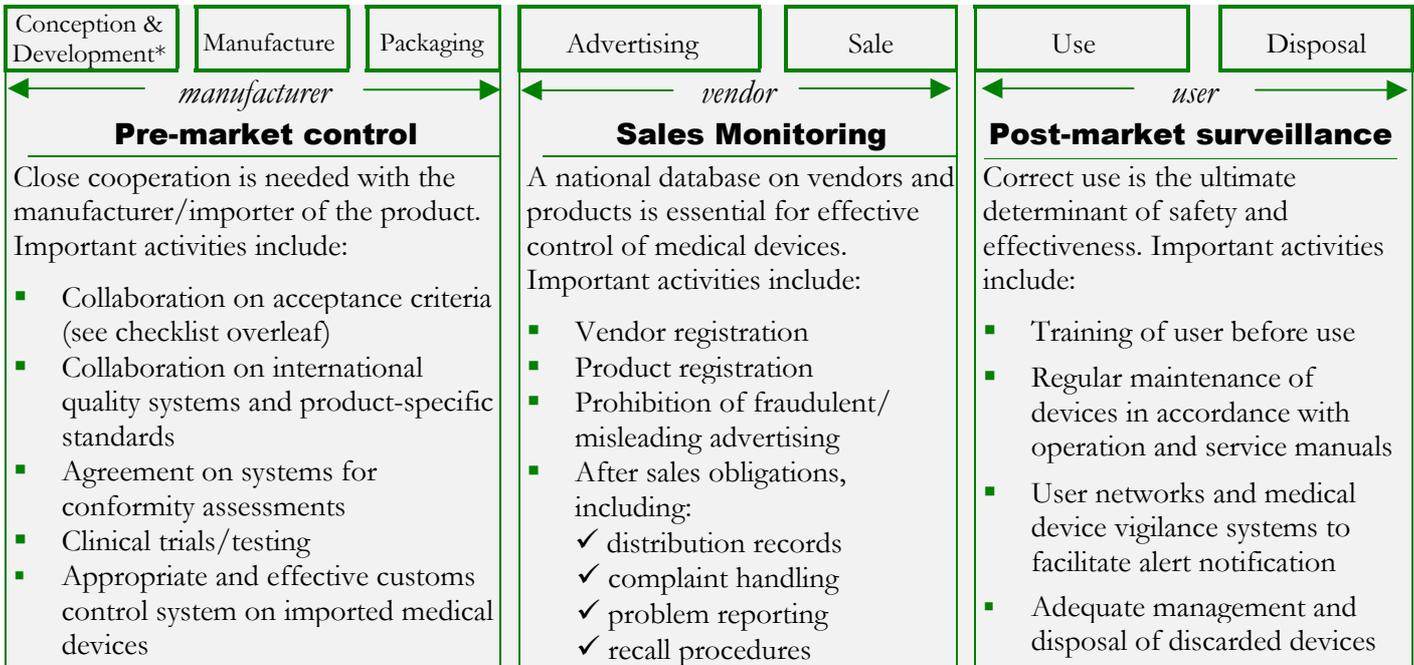
Public

- Become informed and insist on safe, effective, quality, affordable and sustainable products

Key Elements

National medical device regulatory or monitoring programme

The following diagram provides an overview of the different phases in the life span of a medical device. The phases shown may overlap or interact but each can affect safety. Since most developing countries import medical devices, priority should be given to vendor and product registrations, user training and post-market surveillance of devices (correct use, problem alerts and recalls). Although in-country pre-market product control requires resources and expertise, governments could benefit from the work of major medical device manufacturing countries to assure regulatory compliance. International sharing of information on alert systems for medical devices is essential as risk management is more effective with a large population database.



* includes testing and clinical trials

Recognition and use of national and international standards

Regulations address essential safety and performance principles (see Global Harmonization Task Force web site, Doc SG1-N020R5). Detailed technical requirements and characteristics are provided by voluntary product standards developed by national and international expert groups (see ISO TR 16142:1999). The international quality systems standard for medical device manufacturing is ISO 13485. Governments should have a procedure to recognize and publicize standards as a guide for all stakeholders. While certain technical standards can be specified by specialists, in general good standards have the following attributes:

- their development has been overseen by a recognized body ensuring that the process is transparent and not dominated by untoward interests.
- the development process has been open to input from all interested parties and the resulting document based on consensus. Consensus, in a practical sense, means that significant agreement is reached in the preparation of a standard, including steps taken to resolve all objections. This implies more than a majority, but not necessarily unanimity.
- good technical standards are based on consolidated results in science, technology and experience, and aimed at the promotion of optimum community benefits.
- standards do not hinder innovation and must be periodically reviewed to remain in tune with technological advances.

Devices intended for global use should follow international standards (ISO, IEC). A standard can be recognized fully or partially, provided this is clearly specified. Several standards can also be recognized to satisfy the requirements of a particular device. Conformity of a device can be assessed by accredited third party agencies, such as a notified body. In some countries, the publication of government recognized standards mandates product compliance.