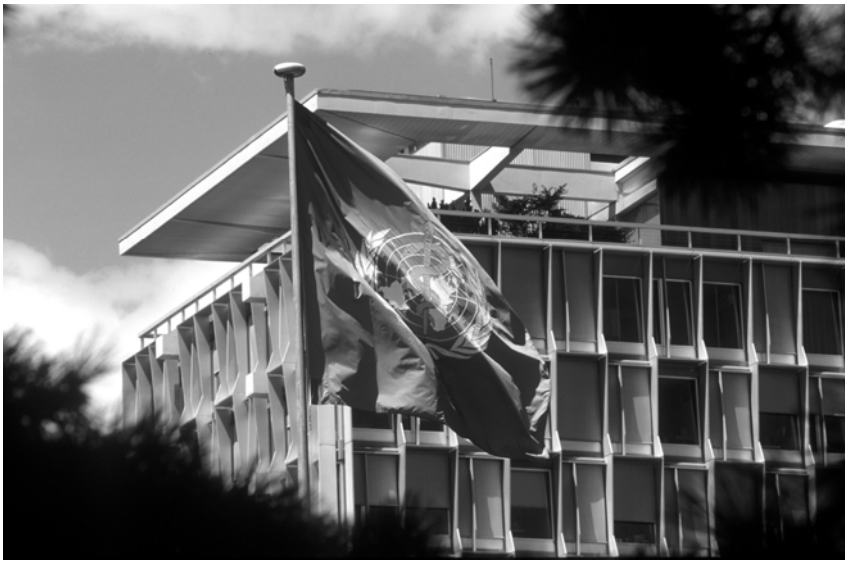

World Health Organization

Medical Device Regulations

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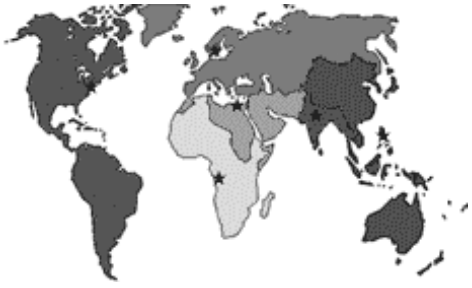
Essential Healthcare Technologies

WHO in brief

- The World Health Organization is the United Nations specialized agency for health, founded in 1948
- 192 member states
- HQ in Geneva

Regional offices



:: Regional Office for Africa
:: Regional Office for the Americas
:: Regional Office for South-East Asia
:: Regional Office for Europe
:: Regional Office for the Eastern Mediterranean
:: Regional Office for the Western Pacific

Article 1 of WHO constitution

"The attainment by all people of the highest possible level of health."

Definition of health technologies :

Health care technologies include medical devices, equipment, supplies and procedures/services.

Department of Essential Health Technologies

Health technologies are essential when they:

- Meet basic needs for health services
- Have been proven to be cost-effective
- Are evidence-based

The objectives of EHT are to:

Strengthen the ability of Member States to address health
problems through the use of essential health technologies

The objectives of EHT are to:

Assist Member States in establishing safe and reliable services for essential health technologies through the adoption of basic operational frameworks covering policy, safety, access and use

The objectives of EHT are to:

Develop norms, standards, guidelines, information and training materials and foster research on essential health technologies in support of the establishment of effective health services by Member States.

WHO recommends to countries/regions to implement global healthcare policies in order:

- To maximize the benefits that rationally used healthcare technologies may generate in a given economical context
- To manage risks associated with healthcare technologies

"Risk management interpretation of EHT objectives"

Why is WHO interested in Regulations?

- Countries need to put healthcare policies in place
- Policies will only be successful if supported by regulations and corresponding sanctions
- Bodies created to manage policies can only be successful if legitimated by legal acts describing the scope of their powers and their accountability

WHO does not promote any particular regulatory system

However certain key points:

- Assessment before placing on the market
- Product and manufacturer registration
- Post-market surveillance and vigilance

Medical device trade

- Medical devices are used worldwide and international trade is extremely important
- No country manufactures every type of device needed
- There is a need to harmonize national regulatory systems in order to minimize barriers to circulation of medical devices thus giving access in principle to safe and efficient medical devices

Medical Device Trade

- Divergent local regulations are likely to increase costs and possibly hinder access to healthcare technologies
- Countries are advised to consider regulatory convergence at international level

Competitiveness of local industry

- Regulatory barriers to trade are obviously a complex issue
- Regulations are necessary
- Should not be overly burdensome
- Local regulations may impact competitiveness of national industry on the domestic market as well as exportation markets.

Competitiveness of local industry

- It is likely that any national regulation which can demonstrate to be at least on a par with international practices, will enable national industry to be better prepared for competing on world markets.

Regulatory systems may be costly

The figures below are not comparative as agencies' scopes differ and are only cited to demonstrate the order of magnitude :

- FY 2004 US-FDA $1.4 billion
- FY2004 Afssaps France $110 millions
- FY 2004 TGA Australia 2004 643 million Australian dollars = $ 459 millions
- FY 2005 Sweden Medical Products Agency 350 MSEK= $45 millions

Resources are limited – Products are extremely numerous

- A risk management approach is a cost effective way of prioritising resource allocation
- Many regulatory systems classify devices on risk criteria
- Use of international standards is another way of limiting resource requirements

Risk management can be used as an allocation tool

- Risk is often defined as the combination of "probability of occurrence of harm" and "severity of harm"
- Spend more resources on surveillance of products that frequently cause serious harm while hoping to maximize risk reduction

Classification based on risk
fictitious example

A. Low risk – Self certification
B. Low/Medium risk – manufacturing control by external body
C. Medium/High risk – design control by external body
D. Complete design and production control by external body for each product

Standards

- "A document established by consensus , and approved by a recognized body , that provides, for common and repeated use, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context".
- Standards best achieve their potential in a regulatory system

Note : Consensus does not necessarily imply unanimity

Requirements on a product, service, technical solution or test-method

- likely that a standard covering that particular concern already exists, corresponding to existing products, services or widespread professional practice which have been extensively tried and tested.
- enormous advantages in terms of safety, performance, delays and cost for all involved parties

Requirements on a product, service, technical solution or test-method,

1) consider if existing standards could not be used.
2) If standard coverage is only partial and a new reference document is obviously needed, reference to standards for relevant points is a practical and widely used solution which contributes to the acceptability of a new reference document.

One standard for each device ?

- The number of international medical device standards is approximately1000.
- The Global Medical Device Nomenclature contains approximately 7000 generic devices.
- Horizontal and vertical standards.

Nomenclatures - Vigilance

- A report data base
- Generic device nomenclature essential
- Additional descriptors may be useful as well (medicinal substance, animal tissue, ionizing radiation, sterile…)
- Do not forget that the product specific information is indispensable !

Manufacturer(s) Registration

- … the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

Legal representative

- Definition needed
- Registration
- Scope of their activity expressed in terms of a nomenclature such as GMDN or its collective terms
- Problem … importer, distributor, vendor and their representatives
- One legal person may play several "roles"

Product registration

- Nomenclature such as GMDN
- Classification such as GHTF model
- When does a modified device become an entirely new device ?

Adverse event reporting

- What events should be reported ?
- How should the national regulatory body process the report ?
- What regulatory actions should be taken ?
- At each stage risk considerations contribute to focus on the most important risks

Trends

- Tissue engineered medical products, advanced therapy products, biologics…
- Nano-technologies
- Devices integrating IT or consisting exclusively of IT, communicating devices…
- Transformation of a product into a service

Challenges

- A certain blurring of frontiers between regulatory categories of health products – Need for cross-cutting
- Medicinal products, biologics and other categories are used in combination with devices
- Non professional use
- Counterfeit devices
- Reuse of medical devices

WHO/EHT INITIATIVE

- Global Action for Health Technologies
- Benchmarking of health technologies in countries
- Comparison with countries of comparable economical strength
- Advice on sustainable investments in health technologies

Health Care Economics

- In numerous developing countries total annual health spending per capita amounts to less than $100 and in a few countries amounts to as little as $15
- In developed countries the annual health spending per capita is from about $1000 to more than $5000
- The quotient between the highest and the lowest level of spending is about 500.

WHO Support activities

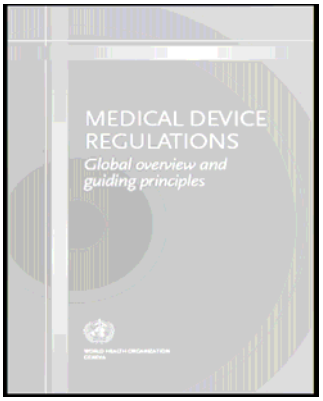
- WHO produces guidelines
- Try to facilitate exchange and collaboration between regulatory agencies
- WHO gives recommendations
- WHO cooperate with organizations such as GHTF and AHWP

Missions to countries

- On request
- Customized report with recommendations based on harmonized technical elements
- Country takes all decisions
- Step by step approach to allow resource limited countries to progress in terms of regulatory controls

Recommended reading: "WHO guidance on Medical Device Regulations" (approximately 40 pages)

http://www.who.int/medical_devices/en/



Thank you for your attention !

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