

Regulatory Model for Development of Device Regulatory Systems - Needs, barriers and Constraints Associated With National Implementation

The way Forward....

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Organization**

Purpose of a regulatory system

The WHO Vision

- To ensure improved access, quality and use of medical products and technologies (WHO Strategic Objective 11)
- ...the main purpose of a regulatory system specific for medical devices is the optimization of benefits resulting from safe and efficient medical devices and control of the risks associated with their utilization...
- ...regulatory systems have other aims including trade, professional practice and third party payer acceptance...



Growing Attention to Medical Devices Within WHO

WHA resolution WHA 60.29 of May 2007 "Health technologies" (in particular medical devices)

Urges Member States: "to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and where appropriate participate in international harmonization;"

http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R29-en.pdf



GHTF Achievements

Establishment of many technical elements which are in the process of reaching universal acceptance such as :

- definition of "medical device"
- the essential principles
- risk classification of devices
- the use of standards in conformity assessment
- the National Competent Authorities Reporting system (NCAR)
- ...



GHTF Regulatory Model - What Can be Expected ?

- Founding Members Fundamentally Keep Their Regulatory Systems
→ Slow convergence, still substantial differences between countries
- Countries adopting new regulations heavily rely on GHTF technical elements → Contributes to convergence
- Three different kinds of situations – Different difficulties
 - 1) Modify well established regulations
 - 2) Implement new regulation with adequate resources
 - 3) Implement new regulation with scarce resources - Currently no regulation at all for medical devices.



Substandard Medical Devices

The Need for Regulation

Two accused over 'fake' HIV tests

Two men have appeared in court in West Bengal over the alleged mis-selling of kits which were used to test people for HIV/Aids and hepatitis.

Police say Monozyme India sold hundreds of thousands of the kits, originally designed to test for pregnancy or other conditions, under false pretences.



Govind Sarda and his brother Ghanshyam were denied bail

Doctors say this led to infected people being given the all-clear, and going on to give blood and infect others.

The company's owners deny charges of malpractice and forgery.

Source: BBC NEWS web-site2006/10/30

GHTF Model Ready for Use for Countries in the Implementation Phase ?

- WHO member states spend between US \$ 10 and US \$ 5000 per capita and year, a ratio of 1/500.
- Need for a model that can be used irrespective of the resources available
- Need for a step by step method for resource scarce countries ? (steps to take in order of increasing benefit cost ratio without assuming any minimum level).



Idea1 – Step by Step Approach In order of Resources Necessary

- 1) Adverse event reporting system
- 2) Registration of the actors in the supply chain
- 3) Registration of products
- 4)



Idea2 Accepting approvals from other trading blocks ?

- What are the practical conditions for actually doing that ?
- The documents needed to prove compliance with the regulation in the country of origin
- How to cater for domestic industry if the system is based on accepting foreign approvals ?
- What if no regulation exists in the country of origin ?
- Confidence cannot be built if verification is impossible



Transparency Enabling Health Technology Assessment and Informed Choice

- IT gives vast opportunities
- Clinical evaluation data about devices is fairly scarce
- Information from an independent source should be available
- Third party payer acceptance should be transparent
- ...



Future Priorities on the International Agenda

- Worldwide network for exchange of regulatory information.
- Need for transparency on regulatory approvals
- More countries to adopt regulations for medical devices
- Need for a better knowledge base regarding device regulations worldwide
- Need to take into account technological change in future work to avoid seeing regulations "drifting apart" for products covered by more than one regulation.
- ...



THE END

Thank you for your attention !

