GHTF to IMDRF

What next?

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International Medical Device Regulators Forum
IMDRF-3; Sophia Antipolis, 20 March 2013
Introduction

- Personal reflections
- Early days for IMDRF
- Questions, concerns, opportunities
Background trends

- Worldwide population continues to grow
- Infant mortality continues to decrease
- Life expectancy increases
- Ageing populations
- Growing policy focus on healthy ageing and assistive technologies
- Shift of burden of disease from communicable to non-communicable conditions
- Reduction in poverty -- but not evenly distributed
Background trends

• Challenges to fiscal sustainability of current social models
• Changing models of health care delivery
• Growing public access to information on health
• Growing public awareness of medical technology
• Rapid expansion of access to enabling technologies such as mobile telephones and Internet
Why seek regulatory convergence?

Age standardized death rates, 2004

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
Map Production: Public Health Information and Geographic Information Systems (GIS)
World Health Organization

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Thesis

Access to safe and effective health care technologies of high quality is an important contributor to economic and social progress in countries at all stages of development.
Enlightened, appropriate, judiciously applied regulation of health care products is a public good

- Protection and promotion of public health
- Good governance
- Expectation of citizens
- Public confidence in products and health care
Regulation and regulatory practice are determinants of successful life sciences innovation

- Regulators are on the life sciences “critical path”
- The efficiency and effectiveness of regulatory authorities in fulfilling their public health mandate is therefore critical to achievement of desired life sciences outcomes
- Importance of international regulatory harmonisation and use of international standards in contributing to life sciences innovation
Thesis

Growing public discussion about needs in less developed countries for “available, accessible, appropriate, and affordable” medical technologies highlights the concomitant need for appropriate and affordable regulation.
Why seek regulatory convergence?

- More efficient use of regulator and industry resources
- More efficient use of taxpayer funds
- Spread compliance costs over more markets
- Develop and promulgate regulatory best practices
- Pooling of expertise
- Regulatory capacity-building
Why seek regulatory convergence?

- Protect and promote public health
  - Directly in-market
  - Indirectly in other markets
Why seek regulatory convergence?

• Protect and promote public health
  • Directly in-market
  • Indirectly in other markets
• Promote investment in innovation
• Facilitate international trade
Costs of regulatory divergence

Incremental sales revenue

Incremental costs of compliance

Low

High

Low

High
Costs of regulatory divergence

Incremental costs of compliance

High
Low

Incremental sales revenue

Low
High

Possibly attractive investment
Costs of regulatory divergence

- High costs, high sales revenue: Possibly attractive investment
- High costs, low sales revenue: Possibly attractive investment
- Low costs, high sales revenue: Possibly attractive investment
- Low costs, low sales revenue: Possibly attractive investment
Costs of regulatory divergence

Incremental costs of compliance

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Incremental sales revenue

- Attractive investment
- Possibly attractive investment
- Attractive investment
- Possibly attractive investment
Costs of regulatory divergence

- **Unattractive investment**
- **Possibly attractive investment**
- **Attractive investment**

Incremental costs of compliance:
- High
- Low

Incremental sales revenue:
- Low
- High

Costs of regulatory divergence:
- High incremental costs of compliance and low incremental sales revenue: Unattractive investment
- Low incremental costs of compliance and high incremental sales revenue: Attractive investment
- High incremental costs of compliance and high incremental sales revenue: Possibly attractive investment
- Low incremental costs of compliance and low incremental sales revenue: Possibly attractive investment
Can regulatory harmonisation help drive creation of more attractive markets for investment?

- High incremental sales revenue
- High incremental costs of compliance
- Low incremental sales revenue
- Low incremental costs of compliance

Possibly attractive investment

Possible attractive investment

Attractive investment
Can regulatory harmonisation help drive creation of more attractive markets for investment? … and does that help bring public health benefits to more people and more societies?
Costs of regulatory divergence

Can regulatory harmonisation help drive creation of more attractive markets for investment? ... and does that help bring public health benefits to more people and more societies?

Incremental sales revenue

High
Low

High
Low

Low
High

Attractive investment
Possibly attractive investment
Possibly attractive investment
Unattractive investment

Incremental costs of compliance

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Do high costs of compliance with regulatory requirements in large established markets compete for and “squeeze out” investment in innovative technologies needed in less developed countries?
Now is the time

• ≈ 85 countries today regulate medical devices
• More developing regulations
• To what regulatory model(s) will they turn?
• Prospective regulatory convergence easier than retroactive
GHTF guidance as rootstock

- International harmonisation initiatives based upon GHTF guidance documents
GHTF guidance as rootstock

• International harmonisation initiatives based upon GHTF guidance documents
  • Asian Harmonization Working Party (AHWP)
  • Asia Pacific Economic Cooperation (APEC)
  • World Health Organization (WHO) guidance
GHTF guidance as rootstock

- New national and regional regulations based upon GHTF guidance documents
  - Association of Southeast Asian Nations (ASEAN) medical device directive
  - South Africa (?)
  - Saudi Arabia
  - India (?)
GHTF guidance as rootstock

• How will GHTF guidance be maintained?
• How will IMDRF fill gaps in GHTF regulatory model?
• Will lack of maintenance lead to obsolescence?
• Will IMDRF founders be seen to use GHTF guidance in their own regulatory systems?
Vision of “success”? 

• What will be different in 3-5 years as a result of IMDRF’s work?

• Can “convergence” be measured?
Vision of “success”? — Graph showing the relationship between Harmonisation (GHTF/AHWP) and Comprehensiveness.
Vision of “success”?

Trend
Vision of “success”? 

Harmonisation (GHTF/AHWP) vs Comprehensiveness 

High

Hong Kong SAR

Low

Australia

Singapore

Canada

Saudi Arabia

Chinese Taipei

Thailand

Korea

USA

New Zealand

Argentina

Brazil

Mexico

Colombia

Japan

EU, EFTA

Notes:
• Position in clusters not necessarily significant
• Subjective assessment of many variables
• Variables not weighted
• Not all countries that regulate medical devices shown
Vision of “success”? 

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GHTF regulatory model
What follows?

Harmonisation (GHTF/AHWP)

High

Hong Kong SAR

Low

Low

Comprehensiveness

High

Notes:

- Position in clusters not necessarily significant
- Subjective assessment of many variables
- Variables not weighted
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Vision of “success”?  

“… The process of convergence represents an important form of regulatory cooperation which in turn makes possible additional, enhanced forms of cooperation and collaboration between regulatory authorities.”

- Functional network of regulators, rather than individual regulators?

Source: IMDRF Terms of Reference, 1 March 2012
What follows?
Converge on all elements of models?
Different levels of regulatory control

Source: GHTF: GHTF Regulatory Model; GHTF/AHWG-GRM/N1R13; 2011

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Converge on all elements of models?

Countries with basic GHTF controls

Countries with full GHTF controls

Countries with full GHTF plus IMDRF controls
What next?

- Who is the intended user of GHTF guidance and IMDRF work products?
- Who will develop guidance for less developed regulatory systems?
- How will implementation of guidance be supported in less developed regulatory systems?
- How will harmonisation forums be coordinated?
- Is there a need for ‘good harmonisation practices’?
Vision of “success”

Are there measurable public health gains?
“… one of the biggest challenges today is to make scientific innovation improve the lives of the poorest”

-- Bill Gates, Philanthropist

Source: Landscape analysis: of barriers to developing or adapting technologies for global health purposes; Global Initiative on Health Technologies; Department of Essential Health Technologies; World Health Organization, Geneva; 2010
Thank you