Convergence and capability

International health convergence, regulatory convergence, and regulatory capability

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Why regulate medical devices?
Why regulate medical devices?

Protect and promote public health
“A world converging within a generation”

A 1990

- High income: 0.82 billion (15.6%)
- Upper-middle income: 0.74 billion (14.0%)
- Lower-middle income: 0.67 billion (12.7%)
- Low income: 3.1 billion (57.8%)

B 2011

- High income: 1.1 billion (16.3%)
- Upper-middle income: 2.5 billion (35.7%)
- Low income: 0.82 billion (11.7%)
- Lower-middle income: 2.5 billion (36.3%)

Source: Jamison, Summers, et al.; Global health 2013: A world converging within a generation; Lancet 2013; 382:1898-955
Figure 21: Relation between income and health spending

N=177 countries
\[ y = 1.04x - 3.1 \]
\[ R^2 = 0.93 \]
Figure 22: The first law of health economics in Organisation for Economic Co-operation and Development countries.

“A unique characteristic of our generation is that collectively we have the financial and the ever-improving technical capacity to reduce infectious, child, and maternal mortality rates to low levels universally by 2035, to achieve a “grand convergence” in health. …
… With enhanced investments to scale up health technologies and systems, these rates in most low-income and middle-income countries would fall to those presently seen in the best-performing middle-income countries. …”
… Achievement of convergence would prevent about 10 million deaths in 2035 across low-income and lower-middle-income countries relative to a scenario of stagnant investments and no improvements in technology.”

Source: Jamison, Summers, et al.; Global health 2013: A world converging within a generation; Lancet 2013; 382:1898-955
With enhanced investment, we could achieve a grand convergence in global health in the next generation on bringing deaths from infections and RMNCH conditions in LICs and MICs down to rates in the best-performing MICs.


* Reproductive, maternal, newborn, and child health
Thesis

Demand for health care and medical technologies will grow and become more widespread
Regulation of health care products is an important element of health care ‘ecosystems’
Thesis

Regulation and regulatory practice are determinants of successful life sciences innovation

• Regulators are on life sciences “critical path”

• The efficiency and effectiveness of regulatory authorities in fulfilling their public health mandate are critical to achievement of desired life sciences outcomes
‘Globalisation’ of R&D, clinical trials, manufacturing, and supply chains leads to growing interdependence of regulators and regulatory controls
Why regulate medical devices?

Protect and promote public health

Block or remove unsafe and ineffective products from market

Promote fair competition

Deter counterfeiting

Secure supply chains

Control promotional practices

Require availability of information
Regulator

evaluates benefits/risks for the population

Health care provider

evaluates benefits/risks for a patient

Patient

evaluates benefits/risks in terms of personal values

Source: Managing the risks from medical product use; Creating a risk management framework; Report to the FDA Commissioner; May 1999 [Adapted]
Thesis

Enlightened, appropriate, judiciously applied regulation of health care products is a public good

- Good governance
- Expectation of citizens
- Public confidence in products and health care
Many AHWP and APEC economies need appropriate and affordable regulation

... and the ability to effectively implement such regulatory systems
Regulatory convergence

“... a voluntary process whereby the regulatory requirements and approaches across countries and regions become more similar or aligned over time as a result of the adoption of the same technical documents, standards and scientific principles (harmonization) and similar regulatory practices and procedures. ...
Convergence of requirements → evidence → forms and format of evidence

- Not necessarily evaluation criteria or regulatory decisions
Regulatory convergence

Harmonisation (GHTF/AHWP)

Low	High

Comprehensiveness

Low	High

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

Adopt and implement laws and regulations

Funding

Establish regulatory authority
   -- Systems and people

Adopt and implement regulations, ordinances, decrees

Establish market surveillance systems

Establish pre-marketing conformity assessment requirements
Final Document

Title: The GHTF Regulatory Model

Authoring Group: Ad Hoc GHTF SC Regulatory Model Working Group

Endorsed by: The Global Harmonization Task Force

Date: 13 April 2011
Medical device life cycle

- **CONCEPT**
- **PRODUCT REALISATION**
- **PLACING ON THE MARKET**
- **PRODUCT USE**
- **END OF PRODUCT LIFE**

- Destruction, Disposal, Manufacture, use of parts

- Design inputs leading to new concept or newer version

- Feedback into new design or manufacturing corrections or improvements based on market experience

Medical device life cycle
Medical device life cycle

[Diagram showing the medical device life cycle with stages: Concept, Pre-market, Post-market, Product realisation, Placing on the market, End of product life, Product use “post-market”]

Source: GHTF/AHWG-GRM/N1R13:2011 (adapted)
Medical device life cycle

Compliance Audit - by Conformity Assessment Bodies and/or the Manufacturer

Quality Management System - Risk Management

Premarket Classification – Conformity Assessment
- Essential Principles
- Standards
- Device Specification
- Design Control
- Design verification and validation
- Clinical Evidence
- STED
- Declaration of conformity

Premarket Registration Listing

Placing on the Market

Postmarket Surveillance
Conformity Assessment (continued)

- Adverse Event Reporting
- Complaint Management
- Maintenance and Service
- Corrective and Preventive Actions
- Postmarket clinical follow up

Source: GHTF/AHWG-GRM/N1R13:2011
Levels of regulatory control

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

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Levels of regulatory control

Figure 10. Suggested priorities for regulatory programme development

- Pre-market evaluation (local team)
- Recall procedure
- Problem reporting
- Complaint handling
- Advertising control
- Implant registration
- Distribution records
- Device listing
- Establishment control
- Import control

CLEAR POLICY GUIDELINES

Source: Medical device regulations: Global overview and guiding principles; World Health Organization, Geneva; 2003
Guides

PROPOSED DOCUMENT

Title: Playbook for Implementation of a Medical Device Regulatory Framework

Authoring Group: AHWP TECHNICAL COMMITTEE (TC) OFFICE BEARERS

Date: August 5th, 2014

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“Anything that is built must rest on a foundation”

-- Lao-tzu
Enabling conditions for regulatory capability

- **Good Decision Making Practices**
- **Good Regulatory Practices** based on international guidance, alignment and effective cooperation and work sharing
- **Harmonisation and convergence** of technical requirements in conjunction with harmonised training principles and model core curricula for regulators
- Applicable modern laws and enabling legal system
- General Good Governance in Public Sector, including transparency and accountability

Source: Dr. Lembit Rägo, World Health Organization; at International Regulatory harmonisation Amid Globalization of Biomedical Research and Medical Product Development; Institute of Medicine, Washington, D.C.; 13-14 February 2013 (Adapted)
Good Decision Making Practices

Good Regulatory Practices based on international guidance, alignment and effective cooperation and work sharing

Harmonisation and convergence of technical requirements in conjunction with harmonised training principles and model core curricula for regulators

Applicable modern laws and enabling legal system

General Good Governance in Public Sector, including transparency and accountability
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Applicable modern laws and enabling legal system

General Good Governance in Public Sector, including transparency and accountability
Desirable attributes of regulatory capability
Desirable attributes of regulatory capability

- Integrity
- Impartiality
- Predictability
- Transparency
- Objectivity
- Safeguards against abuse of power
- Nimbleness
- Good judgment
- Efficiency
- Cost effectiveness
- Adaptability

- Outward looking
- Substantive, timely, meaningful interaction with interested parties
- Memory and learning
- Conducive to technology innovation
- Scientific and technical expertise
- Able to assess and manage risks
Desirable attributes of regulatory capability

- High quality decision making
- Linked to public health priorities
- Coordination between political levels
- Periodically reviewed and updated
- Take into account international regulatory harmonisation guidance
- Sufficient resources

- Political support
- Political accountability
- ‘Joined up’ policy making
Regulatory capability

Attributes of both systems and people

Desired attributes apply regardless of scope of regulatory systems

Capabilities of both regulators and regulated industry
‘Joined-up’ policies

“Our overarching messages are that, the region’s competitiveness and the health and well being of our people, would benefit from

(1) a top-level political commitment to this sector with appropriate resource allocation, and

(2) an integrated approach taken to life sciences and health care policy making. Many different agencies have competing priorities and approaches. Coordination of these will maximize benefits to the community and efficiencies in the administration of government systems in this sector.”

Source: APEC Life Sciences Innovation Forum Strategic Plan; 2006/SOM3/LSIF/010; 6-7 Sept. 2006 [emphasis added]
Regulatory capability

Current regulatory capability and capacity needs vary across AHWP and APEC member economies

In some cases where needs for medical technology are greatest, regulatory capacity is weakest
Regulatory capability

Should all economies have same regulatory capacity?

Can a nation have “full capacity” but only in certain elements of a full “regulatory model”?

Functional cross-national network of regulators, rather than individual regulators?
Regulatory capability as intellectual capital

Skilled competent motivated regulatory affairs specialists
  • Government, conformity assessment bodies, and industry

Retained experience

Institutional memory

Ethical decision-making

Continuing education and professional development
Regulatory capability as intellectual capital

Competency based training

Growing need for competence in cross-border collaboration

Capacity to participate in development and implementation of international harmonisation guidance
Opportunities for AHWP and AHC future work?

- **Good Decision Making Practices**
- **Good Regulatory Practices** based on international guidance, alignment and effective cooperation and work sharing
- **Harmonisation and convergence of technical requirements** in conjunction with **harmonised training principles and model core curricula for regulators**
- Applicable modern laws and enabling legal system
- General Good Governance in Public Sector, including transparency and accountability
Good Decision Making Practices

Good Regulatory Practices based on international guidance, alignment and effective cooperation and work sharing

Harmonisation and convergence of technical requirements in conjunction with harmonised training principles and model core curricula for regulators

Applicable modern laws and enabling legal system

General Good Governance in Public Sector, including transparency and accountability
Vision of “success”

Prepare regulatory workforce of the future

Trust in ability of regulators to protect and promote public health

Confidence in industry to develop needed products

Measurable public health gains and socioeconomic development
Thank you