Understanding Where We Have Been and Where We Are Going With Harmonization

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Presentation Outline

• The Regulatory Lexicon: are we speaking the same language?
• Some observations on IMDRF
• The ‘Big Picture’
• Concluding remarks
Disclaimer

Views expressed are those of the presenter and do not necessarily reflect those of IMDRF or any other organization.
Some Questions

GHTF to IMDRF: Are we any nearer to regulatory convergence?

What will it take?
The Regulatory Lexicon

• Regulatory Cooperation
• Harmoniz(s)ation – Convergence – Alignment – Coherence – Integration
• Equivalence – Mutual/Unilateral Recognition – Reliance
• Guides – Guidelines – Standards
• Laws – Regulations – Directives
• Conformity Assessment
• Treaties – Arrangements
• Bilateral – Plurilateral – Multilateral
• Adopt – Adapt - Implement
Is this Important?

Yes...

- No internationally ‘harmonized’, ‘standardized’ or ‘consensus’ definitions
- Different interpretations can lead to divergent expectations
- Effective cooperation begins with a common language
Harmonization – Some Definitions

• “Bringing into harmony, agreement, accord”
  – Common dictionary usage

• “Yields same result”
  – Pharmacopeial harmonization

• “The establishment, recognition and application of common... measures by different members (jurisdictions)”
  – WTO SPS Agreement
Harmonization

• While may occur at different levels (regulations, policies, procedures, etc.)
  ....greatest focus and success has been in the area of technical guidances and standards

• Simple in concept...more difficult in execution
Adoption...Adaption...Implementation

• Adoption
  – Official (administrative) incorporation of a guidance or standard into the regulatory framework “as is”

• Adaption
  – Deliberate changes, additions, restrictions; may or may not respect principles of source document

• Implementation
  – The true measure of harmonization
ICH Product Life Cycle

ICH

ICH Process:

Steps 1-3 → Step 4 → Step 5

Concept Draft for Comment Finalize Adopt Implement

Implementation Issues
Implementation Considerations

- Regulatory implications
- Collateral policy/guidance work
- Scope of application
- Training/competencies
- Infrastructure/system requirements
- Inherent complexity of product
- Readiness of industry
- Resources
Regulatory Convergence

• Represents process whereby regulatory requirements become more aligned over time as a result of the adoption of the *same* technical guidances, standards, principles (harmonization) and *similar* regulatory practices and procedures (IMDRF ToR)

• Does not generally require the harmonization of laws and regulations

• Broader concept but inclusive of “harmonization”

• A more appropriate term that embodies goals of both GHTF and IMDRF
Equivalence

- Two or more systems are said to be “equivalent” if, despite differences, they are expected to produce the same outcomes
- Should be established through objective means and documented
- Example: Mutual Recognition Agreements relating to conformity assessment of GMPs
Regulatory Cooperation – “The Continuum”

Assess equivalence

Development / adoption of same or similar standards and processes

Enhanced forms of cooperation: e.g., worksharing, reliance

Feedback

Convergence: a dynamic process

Catalysts: workload, globalization, technology, public expectations
Two New Terms

• “Good Harmonization Practices”
• “Interconnectivity”
Good Harmonization Practices

- Set of principles, processes and governance models that together define the elements of an effective harmonization initiative
- Should apply to any harmonization effort
- Examples include:
  - Setting realistic and clear objectives
  - Step-wise approach
  - Well-defined process and work plans
  - Permanent secretariat
  - Appropriate organizational model
  - Transparency of operations
  - Commitment of parties
World of Harmonization Initiatives
Interconnectivity

“WHO should promote the principle of interconnectivity:

Information sharing and cooperation between harmonization initiatives and enabling organizations in order to build synergies, leverage capacity and sustain efforts”

- Recommendation from 13th ICDRA
Observations on IMDRF

- IMDRF efforts build upon solid foundation provided by GHTF work products
- Broader regulatory membership reflects changing global face of product development and marketing
- Lessons learned: importance of selecting limited number of well-defined work items of high value and limited duration, \textit{and implementable by regulators}
- Industry and other stakeholder involvement critical to developing high quality work products and achieving original objectives of GHTF: true regulatory convergence and (where possible) harmonization
The Big Picture

• IMDRF plays a vital role in promoting convergence in the medical device sector
• To effectively achieve stated mission and goals IMDRF should work in concert with other trusted organizations and initiatives as part of a larger global plan
• APEC serves as one example
Regulatory Harmonization Steering Committee

- Formed in June 2009 under the APEC *Life Sciences Innovation Forum* (LSIF), RHSC serves unique role in promoting *regulatory convergence*
- Regional initiative that marshals resources of regulators, industry coalitions and academia towards common goals
- Work guided by Strategic Framework and roadmaps
- Designed to play *complementary role* to other international regulatory initiatives – including IMDRF – by promoting international best practices and standards
- Scope: “medical products”, notably drugs and devices
Members

- Regulators from 15 APEC Economies:
  - Canada, Brunei Darussalam, Chile, China, Chinese Taipei, Indonesia, Japan, Korea, Malaysia, Mexico, Philippines, Peru, Singapore, Thailand and the US

- Four Industry coalitions:
  - Research based pharmaceutical sector
  - Medical Devices sector
  - Generic pharmaceutical sector
  - Biotechnological products sector
Recent Developments

• Agreement on vision and approach to advance convergence and institutional/human capacity through network of Centers of Excellence (CoE)
• Vision: A sustainable platform for promoting regulatory convergence, capacity and cooperation in the area of medical products
• Science and policy focus
A Model for Driving and Sustaining Change

Series of inter-related CoE ‘Hubs’, each with affiliates in various economies

Supply Chain CoE Hub?

Clinical Trials CoE Hub

Affiliate

Affiliate

Affiliate

Other CoE Hubs?

Supported by APEC Harmonization Center and other partners
Synergism

- APEC RHSC positioning itself to become a leading enabler of regulatory convergence and capacity building by promoting international standards and best practices – *including those developed by IMDRF*

- *NB - Activities not restricted to APEC economies*

- Timing right: RHSC currently considering topics of greatest value to medical device industry and regulators
Concluding Remarks

• Language matters: different interpretations of fundamental concepts and terms can lead to divergent expectations
• IMDRF committed to accelerating convergence by developing and implementing work products of greatest value
• True convergence and harmonization will require the concerted, sustained efforts of key players – both regionally and internationally
• Recent developments at the international level hold great promise for advancing a more effective, strategic approach to convergence