Celebrating MHLW's & PMDA's International Strategic Plan

"Aligning International Regulatory Goals Through Innovation and Collaboration"

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Current Needs of Regulatory Stakeholders

Industry

- Improved ROI to sustain development of new products in pipeline
- Stable infrastructure to support commercial engagement and investment
- Transparent and consistent processes leading to more predictable outcomes
- Increased efficiency in regulatory transactions through convergence of requirements

Government/ Regulators

- Efficient and cost-effective regulatory policies
- Framework for quality decision-making
- Engagement of multi-stakeholders and effective communication
- Cross-cutting policies to maximise healthcare outcomes

Current Needs of Regulatory Stakeholders

Healthcare Professionals

- Confidence in regulatory processes
- Support advancing medical practices
- Clarity in information to make better informed decisions for patients

Patients

- Affordability of safe, high quality and efficacious health products
- Acknowledgment as significant contributor to regulatory decision-making
- Active participation in decision-making for their own health conditions

Common goal of faster access to affordable, high quality health products to patients

Industry's Perspective on Regulatory Gaps in Asia

Surveys and Focus Group meetings

- Part of **CoRE project to understand regulatory needs in Asia** from industry's and regulators' perspectives

- Two sessions conducted with **industry**
  - For **therapeutic products** (Jun 2014)
  - For **medical devices** (Oct 2014)

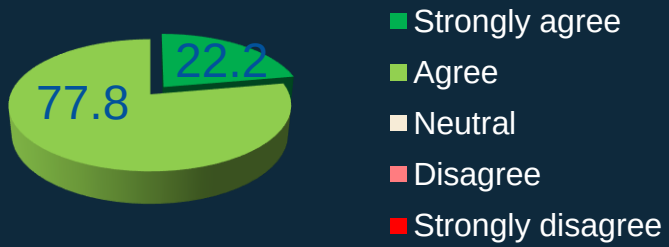
- **Discussions** focused on two topics
  a. Regulatory training and development needs/gaps
  b. Innovations in regulatory science, solutions and challenges

CoRE
Centre of Regulatory Excellence
@ Duke-NUS Graduate Medical School Singapore

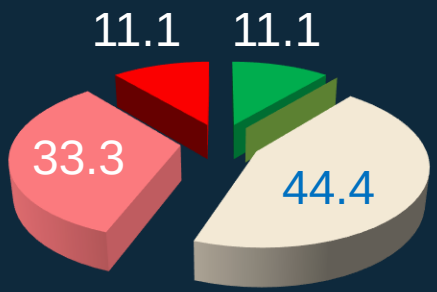
Industry's Perspective on Regulatory Gaps in Asia

Therapeutic Products Companies

Competencies of national regulatory agencies can be improved



There are sufficient initiatives to converge regional regulatory requirements



Industry's Perspective on Regulatory Gaps in Asia

Therapeutic Products Companies

Gaps

- Scientific knowledge
- Knowledge of different cultures in Asia
- Soft skills and strategic planning
- Structure for continuous education in regulatory affairs

Innovation

- Reduction in time and cost, adaptive licencing
- Mutual recognition processes, shared reviews
- Policy changes

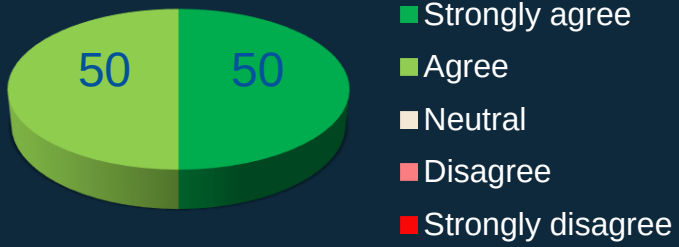
Challenges

- Different levels of receptiveness among regulators
- Capabilities and capacities
- Lack of transparency
- Affordability of regulatory affairs education and training

Industry's Perspective on Regulatory Gaps in Asia

Medical Device Companies

Competencies of national regulatory agencies can be improved



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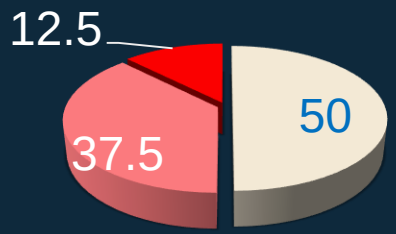


Industry's Perspective on Regulatory Gaps in Asia

Medical Device Companies

Gaps

- Framework for competencies
- Lack of recognition for experienced and qualified regulatory affairs personnel
- Lack of support from management
- Lack of regulatory affairs education at undergraduate level

Innovation

- Policy changes
- Regular training
- Mutual recognition processes

Challenges

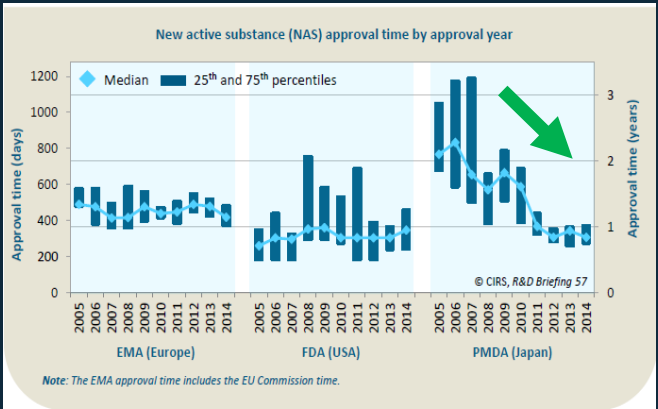
- Compliance risks from outsourcing
- Balancing between regulating and control

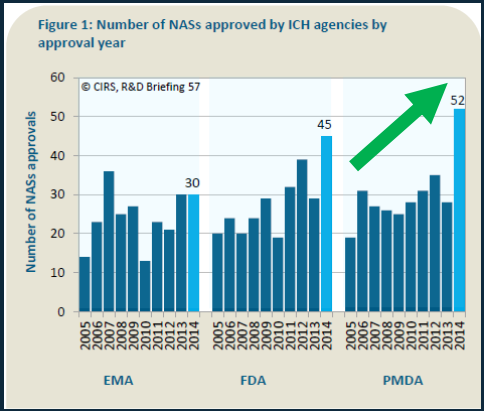
Regulatory System Challenges

- Lack of convergence of regulatory processes and requirements despite harmonised guidelines
- Lack of regulatory talent pool to support regulatory processes and strategy development
- Lack of infrastructure to bridge regulatory processes to rapidly advancing healthcare sciences
- Lack of platforms to exchange ideas, promote representation and foster closer collaborations across regulatory stakeholders
- Lack of regulatory education and training

Innovation in Regulatory Processes

- PMDA's review of regulatory processes and requirements has led to significant decrease in approval times, facilitating faster access to new medicinal products





Source: Centre for Innovation in Regulatory Science. R&D Briefing 57, July 2015.

Innovation in Regulatory Processes - ICH

FDA Fast Track	A process designed to facilitate the development and expedite the review of drugs to treat serious conditions unmet medical need	• More frequent meetings with FDA to discuss drug development plan • More frequent communication on clinical trials
FDA Breakthrough Therapy	A process designed to expedite t development and review of drug demonstrate substantial improve available therapy	
FDA Accelerated Approval	Regulation allowing drugs for ser conditions that filled an unmet n to be approved based on a surro endpoint	
FDA Priority Review	A process that directs resources evaluation of drugs that represer improvements in safety or effect compared with standard applicat	
EMA Conditional Approval	Regulation allowing drugs fulfilling unmet medical need for severe, life-threatening or rare diseases to be approved with limited clinical safety or efficacy data, provided a positive benefit-risk balance	• Conditional approval is granted before all data are available (valid for one year, on a renewable basis; once pending studies are provided, it can become a "normal" marketing authorisation)
EMA Exceptional Circum-stances	Regulation allowing drugs fulfilling unmet medical need for severe, life-threatening or rare diseases to be approved without comprehensive efficacy and safety data	• Conditional approval is granted before all data are available (reviewed annually to re-assess the risk-benefit balance)
EMA Accelerated Assessment	A process designed to expedite products of major interest in terms of public health and therapeutic innovation	• CHMP opinion shortened from 210 days to 150 days

PMDA Priority Review	A process that provides faster access to new therapies responding to high medical needs; includes products such as orphans, HIV medicines and products given "Extraordinary Approval"	• Review time shortened from 9 to 6 months
PMDA Sakigake (pioneer)	A system to put into practice innovative medicines/medical devices, regenerative medicines initially developed in Japan	• All Priority Review designation features • Prioritised clinical trial and pre-application consultation • Assigned PMDA manager as a concierge • Post-marketing safety measures

Source: Centre for Innovation in Regulatory Science. R&D Briefing 57, July 2015.

Innovation in Regulatory Processes

- **Advances in Adaptive Licencing**
- **Regulatory research to support new policies and methodologies**
  - US FDA CERSI
  - Innovative Medicines Initiative (IMI) – Strategic Research Agenda 2014-2024
- **Good Reliance Practice and Referencing in regulatory decision-making**

PMDA is in a well-placed strategic and networked position to pilot and promote regulatory innovation, e.g. ICMRA

Collaboration and Synergy

Between Industry and Health Authorities

- US FDA Technology Transfer Program – Cooperative Research and Development Agreements (CRADA)
- Innovative Medicines Initiative – joint undertaking between EU and European Federation of Pharmaceutical Industries and Associations (EFPIA)

Collaboration and Synergy

Among Health Authorities/ Regulators

- International Coalition of Medicines Regulatory Authorities (ICMRA)
- International Generic Drug Regulators Pilot (IGDRP)
  – aims for convergence and cooperation towards timely availability of safe, effective and quality generics
- International Medical Device Regulators Forum (IMDRF)
  – aims to accelerate harmonisation and convergence for regulation of medical devices
- International Pharmaceutical Regulators Forum (IPRF)
- APEC Regulatory Harmonisation Steering Committee (RHSC)
- ASEAN Pharmaceutical Product Working Group (PPWG) and Medical Device Product Working Group (MDPWG)
  – focus on integration, harmonisation and efficiency

Collaboration and Synergy

Among Industry

- IFPMA
- EFPIA
- PhRMA
- JPMA and APAC
- APACMed

Collaboration and Synergy

Convening of key opinion leaders and domain experts

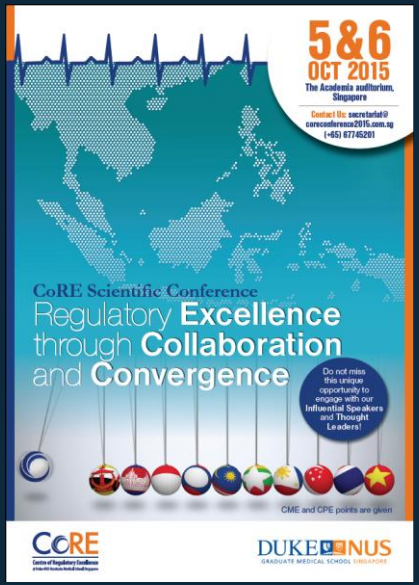
- *National Academy of Medicine (NAM*) – IOM roundtables & white papers
- *Centre for Innovation in Regulatory Sciences (CIRS*) – workshops & papers
- *Centre of Regulatory Excellence (CoRE)* – Roundtables and Focus Group meetings

NATIONAL ACADEMY OF MEDICINE

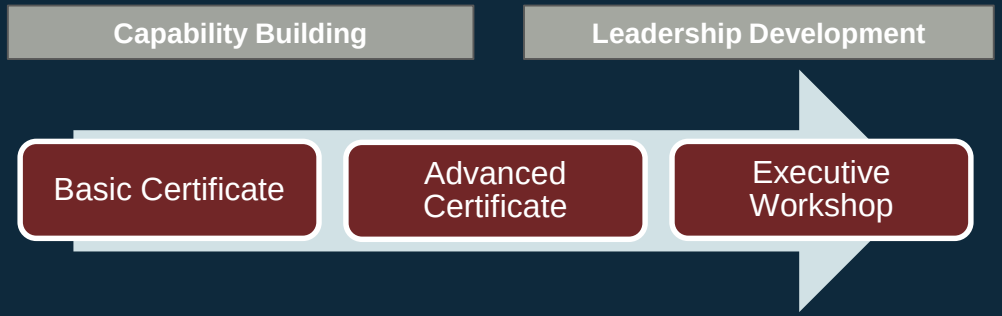
CIRS CENTRE FOR INNOVATION IN REGULATORY SCIENCE

Collaboration and Synergy

Convening of key opinion leaders and domain experts



Regulatory Capacity Development



Regulatory Capacity Development

Initiatives and Opportunities

1. ***Innovation in regulatory processes to facilitate access to health products and address manpower constraints***
   - Collaborative initiatives to harness strengths of different partners through good reliance / referencing practices
   - Promote regulatory convergence to minimise burden of different cross-regional requirements

2. ***Dedicated efforts to enhance regulatory competencies and increase capacity***
   - Customised curriculum and training focusing on key needs
   - Novel teaching methodologies to accommodate working professionals in regulatory affairs
   - Certification and professional development framework

Initiatives and Opportunities

3. ***Pursuit of regulatory excellence***
   - Define, teach and promote Good Regulatory Practices
   - Convene key opinion leaders and regulatory experts across stakeholder spectrum to discuss innovative options
   - Develop regulatory leadership networks

Building Momentum

Building on experience of earlier initiatives

- Allows more realistic scoping, e.g. convergence instead of harmonisation

Building on initiatives already in progress

- Avoids duplication and promotes collaboration
- Promotes convergence of requirements and processes
- Extends reach respective programmes
- Promotes globalisation of sound regulatory innovation

Key Expectation:

Ongoing engagement of MHLW/PMDA with regional and international initiatives to promote innovation, collaboration and capacity development

"Alone we can do so little;
together we can do so much"
– Helen Keller

Thank you