EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Convergence through Regulatory Science – thinking Globally and Collaboratively

MHLW/PMDA Lecture Meeting celebrating International Strategic Plan

Tokyo, Japan– September 2015

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EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

Science, Medicines and Health are the cornerstones of our work

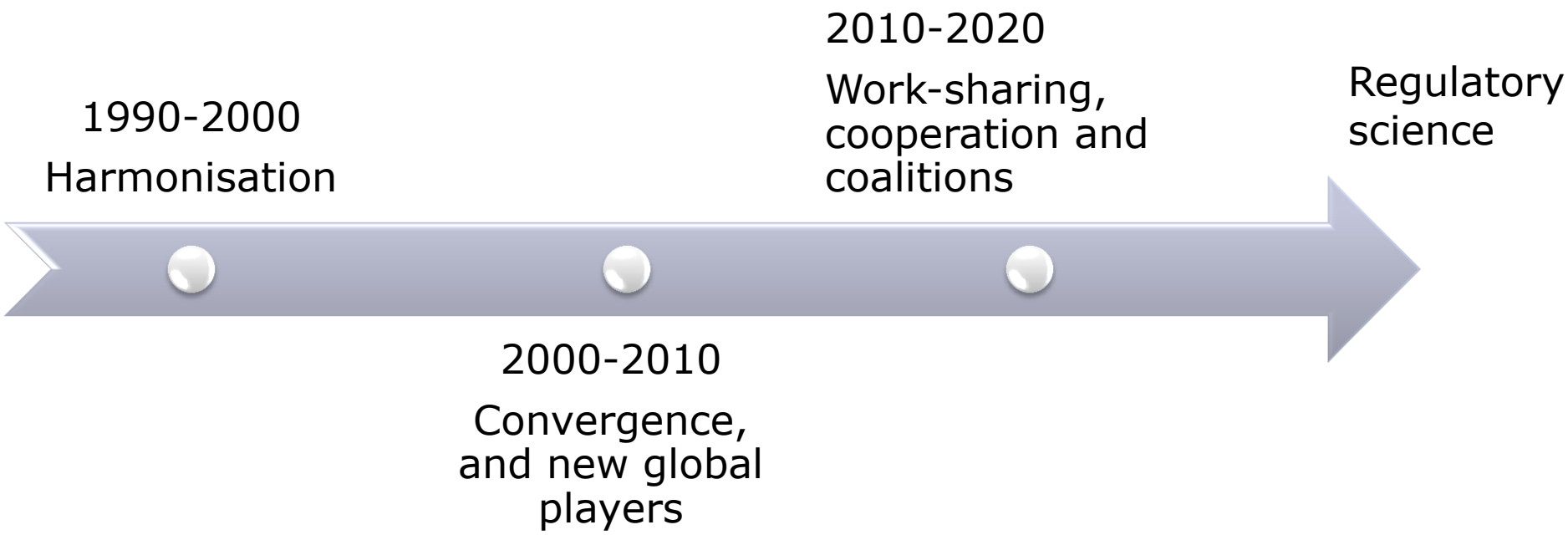
Why do we need to converge globally and collaboratively?

- Changing pharmaceutical environment due to **global** nature of medicine development and research :
  - Global movement of **clinical trials** and increasing use of MRCTs
  - Increasing complexity of **supply chains** and manufacture in multiple countries and regions – increasing risks of falsification, counterfeits, and concerns over data integrity
- Increasing needs for international **collaboration**, information/**knowledge** sharing and work sharing to achieve a global vision
- Emerging Science and new **opportunities** for patients
- New **challenges** for Health Systems

Why does it matter?

- Thinking Globally saves lives!
- Patients are precious
- Especially important in clinical trials for orphan medicines, paediatric development
- Using global resources more effectively helps the patient
- Collective thinking on Adverse Drug Reactions
- Regulatory science helps us to imagine the future together

Changing face of international collaboration



What are the public health challenges?

- Need to ensure **product quality** and **supply chain security**
- Need to ensure **data integrity** – can we rely on the data we get to support clinical trials/manufacture?
- How can we support a **global approach to authorisation and supervision** of medicines?
- How can we **avoid duplication** and help to create synergies?
- How can **global resources** be used more effectively?
- Multiplicity of initiatives and **lack of a strategic oversight**

The role of regulatory science?– Some definitions (2009)

- **Tatsuya Kondo (PMDA)**

  "Science of Estimation", specifically *"Regulatory Science estimates social impacts (benefit and risk) of scientific / technological progresses, and regulates and adjusts them for optimal social acceptance".*

http://www.cdisc.org/regulatory-science-japan

The role of regulatory science?– Some definitions (2009) (Cont.)

- **Margaret Hamburg (ex-US FDA)**

"We must also modernize our evaluation and approval processes to ensure that innovative products reach the patients who need them, when they need them. These new scientific tools, technologies, and approaches form the bridge to critical 21st century advances in public health. They form what we call *regulatory science: the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.*"

http://www.fda.gov/NewsEvents/Speeches/ucm191356.htm

The role of regulatory science?– Some definitions (Cont.)

- **Guido Rasi (EU EMA)**

"Regulatory science is defined as a range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision making throughout the lifecycle of a medicine.
It encompasses basic and applied medicinal science and social sciences, and contributes to the development of regulatory standards and tools."

http://emeaplus.corp.eudra.org/EMEAPlus_Documents/Planning_and_reporting/RoadMap/Road_map_to_2015.pdf

A better ICH, fit for the future

- **Governance and transparency:** Reinforce role of regulators and improve transparency and openness
- **International Outreach:** Increase the involvement of other regulators as well as global industry sectors affected by ICH guidelines
- **Funding:** identify an alternative funding model that would make ICH less dependent on industry funding
- **Legal entity:** set up ICH as a legal entity to take account of changed environment, more members etc.

Examples of successful convergence

- Single application form and annual report for **Orphan designations**
- Parallel **scientific advice**
- Common Commentary for **Paediatric** clinical trials
- Joint assessment pilot for **Quality By Design**
- EMA shares assessment reports for Orphan medicines with Australian TGA
- **Generic** medicines assessment pilot – HC, TGA, Swissmedic, Taiwan rely on EU assessments
- Enabling parallel submissions for **Drug Biomarker** or **Clinical Outcome Assessment Qualification** – Joint template agreed and published

What does convergence really mean?

- Convergence on standards/good practices?
- Convergence on assessments?
- Convergence on approaches to new science and technologies?

Convergence on standards/Good practices is essential

- Convergence on GMP ⇨ means we can rely on the conduct of manufacturing and its supervision anywhere in the world
- Convergence on GCP ⇨ means we can rely on the conduct of clinical trials and their supervision wherever they come from
- Convergence on GLP ⇨ means we can rely on the conduct of non-clinical studies and their supervision wherever they come from
- Convergence on standards for ADR reports ⇨ helps us exchange pharmacovigilance information, avoidance of duplication, best use of global resources

Must be based on international **standards** and mutual **trust**

Can we converge on assessment approaches?

- YES and NO
- Data set: ✔ based on CTD
- How to evaluate: ✔ based on harmonised criteria and good regulatory practices
- Benefit/risk decisions: **+/-** may depend on clinical practices/culture and other products on the market
- Lack of convergence of therapeutic guidelines is a problem

Regulatory Science is the evolution of convergence

Challenges:

- Stimulating innovation in clinical evaluation
- Supporting new approaches to improve product manufacturing and quality
- Ensuring Agency readiness to evaluate innovative emerging technologies

Possible Evolution

- A new assessment approach is needed addressing an evolving business model
- Harnessing new methods of generating evidence including real world data (big data!) to improve health outcomes

Regulatory Science is the evolution of convergence

Building together creates an easier framework for convergence!

Thank you for your attention

Further information

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