Opportunities for International Regulatory Cooperation

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What’s new?
- Implementing the EU Network strategy
- Involving emerging market regulators
- How can industry help?
- Conclusion
Opportunities for International Regulatory Cooperation – what’s new for IGBA?

- Network strategy to 2020 – specific globalisation theme - supported by EMA work programmes and HMA Multiannual Work Plan
- New confidentiality arrangements with SwissMedic and WHO
- ICH Reform – opening up to new partners
- IPRF WG on Biosimilars, ICMRA Generic group
- TTIP negotiations – progress on Mutual Recognition of Inspections with FDA, Biosimilars and Generics
- Increasing reliance on EU-Network outcomes - IGDRP, WHO Collaboration, Article 58, Other regulators

Network Strategy to 2020: Contributing to the global regulatory environment

- Assure product supply chain and data integrity
- Convergence of global standards and contribute to international fora
- Support training and capacity building and promote the EU regulatory model
- Ensure best use of resources through promoting mutual reliance & work sharing
Objective 1: Assure product supply chain and data integrity – Activities impacting on IGBA

- Exchange of GMP/GCP/BE/PVIG inspections information with FDA, PMDA, HC, WHO
- Communication and training activities on data integrity jointly with FDA
- Including local authorities as observers in GMP and GCP inspections – strengthen practices and mutual understanding – recent Bilaterals with Chinese and Indian authorities

Objective 2: Convergence of global standards and contribution to international forums - Activities impacting on IGBA

- Supporting ICH reform and involvement of new partners
- Biosimilar cluster (FDA, HC, PMDA) activities to align international approaches
- Co-chair of IPRF Biosimilars WG
Biosimilars Cluster

EMA/FDA cluster originally established in 2011

Meeting frequency: three times a year by teleconference

Health Canada and the PMDA joined in May 2013 and October 2014

Objectives:
- Alignment on scientific approaches to the evaluation of biosimilar medicines
  - Increase convergence
  - Data acceptable to all regulatory authorities
- Exchange of information on biosimilar guidelines in development
  - Avoid major divergences in requirements
- Facilitate interactions and discussion on product-specific issues

International Pharmaceutical Regulators Forum (IPRF) Biosimilars Working Group (BWG)

Established 2014: >30 members from 10+ countries and 3 international organizations: Co-Chairs: Korean MFDS/EMA

Objective: discuss and harmonize issues and challenges in terms of regulation of biosimilars

Deliverables:
- Convergence through transparency and information sharing (e.g. PASIB),
- Reflection paper on extrapolation of indications
- IPRF manual focused on quality assessment of mAbs
- Training
Objective 3: Ensure best use of resources promoting mutual reliance and work-sharing – What are we doing?

- Enhancing cooperation through confidentiality arrangements including on biosimilars and generic medicines
- Increasing global coverage of inspections through minimising duplications – MRA through TTIP
- IGDRP information sharing pilot
- Enhancing involvement of non-EU regulators in EU processes with a view towards future work-sharing (Article 58, collaboration with WHO, Ad hoc requests)

TTIP – Progress on Pharmaceuticals Update from 13th round

- Focus on GMP inspections: equivalence assessment, FDA observing EU audits, moving towards mutual recognition
- Exchange of confidential and trade secret information
- Biosimilars: convergence of authorisation approaches, international collaboration
- Generics: EU proposal on cooperation: engagement in IGDRP, Harmonisation of BCS biowaivers through ICH, harmonisation of requirements for complex generics

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Objective 4: Support training and capacity building and promote the EU regulatory model

- What are we doing?
  - Identifying training and capacity building priorities: Focus on China and India
  - Involving experts and observers from non-EU regulators in training, review and inspection activities
  - BE workshop October 2015, regular GCP inspectors training activities
  - Planned assessor training on Biosimilars end 2016 (open to EU and Non-EU regulators)

Involving emerging market regulators

ICH – now open to new regulators e.g. from China, India, Russia, Brazil, Korea, Singapore, Chinese Taipei, Mexico, Australia etc

IPRF Biosimilars Working Group chaired by Korean MFDS and EMA, currently involves Brazil (ANVISA), Chinese Taipei (TFDA), Korea (MFDS), Saudi Arabia (SFDA), Singapore (HSA) Mexico (COFEPRIS), the East African Community, PANDRH (Pan-American Network for Drug Regulatory Harmonization) and the World Health Organization (WHO)

ICMRA: Current members includes Brazil (ANVISA), China (CFDA), India (CDSCO), Korea (MFDS), Mexico (COFEPRIS), New Zealand (Medsafe), Nigeria (NAFDAC), Singapore (HSA), South Africa (MCC), with the World Health Organization (WHO) as an observer
Involving emerging market regulators (2)

IGDRP: ANVISA (Brazil), CFDA (China), European Commission (EC), COFEPRIS (Mexico), Roszdravnadzor (Russia), Health Canada, HSA (Singapore), MFDS (Korea), MHLW (Japan), MCC (South Africa), Swissmedic (Switzerland), TFDA (Taiwan), TGA (Australia), US FDA (USA), WHO (Observer), EDQM (Observer)

Article 58 – Scientific opinions for non-EU markets: involving WHO and non-EU regulators as experts and observers

Collaborative registration pilot with WHO – 11 African countries

Training activities – regular invites to EU training – 118 non-EU attendees in 2015

Regulators are converging and engaging together– what can/is industry do(ing)?

Raise awareness across companies of ongoing initiatives and understand limitations

Speak with one voice as far as possible

Promote concepts of reliance, convergence and risk based approaches

Promote a quality culture within organisations and across supply chains

Encourage information sharing – improve cooperation in non-competitive spaces

Identify challenges and constructive solutions
Conclusions and Future Trends

- Increasing international activities on worksharing, information sharing, mutual cooperation and efficiencies in Biosimilar and Generic areas

- EU Network Strategy promotes sharing outputs and involvement of non-EU regulators (IGDRP pilot, WHO collaborative registration pilot, Article 58, Mutual Recognition, other ad hoc mechanisms)

- Greater transparency also provide basis for convergence, recognition, reliance and resource savings – in the interest of patients worldwide

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Thank you for your attention

Further information

Contact the EMA International Affairs team at EMAInternational@ema.europa.eu.

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Biosimilars: Surfing the wave

80's: rDNA insulin

90's: Comparability guidelines

00's: EU + WHO Biosimilar guidelines

2016: Strong global interest in biosimilars
2016 – Global implementation

Major regions have developed and adopted guidelines to WHO standard (not all represented)

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Biosimilars – WHO international role

- ICDRA 2006
- Implementation meetings -
- 2015: SBP Guideline review

WHO guideline: very important tool to assist global convergence

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Biosimilars / Similar Biotherapeutic Products

Key learning during WHO implementation

- Biosimilar (SBP) ≠ Generic
  (not BE study or repeat of benefit / risk)
- Comparability v RBP
  (head to head required)
- Terminology important
  (e.g. not biogenerics)
- Quality is foundation of SBP
  (a key communication message)
- Biosimilarity: Stepwise approach
  (start with quality: Totality of Evidence)
- Experience has refined approach
  (efficient / science based data requirements)

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Additional effort required

(WHO Implementation)

Outcomes of more recent implementation workshops

- Increasing alignment between jurisdictions: noted importance of WHO in furthering standardized global approach, a convergence, but many challenges
- Most biotherapeutics in developing countries licensed by a stand alone approach with reduced data package rather than strict comparability exercise
- Some countries have regulatory pathway for “non- innovative biotherapeutic products" but requirements generally unclear
- Comparability studies with RBP: concept not well understood and used
- Lack of expertise and capacity for evaluation of biotherapeutics at NRA

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International Pharmaceutical Regulators Forum – Biosimilars Working Group (BWG)

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