Collaborative Registration Pilot Efforts – Learning and Applications to TB Drugs and Regimens

Perspective from European Medicines Agency

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Who do we work for?

- over 500 million people living in the European Union
- 28 member states
- 27% of global sales of medicines
- 24 official languages

1 Collaborative Registration Pilot Efforts – Learning and Applications to TB Drugs and Regimens
What do we do?

- Facilitate development and access to medicines
- Evaluate applications for marketing authorisation
- Monitor the safety of medicines across their life cycle
- Provide information on human and veterinary medicines to healthcare professionals and patients

Protect human and animal health
Who we are

~4000 Scientific experts from right across Europe

7 Scientific committees

1000 marketing authorisations recommended

1995 EMA established to evaluate medicines for use in the EU

28 Working parties

~840 Staff members
Focus on innovation - which medicines are approved through the centralised procedure?

- Human medicines for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune, and other immune dysfunctions, and viral diseases
- Medicines derived from biotechnology processes, such as genetic engineering
- Advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines
- Officially designated ‘orphan medicines’ (medicines used for rare human diseases)
How do we deal with globalisation?

Clinical trials

Need to ensure data integrity – can we rely on data we get from clinical trials?

Manufacturing

Need to ensure product quality and supply chain security
EU Medicines Agencies Network Strategy to 2020 – Heads of Medicines Agencies / EMA

- Identified 4 objectives under Global Regulatory Environment:
  - Assure product supply chain and data integrity
  - Convergence of global standards and contribution to international fora
  - Ensure best use of resources through promoting mutual reliance and work-sharing
  - Support training and capacity building and promote the EU regulatory model

- Approached through:
  - Closer working with international partners – bilateral and multi-lateral international cooperation
  - Training and capacity building initiatives
Cooperation initiatives

EU/EMA bilateral cooperation

- Confidentiality arrangements (CA)
  - US FDA, Health Canada, Japanese PMDA and MHLW, Australian TGA; Swissmedic; WHO

- Mutual recognition agreements (MRA)
  - GMP: Canada, Australia, New Zealand, Switzerland, Japan, Israel

Multilateral international cooperation – EMA / EU Regulatory Network

- International standardisation initiatives
  - ICH, VICH (Veterinary ICH), ISO, Codex Alimentarius, CIOMS, HL7, PIC/S

- International organisations, other regulators and stakeholders
  - WHO, OECD, World Organisation for Animal Health (OIE), Council of Europe
  - ICMRA, IPRF, IGDRP
EU model, training and capacity building

- Non-EU regulators look to the European approach as a model
  - Creation of an African Medicines Agency
  - The East African Community has developed a decentralised authorisation model for 5 African countries.
  - Latin and South America & ASEAN

- Build on existing approaches to training and capacity building for non-EU regulators in order to promote international best practices
  - GCP and Pharmacovigilance inspector training courses, ICH training and IPRF activities
Training opportunities

- Training is key part of the European system

- International partners regularly invited to workshops and training opportunities e.g. GMP, pharmacovigilance and GCP inspectors, PK/PD

- EU Network Training Centre launched 2015 (access for non-EU regulators planned for future)
Capacity building activities provided by EMA
Collaborative registration processes in practice

- ‘Article 58’ procedure
- WHO collaborative registration: EMA launched first pilot procedure in 2015 with 11 African countries
- International Generic Drug Regulatory Programme (IGDRP): pilot for sharing generics’ assessment reports begun in 2015
- Sharing full EMA assessment reports always possible with permission of company
The EU ‘Article 58’ procedure

- Introduced in 2004 as a tool to help to expand low and medium income countries (LMIC) access to new medicines and improve public health
- Supporting regulatory science and capacity building in non-EU countries
- Involvement of NRA experts and observers from ‘target’ countries and WHO
- Cooperation with WHO
- Scientific opinion on use outside the EU
- Same scientific standards
The ‘Article 58’ procedure: some more details

- Eligible products (but not limited to): Vaccines that could be used in the WHO Expanded Programme of Immunization, Vaccines against WHO public health priority diseases, Medicinal products to treat HIV/AIDS, Malaria, TB.
- Eligibility checked with WHO before acceptance of all applications
- Benefit-risk assessment in populations of target countries
- Eligible for scientific advice in early stage development
Review of Experience with ‘Article 58’

Strategic review commissioned 2015 with support of BMGF:

- Experts from NRAs consider involvement valuable in helping their local review and in building capabilities
- Few NRA experts involved, few procedures so far (8)
- Need to address impression of ‘double standard’ because no EU market approval
- Engage, promote and explain better to improve awareness at all levels in NRAs and other stakeholders
- Strengthen links with NRAs to facilitate local approvals
Other opportunities to engage with EMA

- Informal discussions (telecon or face-to-face)
- Business pipeline meetings
- Innovation Task Force
- Scientific Advice meetings
- Support for SMEs
- Pre-submission meetings
WHO Collaborative Registration Pilot (1)

- EMA agreed in 2014 to participate in the pilot to facilitate registration of Centrally Authorised Products in developing countries

- EMA assessment/inspection reports are exchanged with regulators in developing countries through the MAH/manufacturer

- EMA confirms in writing no objections to sharing
  - NRAs in African countries have access to detailed regulatory and scientific information
  - NRAs retain their regulatory responsibility
WHO Collaborative Registration Pilot (2)

EMA is so far the only “Stringent Regulatory Authority” (SRA) involved in the pilot

- Consistent with the EMA international strategy
- Potential for avoiding duplication of work
- Potential to facilitate and accelerate access to essential medicines
- A good example of practical application of the concept of “reliance”
WHO Collaborative Registration Pilot (3)

- First Centrally Authorised Product in the pilot: Intelence (etravirine)
- Pilot run in 11 African countries, reducing the expected registration time to between 3 and 11 months (down from 24 months) in 6 of the countries
  - Faster access to essential medicines already achieved in the initial phase
- 2 more products in the pipeline
- The pilot is open to Article 58 products
  - Potential for faster registration of products for unmet medical needs in developing countries
Conclusions and Future Trends (1)

- The EU regulatory system is based on mutual cooperation and efficiencies
- Transparency of outputs/evaluations provide basis for reliance and resource savings
- Increased sharing of outputs and involving non-EU regulators (Article 58, IGDRP pilot, collaborative registration pilot)
- Sharing experiences helps to meet challenges of globalisation
Conclusions and Future Trends (2)

- In the current global regulatory environment, EMA participation in collaborative registration process contributes to fast access to essential medicines in less resourced countries.
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