



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



International Affairs

International Cooperation



Why is international cooperation important?

- Ensure product quality and supply chain security.
- Ensure integrity of data used to support clinical trials and manufacturing.
- Encourage global approach to authorisation and supervision of medicines.
- Avoid unnecessary duplication of efforts and work more efficiently with our partners.
- Promote effective use of global regulatory resources.

Examples

EU-US Mutual Reliance Initiative on GMP inspection launched

Increasing collaboration with China and India

Reform of International Harmonisation Conference (ICH) governance and science

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Common FDA-EMA application form and annual report for orphan designation

International Generic Medicines Assessment pilot launched

International cooperation on approaches to Ebola treatment and prevention

International Coalition of Medicines Regulatory Authorities (ICMRA)

Our long-term goal - a truly global approach - will benefit patients both in Europe and throughout the world.

Background to EMA international activities

- 80% of all active pharmaceutical ingredients used in Europe come from other countries.
- Clinical trials take place in increasing number of different countries around the world.
- Manufacturing and clinical trial (GMP and GCP) inspection capacity is limited. There is a need to strengthen local capacity and to streamline foreign inspection activities to facilitate their use by multiple authorities.
- International cooperation is moving from strict harmonisation of technical requirements towards a more convergence-based approach, emphasising information and work-sharing through multilateral cooperation and coalitions.
- EMA has played an international role since its creation in 1995. This includes technical and scientific support to international organisations on issues related to the evaluation of medicinal products, international standardisation, (e.g. ICH and VICH), as well as collaboration with WHO on international pharmacovigilance.

Changing face of international collaboration

- **1990 – 2000:** Focus on harmonisation (EU, Japan, US), especially (V)ICH model.
- **2000 – 2010:** More global outreach, with new countries (Brazil, China, India, etc.) emerging

as global players. Convergence as well as harmonisation.

- **2010 – 2014 and beyond:** From information-sharing to work-sharing. From bilateral to multilateral cooperation. Idea of global coalitions – International Coalition of Medicines Regulatory Authorities (ICMRA).

Bilateral international activities

Most bilateral activities are carried out through confidentiality arrangements or mutual recognition agreements. The Agency and the European Commission work closely in all international activities.

Confidentiality arrangements facilitate exchange confidential information between regulators. They are frameworks for regulatory cooperation and exchange of information on guidance, legislation and non-public information on products, pharmacovigilance and inspection information. They can be trilateral with the European Commission or bilateral.

The Agency has arrangements with regulatory authorities in Australia, Canada, Japan and USA which allow for daily interactions on scientific matters. Much of this cooperation takes place through regular 'cluster' meetings.

Mutual recognition agreements (MRAs) on good manufacturing practice (GMP) allow EU authorities to rely on GMP inspections performed by other regulators, the waiving of batch testing of products on entry into the EU, and information sharing on inspection related information and quality defects. The EU has

MRAs in place with Australia, Canada, Japan, New Zealand and Switzerland and a similar agreement with Israel.

EMA also cooperates with the European Commission in the BRIC countries. Activities with China, India and Russia are through specific EU frameworks; contacts with Brazil are less formalised. Together with the European Commission, the Agency cooperates with a large number of other third country regulatory authorities.

Multi-partner international activities and multilateral frameworks

EMA cooperates with authorities from many countries within a variety of multilateral frameworks including ICH, VICH, IPRF, WHO, Council of Europe, OECD, Codex alimentarius, OIE and EFTA.

It also works alongside some Member States and European Commission in an international coalition of medicines regulatory authorities (ICMRA) to provide strategic oversight and streamline various international initiatives.

Capacity building activities are undertaken in the context of multi-country initiatives, for example, ASEAN, NEPAD, PAHO, WHO, etc and through inviting non-EU regulators to join selected EU training activities. There is significant interest in the experience of the EU regulatory model as the basis for other intra-regional regulatory cooperation.



Further information

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