EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA-HMA Network international initiatives on innovation

EuropaBio™
The European Association for Bioindustries

EMA-EuropaBio Information Day, 22 November 2016

Presented by Martin Harvey Allchurch
International Affairs, EMA

Disclaimer

Network Strategy to 2020: Contributing to the global regulatory environment

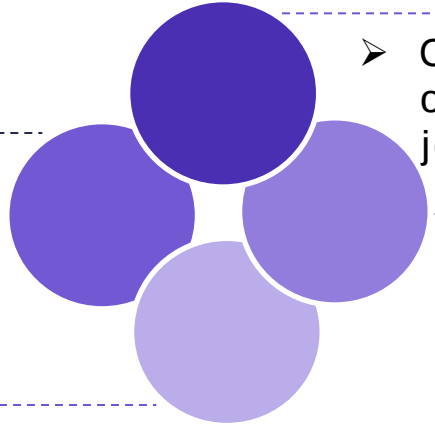
- Assure product supply chain and data integrity
- Convergence of global standards and contribute to international fora
- Support training and capacity building and promote the EU regulatory model
- Ensure best use of resources through promoting mutual reliance & work sharing

What are the public health imperatives?

- 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 and manufacturing?
- How can we support a **global approach to authorisation and supervision** of medicines?
- How can we **avoid duplication** and help create synergies?
- The 4Cs: **Communication, Collaboration, Cooperation, Coalitions**

Cooperation with international partners

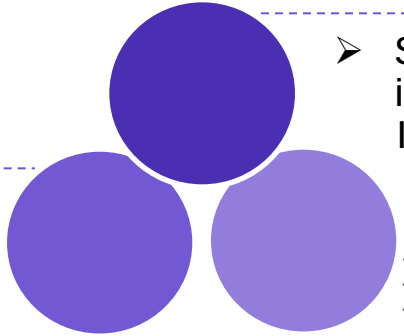
Objective 1: Assure product supply chain and data integrity - What are we doing?



- Exchange of GMP (H+V)/GCP/BE/PhV inspections information with FDA, PMDA, HC, WHO
- Communication and training activities on data integrity to be developed jointly with FDA
- Including local authorities as observers in inspections – strengthen practices and mutual understanding
- Contribution to ICMRA Track and Trace, APEC supply chain roadmap

Objective 2: Convergence of global standards and contribution to international forums - What are we doing?

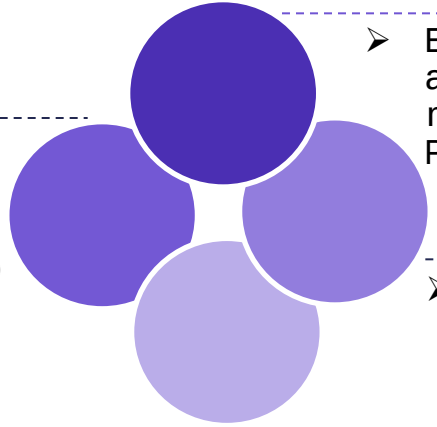
- Supporting ICH reform and involvement of new partners in ICH and VICH



- Bi- and multilateral cluster activities to align international approaches to development/ evaluation
- Implementing IDMP and Telematics strategy

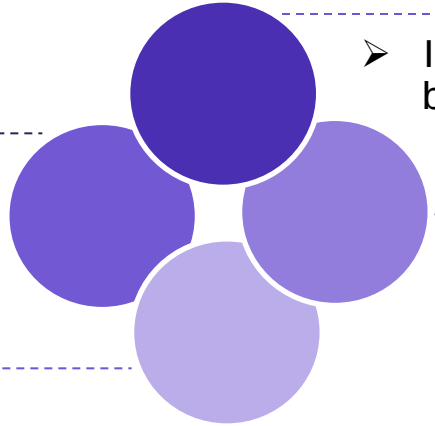
Objective 3: Ensure best use of resources promoting mutual reliance and work-sharing – What are we doing?

- Enhancing involvement of non-EU regulators in EU processes with a view towards future work-sharing (also included in CHMP work plan) (Article 58, IGDRP, Confidentiality arrangement partners, ad hoc requests)



- Enhancing cooperation through confidentiality arrangements in areas such as paediatric medicines, biosimilars, veterinary medicines, PRIME/Breakthrough/Sakigake
- Increasing global coverage of inspections through minimising duplications (ICMRA, TTIP, risk-based approach)
- Article 58 strategic review and action plan

Objective 4: Support training and capacity building and promote the EU regulatory model - What are we doing?



- Identifying training and capacity building priorities
- China and India: engagement and training
- Involving experts and observers from non-EU regulators in training review and inspection activities
- Areas of demand: biosimilars, GXP, assessment

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, etc
- EU Network Training Centre launched 2015 *(access for non-EU regulators planned for future)*
- Contributes to capacity building

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EMA collaborations with other regulatory authorities around the world

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International collaboration at EMA

- Activities with FDA, PMDA and WHO part of our daily work
- Almost every part of EMA involved in some way
- ~80% of all products going through EMA committees have some discussion at international level
- Growing interactions through multilateral ‘Clusters’
- 8-10 international calls per week
- Host 3-4 international visitors per month
- FDA and PMDA main partners, but other engagements growing
- New countries and regions emerging as important players, especially China, India, Brazil, Africa

Confidentiality agreement partners

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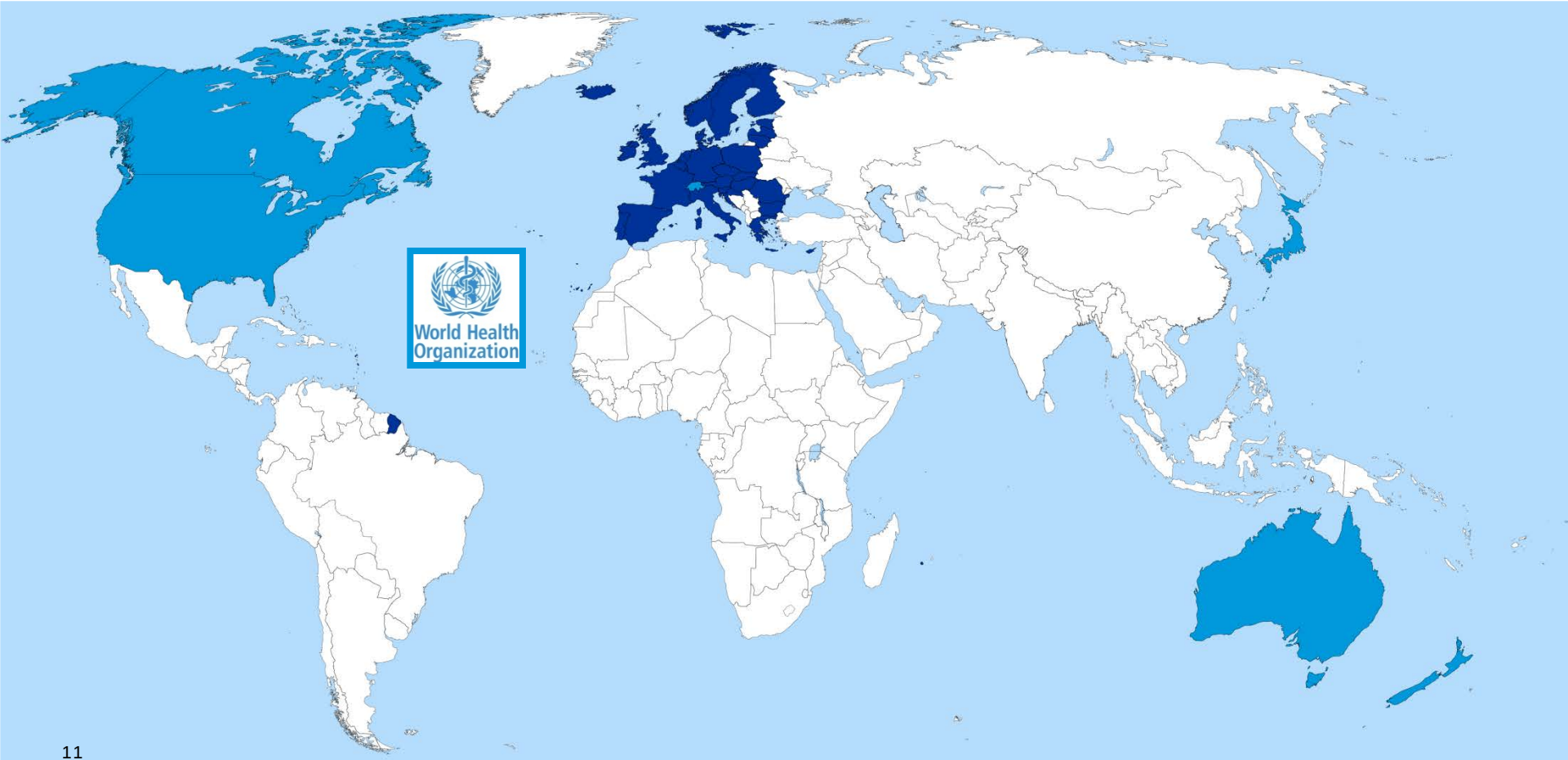

Mutual recognition agreement and ACAA* partners

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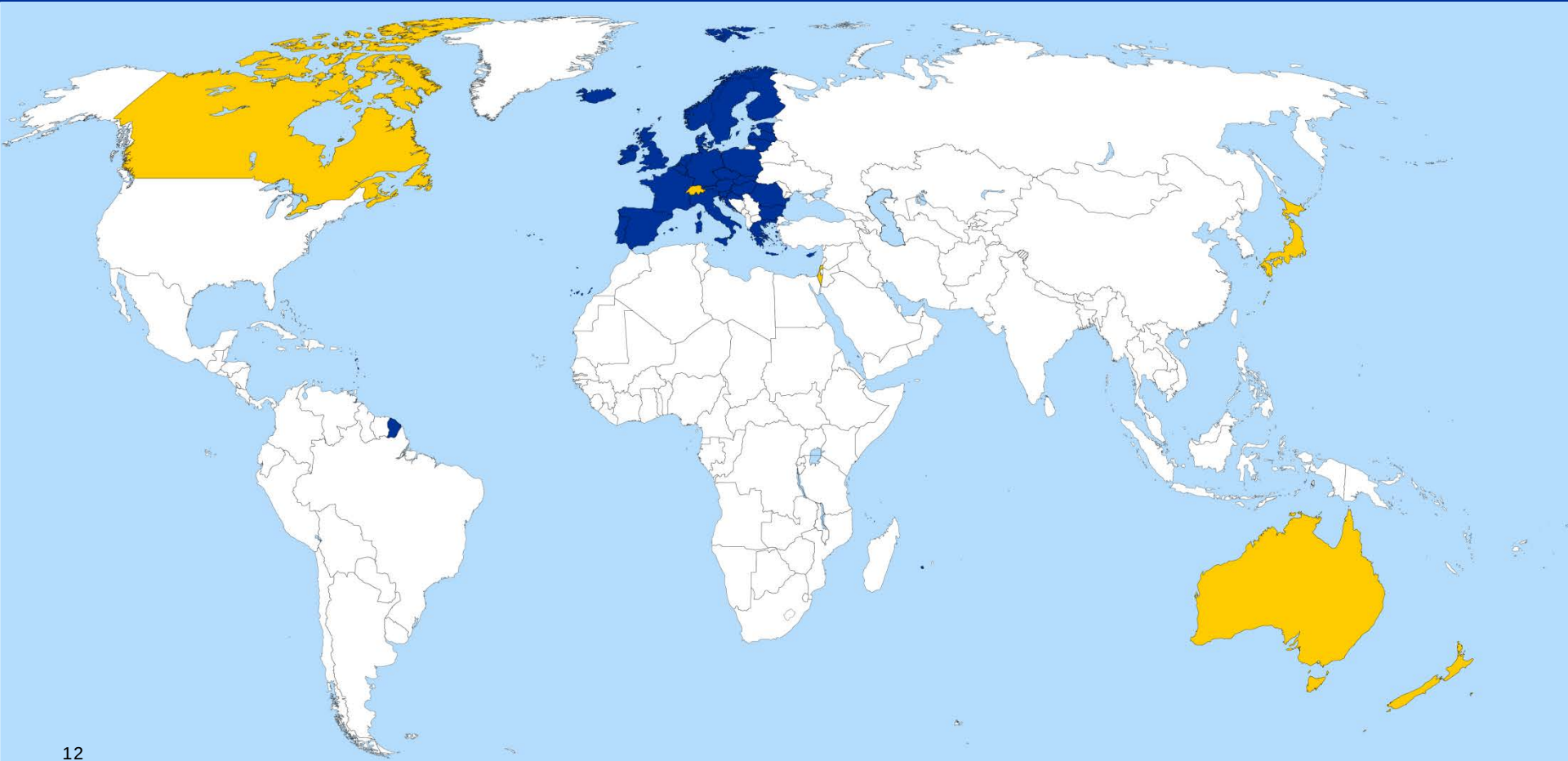

*ACAA: Agreement on Conformity Assessment and Acceptance of Industrial Products (Israel only)

Formal bilateral discussion partners

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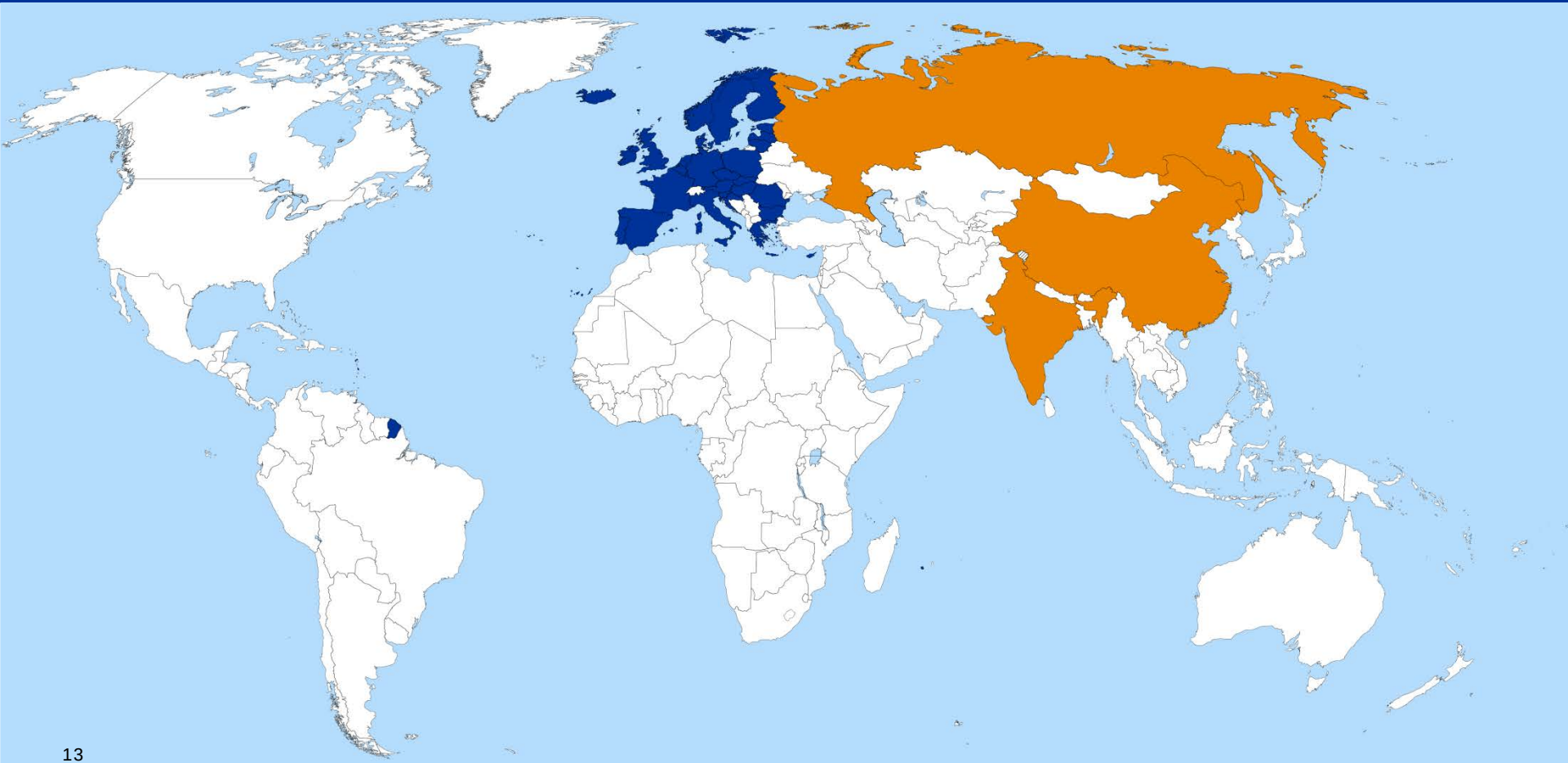

Global international engagement

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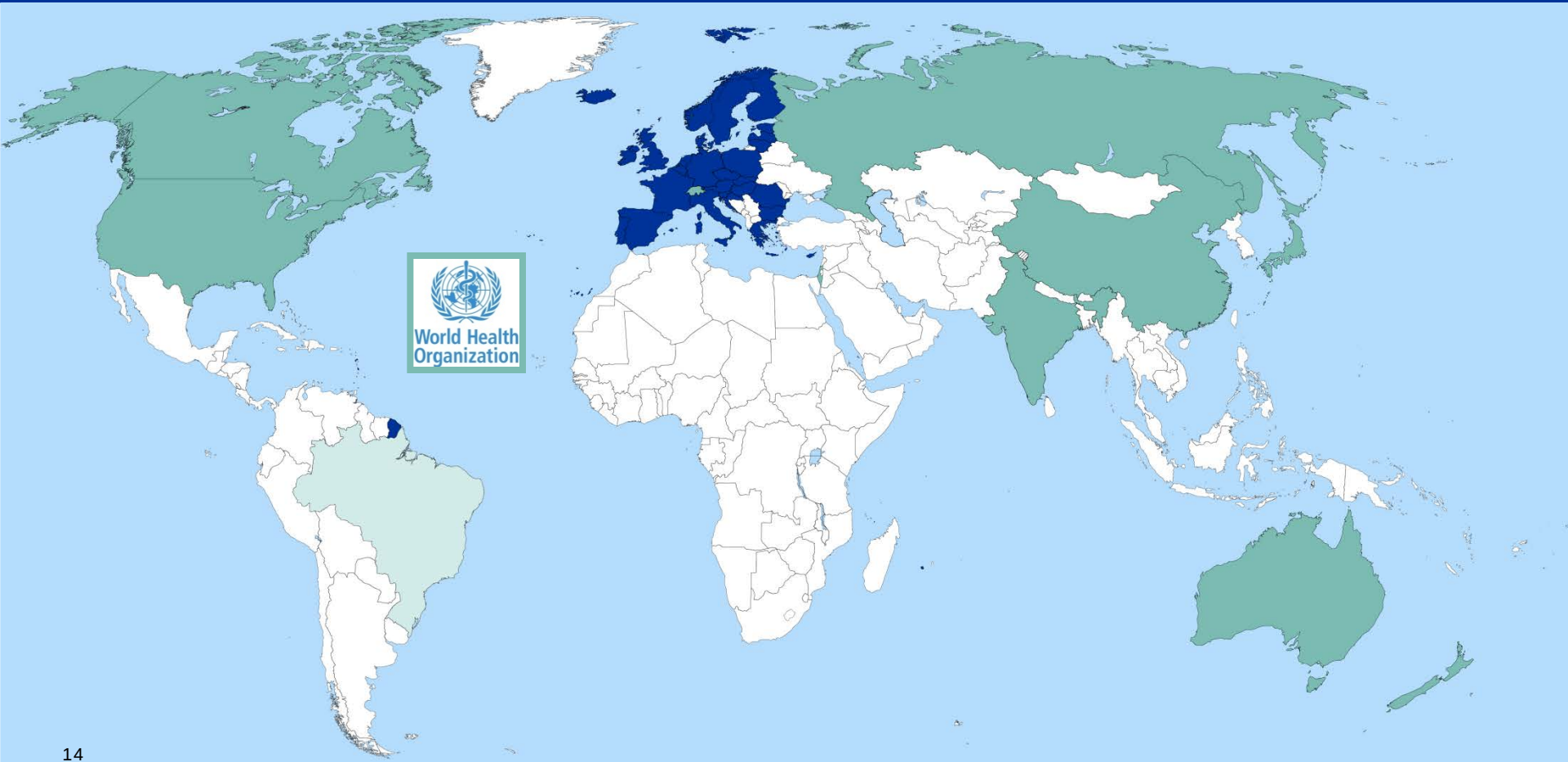
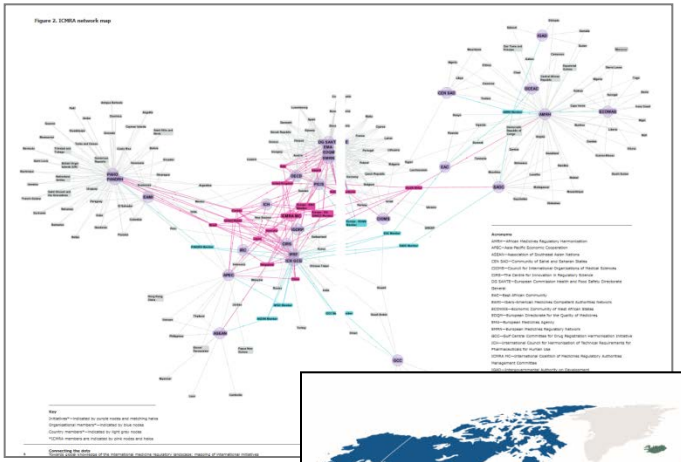
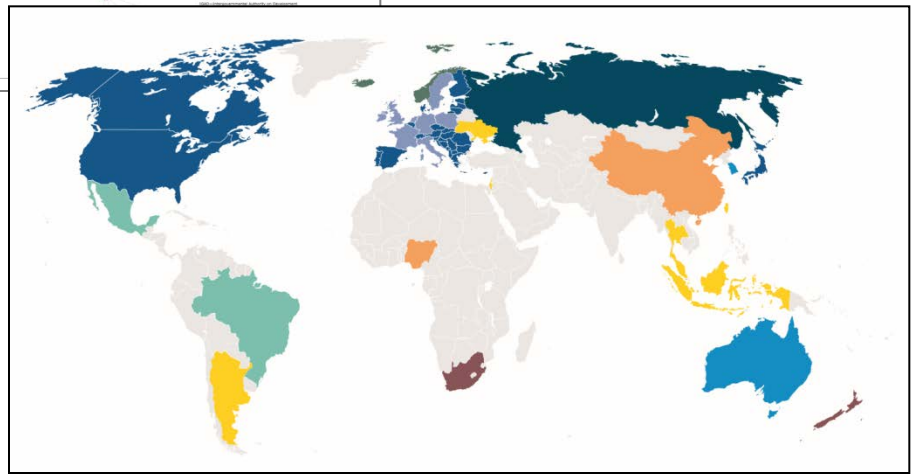
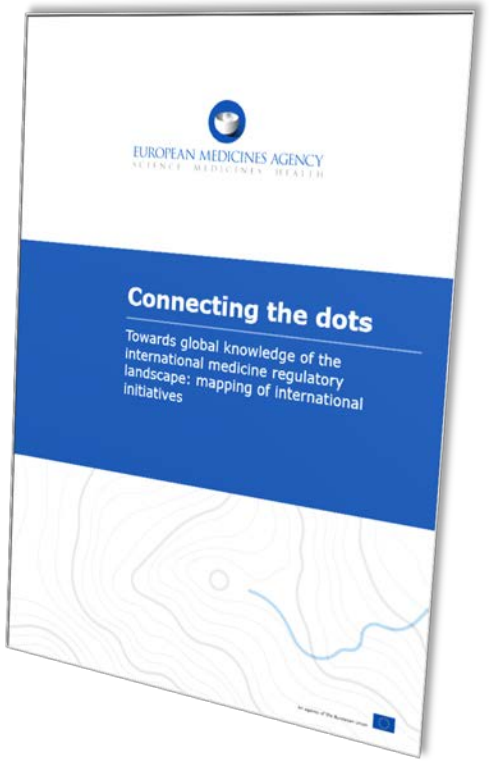


Connecting the dots: mapping initiatives







Examples of EMA engagement in multilateral and regional forums

- ICH International Council for Harmonisation
- IPRF International Pharmaceutical Regulators Forum
- ICMRA International Coalition of Medicines Regulatory Authorities
- PIC/S Pharmaceutical Inspection Convention/Cooperation Scheme
- EDCTP European & Developing Countries Clinical Trials Partnership
- IGDRP International Generic Drug Regulators Programme
- DCVRN, AVAREF, African Medicines Regulatory Harmonisation
- Others: EAC, ZaZiBoNa/SADC, APEC/ASEAN, Ibero-American regulators

EMA–World Health Organization engagement

- EMA-WHO confidentiality arrangement since September 2015
- Participation in regular and ad hoc WHO expert groups/committees such as:
  - SAGE, INN consultations, Global Vaccine Safety Initiative (GVSI), ICDRA
  - Biological standardisation and specifications for pharmaceutical preparations groups
  - WHO Strategic and Technical Advisory Group on antimicrobial resistance
  - Managing global stock-outs consultation
  - WHO vaccines/micro-needle patch development workshop
  - International Clinical trials Registry Platform

EMA–World Health Organization engagement

- Article 58 procedure for products intended for use outside EU
- WHO participates in EMA Vaccine Working Party, also API/GMP discussions, seasonal flu vaccine strain selection, etc.
- EMA handles some 4,000 requests each year for WHO CPP certificates (sets)
- Other examples of engagement include:
  - Scientific support for EUAL of Ebola vaccine
  - WHO regulatory system strengthening (EMA leads one of the working groups)
  - Joint Unicef, UNFPA & WHO meeting with manufacturers

Examples of multilateral forums

ICH

- Regulators and industry associations involved as Members/Observers
- Industry involved in guideline development and consultation
- Implementation at global level
- Formal process for industry engagement
- New topics can be proposed by industry Members
- 💻 www.ich.org

IPRF

- Regulators only, to identify need for convergence/harmonisation by members
- 4 working groups (+ 1 new one TBA): Biosimilars, Cell + Gene Therapy, Nano
- Reflection papers show direction of travel → consultation with stakeholders
- Concrete work products like Public Assessment Summary Information for Biosimilar (PASIB)
- 💻 www.i-p-r-f.org

ICMRA

- Regulators only forum, intended to give global strategic leadership for regulatory authorities working together to:
  - address current and emerging regulatory and safety challenges globally
  - provide direction for areas and activities
  - identify areas for potential synergies, and leverage existing initiatives and resources
- Current priority areas: crisis management, pharmacovigilance and supply chain integrity, with ongoing work on capacity building, GMP inspection, mapping
- Global membership: EC/EMA/some Member States, Russia, Switzerland; Brazil, Canada, Mexico, USA; China, India, Japan, Korea, Singapore; Nigeria, South Africa; Australia, New Zealand
- 💻 www.icmra.info

Promoting EU approaches and supporting convergence – some examples

- WHO collaborative registration: EMA launched first pilot procedure in 2015 with 11 African countries, fourth pilot now running (including an Article 58)
  - Preliminary outcomes: More rapid national approvals, with fewer questions raised
- IGDRP: pilot for sharing generics' assessment reports begun in 2015
  - Decentralised pilot began first, Centralised pilot launched in 2016, more experience needed
- Exchange of assessment reports under confidentiality arrangements
- Sharing full EMA assessment reports always possible with permission of applicant/marketing authorisation holder

Conclusions and future trends

- EU regulatory system based on work-sharing, mutual cooperation and efficiencies
- Transparency of outputs and evaluations provide basis for convergence, reliance and resource savings
- Increasing trend to share outputs and involve non-EU regulators (Article 58, IGDRP pilot, WHO collaborative registration pilot, ad hoc mechanisms)
- Sharing information helps to meet challenges of globalisation, both regionally and internationally

Thank you for your attention

Further information

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Glossary

- AMR: Antimicrobial Resistance
- ANVISA: Brazilian Health Surveillance Agency
- APEC: Asia-Pacific Economic Cooperation
- AU NEPAD: The New Partnership for Africa's Development
- AVAREF: African Vaccine Regulatory Forum
- BIO: Biotechnology Innovation Organization
- DIA: Drug Information Association
- DNDi: Drugs for Neglected Diseases initiative
- EAC: East African Countries
- EGA: European Generic Medicines Association
- GCP: Good Clinical Practice
- GHRT: Global Health Regulatory Team
- HC: Health Canada, Canada
- ICDRA: International Conference of Drug Regulatory Authorities
- ICH: International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
- ICMRA: International Coalition of Medicines Regulatory Authorities
- IDMP: Identification of Medicinal Products
- IGBA: International Generic and Biosimilar Medicines Association
- IGDRP: International Generic Drug Regulators Programme
- IPRF: International Pharmaceutical Regulators Forum
- MHLW: Ministry of Health, Labor and Welfare
- MRI: Mutual Reliance Initiative
- NAFDAC: National Agency for Food and Drug Administration and Control
- PhV: Pharmacovigilance
- PMDA: Pharmaceuticals and Medical Devices Agency, Japan
- Swissmedic: Swiss Agency for Therapeutic Products
- TGA: Therapeutic Goods Administration, Australia
- TTIP: Transatlantic Trade and Investment Partnership
- U.S. FDA: U.S. Food & Drug Administration
- WHO: World Health Organization
- ZaZiBoNa : Collaboration between national medicines regulatory authorities (NMRAs) in Botswana, Namibia, Zambia, and Zimbabwe