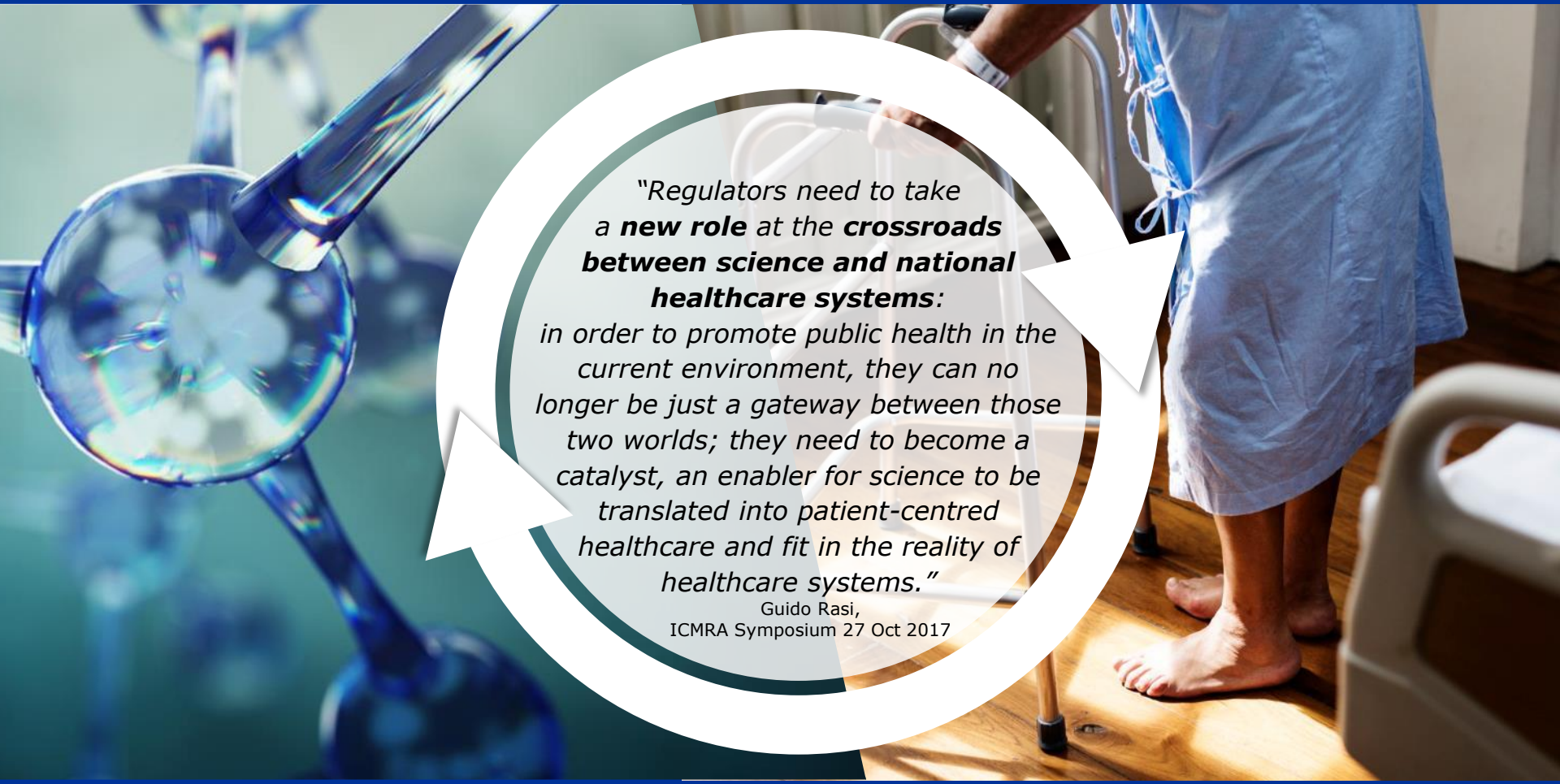
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The European Medicines Agency

Working to protect public health in the European Union

Presented by Ivana Silva on 29 May 2018
Public Engagement Department, Stakeholders and Communication Division

An agency of the European Union



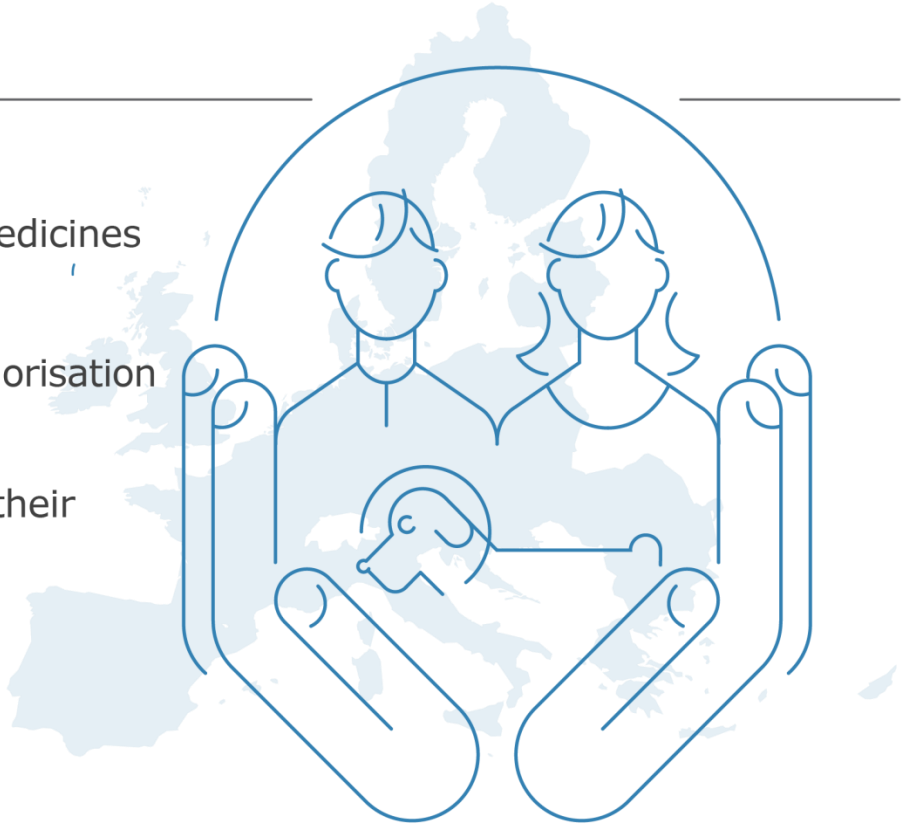
*"Regulators need to take a **new role** at the **crossroads between science and national healthcare systems**: in order to promote public health in the current environment, they can no longer be just a gateway between those two worlds; they need to become a catalyst, an enabler for science to be translated into patient-centred healthcare and fit in the reality of healthcare systems."*

Guido Rasi,
ICMRA Symposium 27 Oct 2017

What we do

Protect human and animal health

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



Who we are

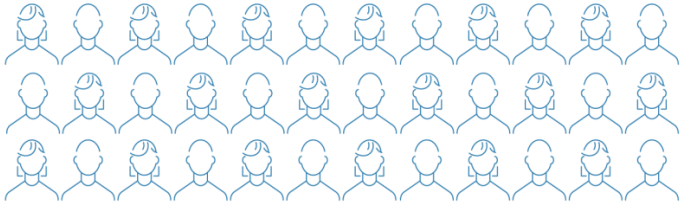
~4000 scientific experts from across Europe

7 Scientific Committees

- CHMP
- CVMP
- COMP
- HMPC
- PDCO
- CAT
- PRAC

1 Management Board

- **28** Member States' representatives
- **4** Civil society representatives
- **2** European Commission representatives
- **2** European Parliament representatives



1995 EMA established

28 working parties

~900 staff members

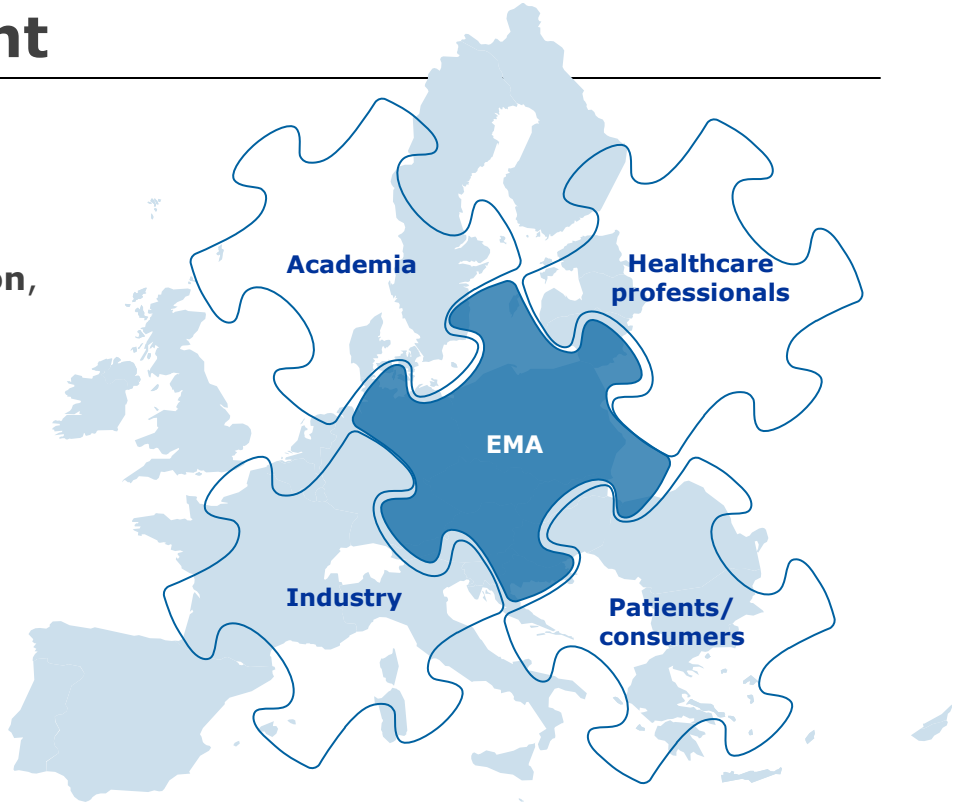
The European medicines regulatory network

- ~50 national regulatory authorities
- European Medicines Agency
- European Commission

European experts

EMA Stakeholder engagement

- Promote appropriate **engagement and dialogue**
- **Provide efficient, targeted and timely information**, in a proactive manner
- **Enhance stakeholders' understanding of the EU medicines Regulatory network** and enrich EMA's understanding of issues that are pertinent from the stakeholders' perspective
- **Increase transparency** on how EMA engages with stakeholders
- Structure stakeholder relations and **better support EMA's strategic priorities**



Promoting multi-stakeholder discussions

EMA Stakeholder engagement

Patients and healthcare professionals

Why?

- Experience of living with a disease and its treatment
- Reality of clinical practice

Who?

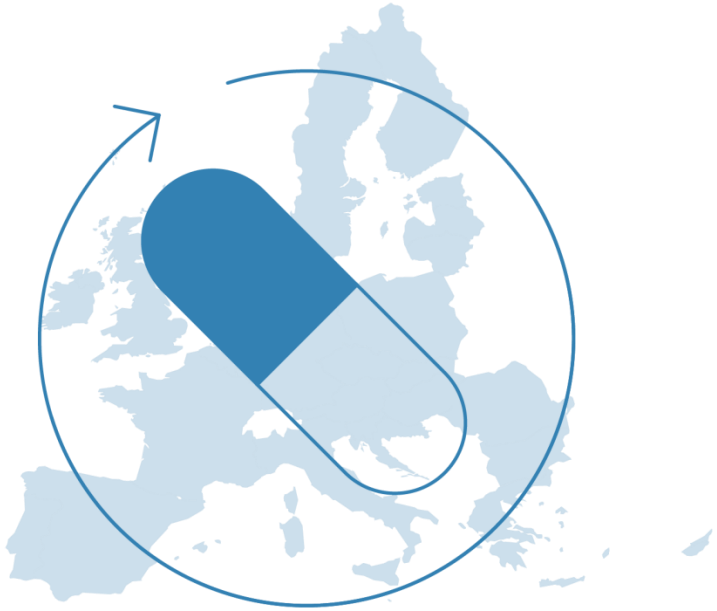
- European organisations, established representative groups
- Individual patients and healthcare professionals
- EC nominated members in scientific committees and management board

When? How?

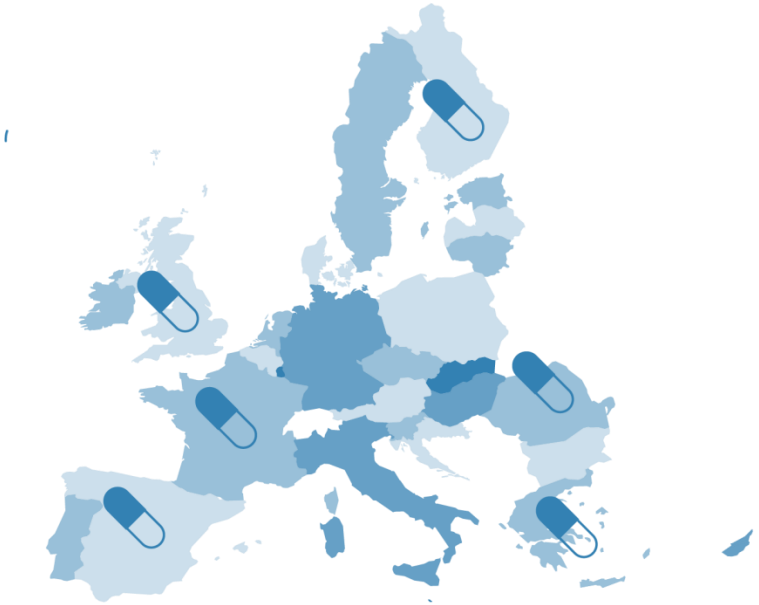
- All along the medicines regulatory lifecycle (committees, medicines evaluation..)
- Platforms for dialogue (PCWP and HCPWP)
- Workshops and public consultations on policies and guidelines

How are medicines approved?

Different authorisation routes: one set of common rules

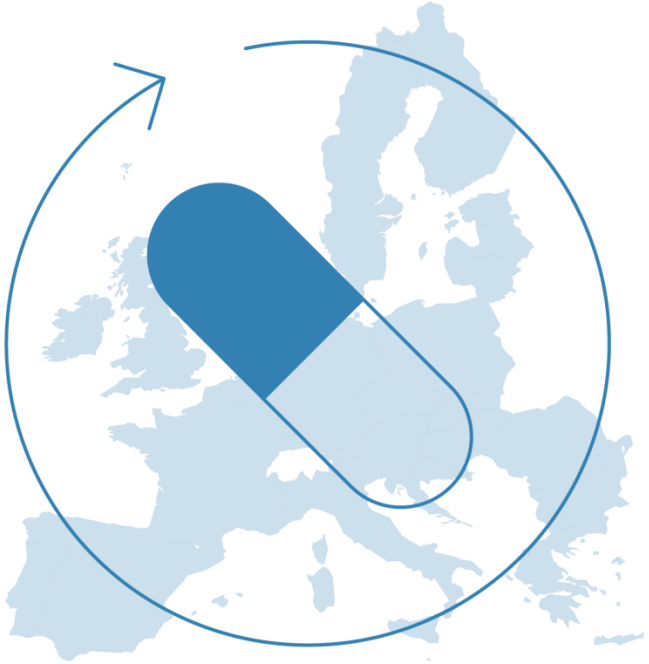


Centralised procedure (via EMA)



National procedures (via NCAs)

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)
- Veterinary medicines for use as growth or yield enhancers

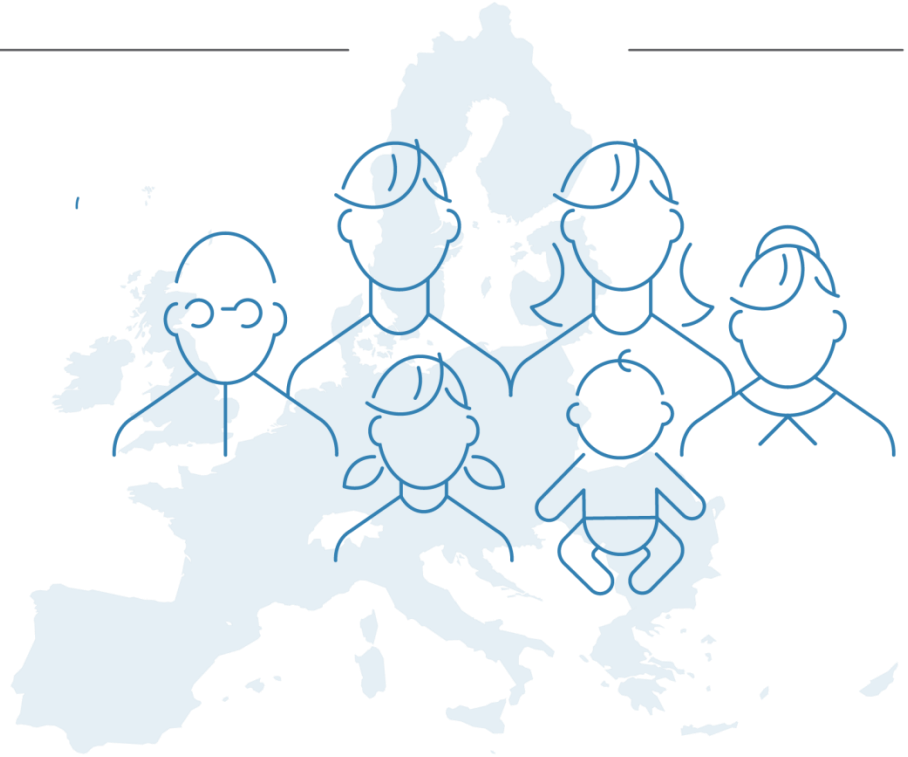
What is the benefit of the centralised procedure for EU citizens?

Medicines are authorised in all EU countries at the same time

Centralised safety monitoring

ABC
XΨΩ
Product information available in all EU languages at the same time

Access to the largest network of experts in medicines regulation



ERNs navigating the regulatory system

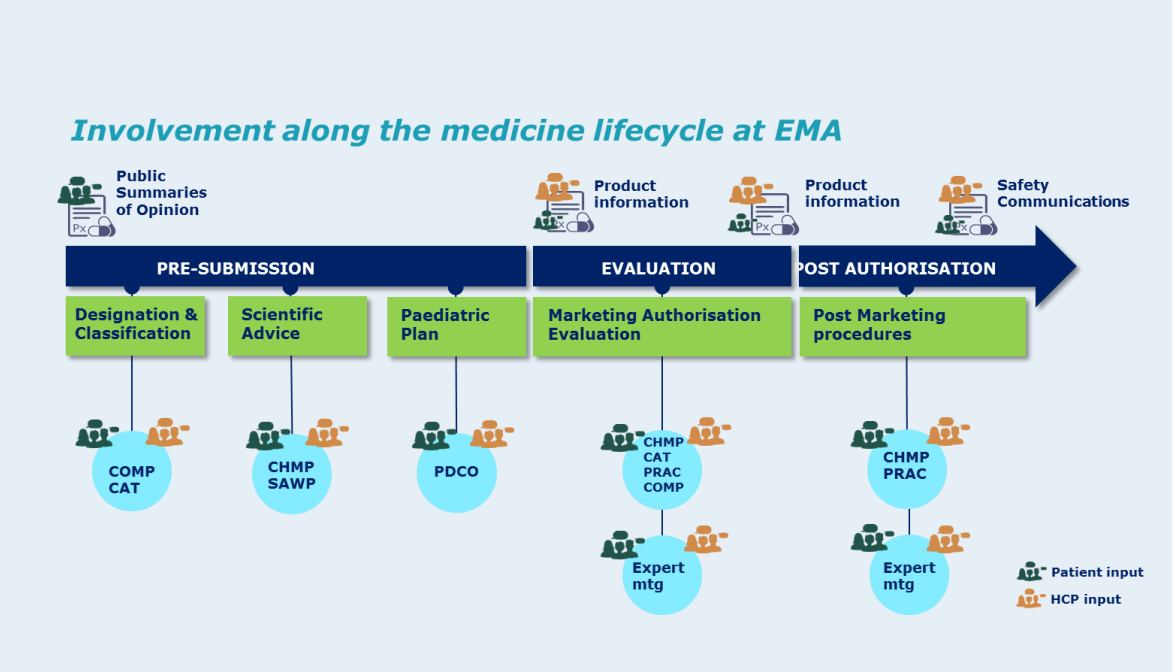
As users of the EU medicines regulatory system

- Users of published clinical data for secondary use in research
- Users of the Innovation Task Force
- Applicants for qualification of novel methodologies
- Applicants for orphan designation
- Applicants for ATMP classification
- Applicants for Scientific Advice/ Protocol Assistance
- Applicants for PRIME

Required or supporting components to a future marketing authorisation application

Bringing expertise into the EU medicines regulatory system

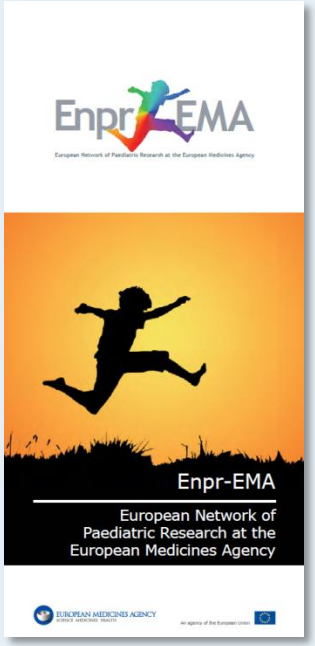
- Assessor / Expert
- Member of the Scientific Advice Working Party (SAWP)
- Member of a Scientific Committee (e.g. CHMP, COMP, CAT)
- Expert in a scientific advisory group (SAG) or ad hoc expert group



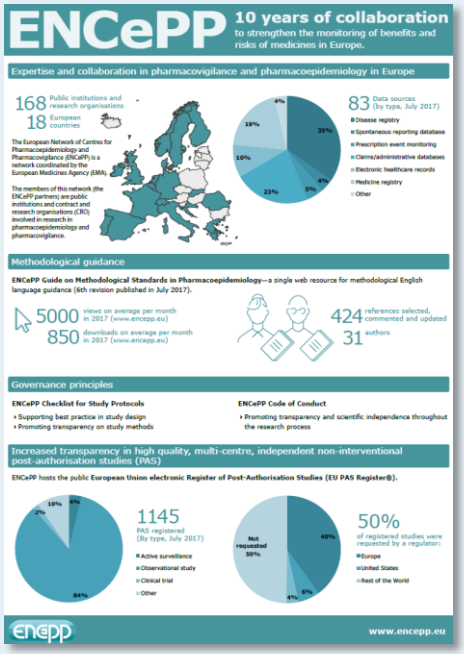
Generating data

Participating in EMA-supported research networks

European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)

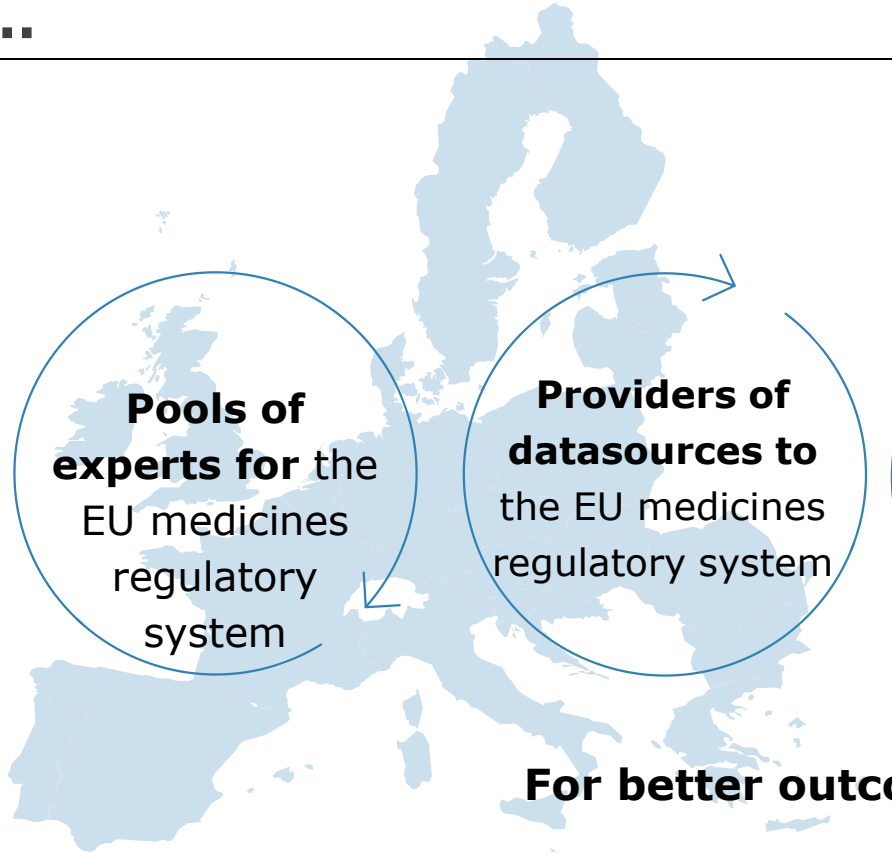


European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)



In conclusion…

ERNs add value as



Users of the EU medicines regulatory system

Pools of experts for the EU medicines regulatory system

Providers of datasources to the EU medicines regulatory system

Members of EMA networks

For better outcomes for patients

Thank you for your attention

Further information

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