EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Setting the Scene: Introduction to the EU Regulatory Network

The EU and the EU regulatory system for medicines

2nd International Awareness Session - The EU medicines regulatory system and the European Medicines Agency

Presented by Riccardo Luigetti on 8 March 2018
Principal International Affairs Officer

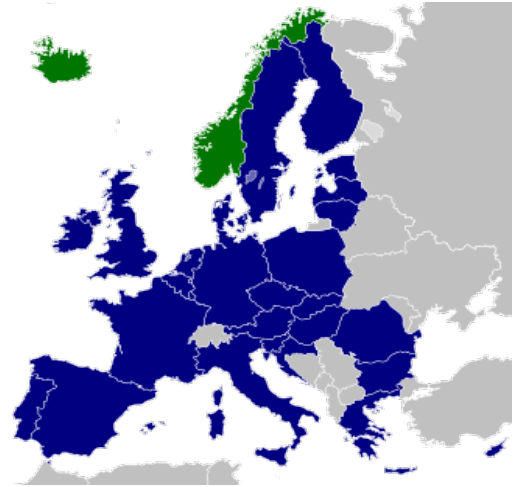
An agency of the European Union

The European Union (EU)

The EU is an union of 28 independent sovereign Member States located in Europe

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

The European Economic Area (EEA) is formed of the 28 EU Member States plus Island, Liechtenstein and Norway



The EU – Key Facts

Population: >500m

GDP: ~€ 13tn

Global sales of medicines: 27%

Official languages: 24

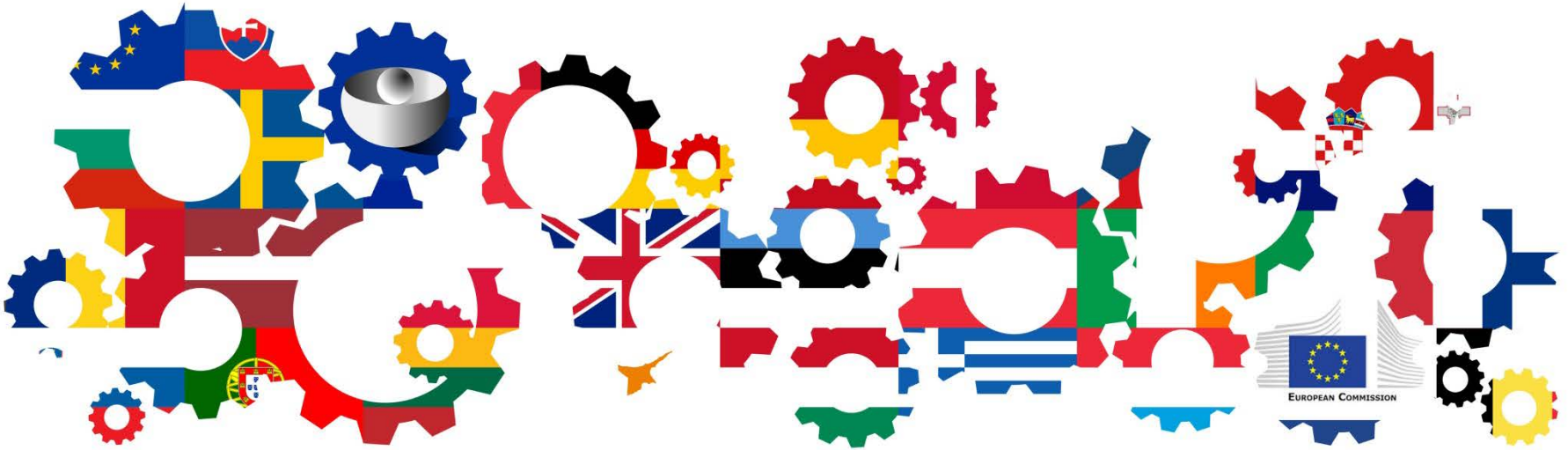
More Key Facts

The EU:

- Has developed a single market* through a standardised system of laws that apply to all its Member States
  - The same rules and procedures apply to all the 28 Member States (e.g. regarding authorisation and supervision of safety of medicines)
  - Accession to the EU means a commitment to apply the “acquis communautaire” (the body of legislation and guidance) to ensure that all EU Member States operate to the same standard

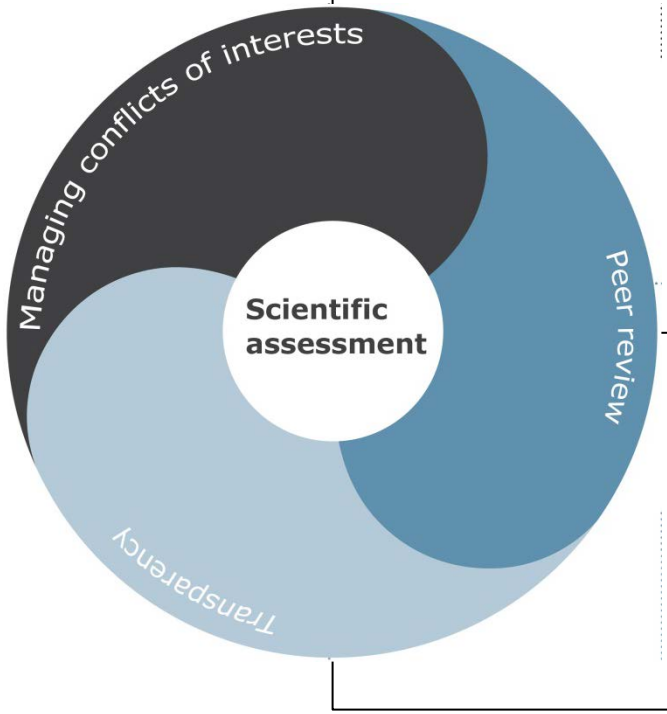
**The Single Market refers to the EU as one territory without any internal borders or other regulatory obstacles to the free movement of goods and services…. The EU single market is based on 4 fundamental freedoms: free movement of people, services, goods and capital (Treaty of Rome).*

The EU Regulatory Network for Medicines



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

A Fully Transparent System



EMA scientific experts, staff and Management Board members must not have any financial or other interest that could affect their impartiality

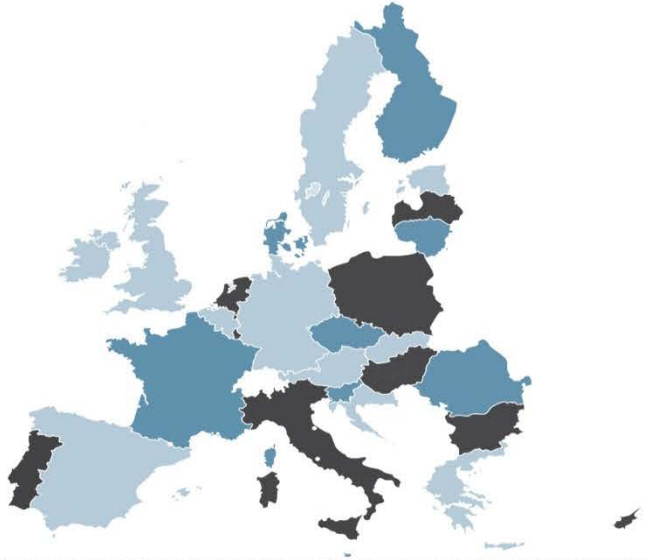
EMA assessments are carried out by a Rapporteur and a Co-rapporteur and are subject to committee discussion and peer review

EMA assessment reports are published, agendas and minutes are public and allow public scrutiny of how EMA works

Authorisation of Medicines in the EU

Different authorisation routes: one set of common rules

Centralised procedure (via EMA)



National procedures (via NCAs)

Centralised Procedure

- Single EU-wide Assessment and authorisation valid throughout the EU
- CHMP or CVMP carries out the assessment and EMA gives a recommendation to the European Commission on weather or not to grant a MA
- The MA is granted by the European Commission

The Centralised Procedure is mandatory for most innovative medicines and critical therapeutic areas

EMA enables one application, one assessment, one market authorisation for the whole of the EU

Centralised Procedure: Mandatory Scope

- 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)

Centralised Procedure: Optional Scope

New Active Substances

"Known" Substances

Significant Innovation:

- *Therapeutic*

&/or

- *Scientific*

&/or

- *Technical*

OR

Interest of patients at community level

National Procedures

- Decentralised procedure
  - Medicines not yet authorised in the EU that do not fall in the mandatory scope of the centralised procedure
  - Companies can apply to one or more Member States
- Mutual Recognition Procedure
  - Medicines already authorised in one or more EU Member States
  - Companies apply for recognition of the authorisation in other Member States
- Purely National Procedures

Many generics and medicines with "known" active substances are authorised by NCAs

Decentralised/Mutual Recognition Procedure

- A Reference Member State is identified which carries out the assessment on behalf of the Union
- The other Member States involved in the procedure (Concerned Member States) can object to the RMS assessment report
- If no agreement, the Coordination Group for Mutual Recognition and Decentralised Procedure – Human (Veterinary) (CMDh/v) considers points for disagreement
- If agreement at CMDh/v not possible, referral to CHMP (CVMP)

✓ The outcome of the CHMP (CVMP) referral is binding for all Member States

Conclusions

The EU regulatory system is complex, but one of the most advanced in the world

A single system: different authorisation routes: one set of common rules

The diversity of experts involved in the regulation of medicines in the EU encourages the exchange of knowledge, ideas and best practice between scientists striving for the highest standards for medicines regulation

By working closely together, Member States avoid duplication and share the workload

https://ec.europa.eu/health/documents/eudralex/vol-2_en

Thank you for your attention

Further information

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Setting the scene: Introduction to the EU Regulatory Network

The EMA role in the EU regulatory network

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Presented by Martin Harvey on 8 March 2018
Principal International Affairs Officer

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EMA in the EU

Who do we work for?

tervist salud
zdravie saúde saħħa gezondheid
veselība
sundhed υγεία
zdrowie
Gesundheit
terveys здраве
egészségügyi
santé zdravlje
zdravie
sveikata
health
zdravje hälsa
sláinte sănătate

over **500** million people living in the European Union

28 member states

27% of global sales of medicines

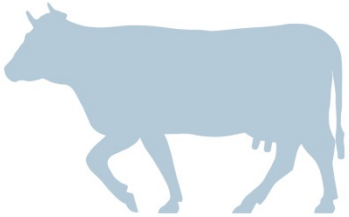
24 official languages

Who we are

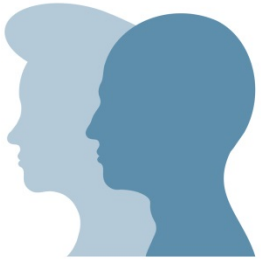
~4000 Scientific experts from right across Europe

7 Scientific committees

over 1000 marketing authorisations recommended



CHMP
CVMP
COMP
HMPC
PDCO
CAT
PRAC



1995 EMA established to evaluate medicines for use in the EU

28 Working parties

~890 Staff members

How is EMA organised?

Management Board

Executive Director

EMA staff

CHMP | **CVMP** | **COMP** | **HMPC** | **PDCO** | **CAT** | **PRAC**

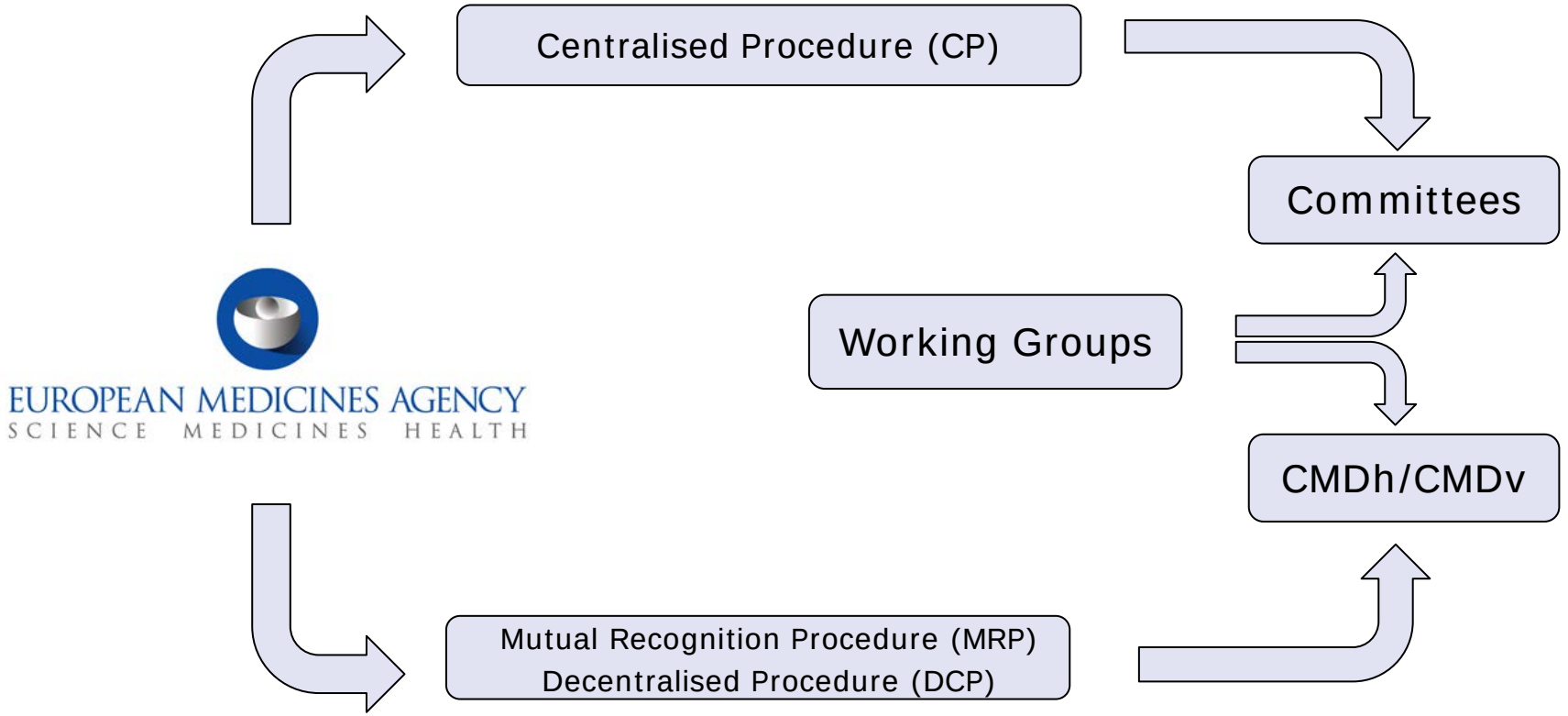
+ 28 working parties
+ 8 scientific advisory groups

National competent authorities
~4000 European experts

EU institutions

European Commission

European Parliament


Centralised Procedure (CP)
Committees
Working Groups
CMDh/CMDv
Mutual Recognition Procedure (MRP)
Decentralised Procedure (DCP)
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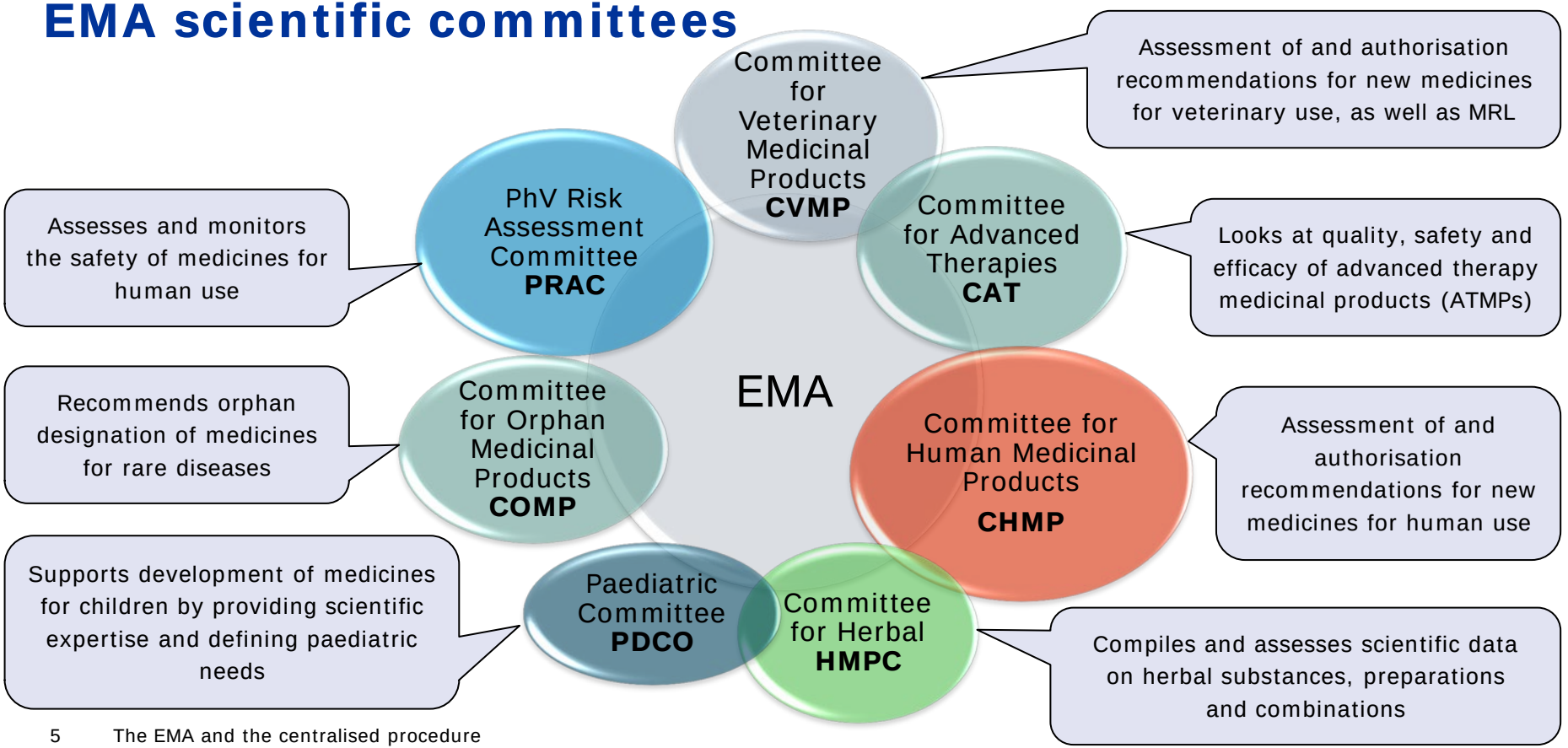
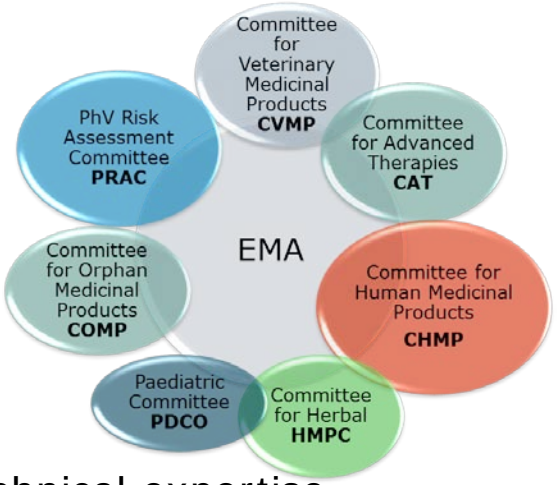
EMA scientific committees



Committee membership



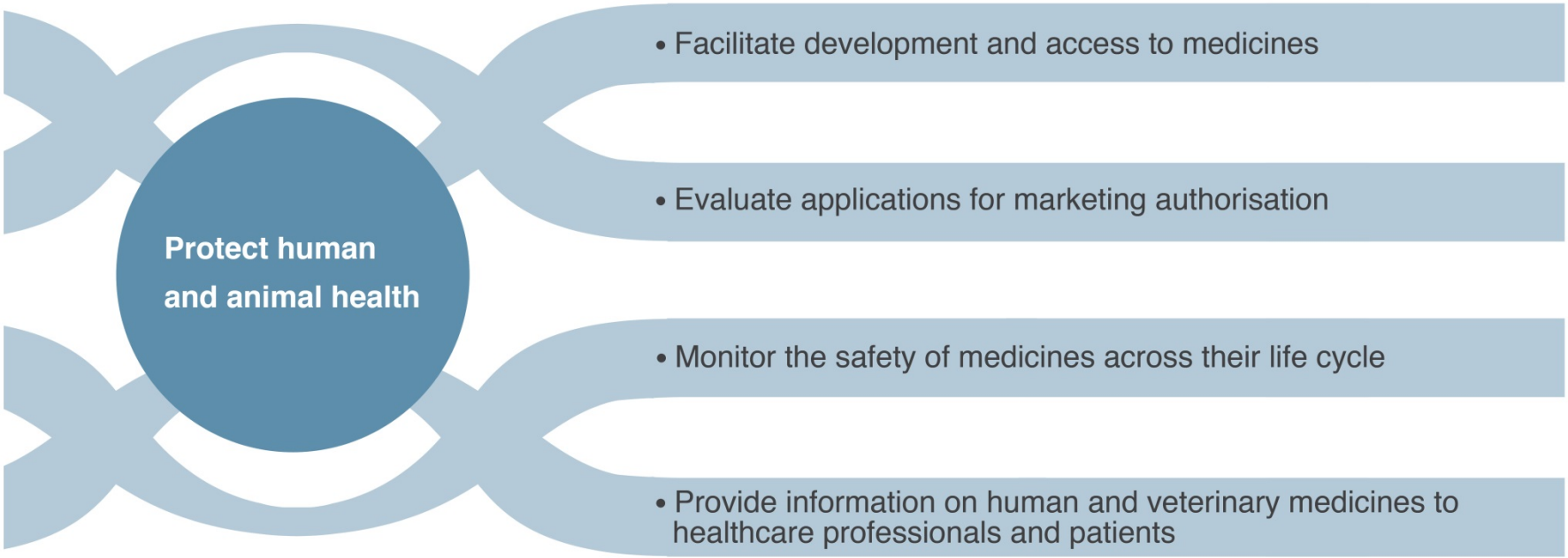
Seven EMA committees, with different roles and compositions:

- 1 member + 1 alternate nominated by each Member State
- 1 member + 1 alternate from Iceland and Norway
- Some have additional members with specific scientific or technical expertise
- Patients and healthcare professionals full members in 4 out of 7 committees
- Elected Chair and Vice-Chair
- All members have 3 year renewable mandate
- Assessments are prepared by Rapporteurs and Co-Rapporteurs, with peer review

European experts

- Over 4,000 experts contribute to the EMA work as members of committees, WGs and assessors
- Bring diversity, exchange of knowledge and best practice from across EEA striving for the highest scientific standards
- Pool expertise, especially in areas of rare or limited scientific knowledge
- Mainly from national regulators, but also academia, patient representatives and healthcare professionals
- All experts make annual public declaration of interest, EMA manages any competing interests to ensure impartiality and integrity of outcome

What do 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 information on human and veterinary medicines to healthcare professionals and patients

Development and access to medicines

- EMA is committed to enabling **timely patient access** to new medicines, and plays a vital role in supporting medicine development for the benefit of patients
- EMA prepares **scientific guidelines** on requirements for the quality, safety and efficacy testing of medicines, reflecting the latest thinking on developments in biomedical science
- EMA provides product-specific **scientific advice** through the Scientific Advice Working Party
- EMA supports **research and innovation** in the pharmaceutical sector, and promotes innovation and development of new medicines by European micro-, small- and medium-sized enterprises

Evaluation of medicines

- EMA **scientific committees** provide independent recommendations on medicines for human and veterinary use, based on a comprehensive scientific evaluation of data.
- **EU experts** participate in the work of EMA as members of its scientific committees, working parties, scientific advisory groups, or as members of the national assessments teams that evaluate medicines.
- Increasingly, **patients and healthcare professionals** (HCP) are involved in the work of the Agency including evaluation of medicines.
- By **working together**, Member States reduce duplication, share the workload and ensure an efficient and effective regulation of medicines across the EU.

Safety monitoring of medicines

- EMA continuously monitors and supervises the safety of medicines that have been authorised in the EU, to ensure that their benefits outweigh their risks.
- The **Pharmacovigilance Risk Assessment Committee (PRAC)** of EMA is dedicated to the safety of medicines.
- EMA coordinates the **EU pharmacovigilance system** and operates services and processes to support pharmacovigilance in the EU.
- EMA operates **EudraVigilance**, an EU web-based information system that collects, manages and analyses report of suspected side effects of medicines.
- **Public hearings** are now a tool available during EU safety reviews of medicines.

Thank you for your attention

Further information

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