EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The PRAC – Pharmacovigilance Risk Assessment Committee

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New Pharmacovigilance Risk Assessment Committee PRAC

The Mandate shall cover…

All aspects of the risk management of the use of medicinal products including the **detection, assessment, minimisation and communication relating to the risk** of adverse reactions, having due regard to the therapeutic effect of the medicinal product, the design and evaluation of post-authorisation safety studies and pharmacovigilance audit

Pharmacovigilance Risk Assessment Committee

Responsibilities:

The Pharmacovigilance Risk Assessment Committee shall be responsible for providing recommendations to the **Committee for Medicinal Products for Human Use** and the **Coordination group** on **any question relating to pharmacovigilance activities** with respect to medicinal products for human use and on **risk management systems** and it shall be responsible for **monitoring the effectiveness of these systems**

Pharmacovigilance Risk Assessment Committee

Responsibilities:

For the fulfillment of it's pharmacovigilance tasks, **approving risk management systems and monitoring their effectiveness**, the CHMP and coordination group shall rely on the scientific assessment and the recommendations of the Pharmacovigilance Risk Assessment Committee.

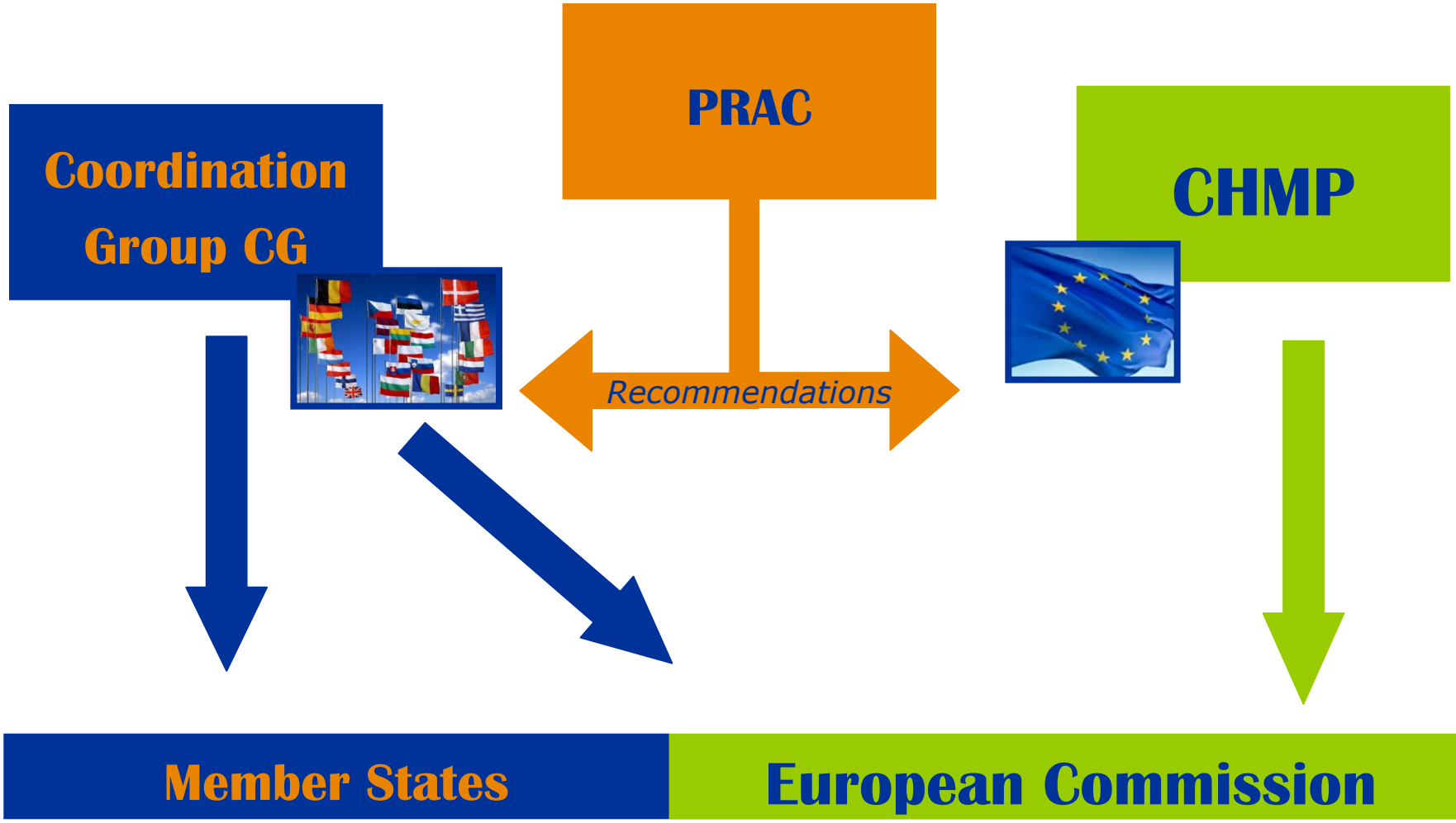
Identified PRAC Activities (1/2)

Activity	Involvement
Risk Management Systems	Agreement on RMPs + monitoring their effectiveness
Periodic Safety Update Reports PSURs	List of harmonised submission frequencies and substances, assessment + recommendation
Eudravigilance + Periodic Safety Update Reports repository	Functional specifications, any substantial changes
Medicines subject to additional monitoring	Addition to/removal from list, extension of timeframe, symbol
Signal Detection	Initial analysis + prioritisation assessment + recommendations

Identified PRAC Activities (2/2)

Activity	Involvement
Urgent Safety Procedures for the EU	Assessment, public hearings, recommendations
Post Authorisation Safety Studies	Consultations on requests (pre and post MA), assessment of protocols (incl. amendments) + recommendations, assessment of results + recommendations
Literature Adverse Drug Reactions monitoring	Consultation on list of active substances and medical literature subject to monitoring?
Safety announcements	Advice

PRAC and the other Groups/Committees



Role of PRAC in decision-making pro

When at least one centrally authorised medicine is involved

Assessment report by a rapporteur appointed by PRAC

PRAC: adoption and recommendations

CHMP: opinion on regulatory action, based on PRAC recommendations

CHMP≠PRAC

Written explanation together with a decision

Decision transmitted to **EC**

Role of PRAC in decision-making process

Only nationally authorised medicine are involved

Assessment report by rapporteur

PRAC: Adoption and recommendations

CG: Opinion on regulatory action, based on PRAC recommendations

GC= PRAC	***Consensus***	*GC≠PRAC*	***No Consensus,*** *majority position*	*GC= PRAC*
Agreement sent to Member States	Written explanation annexed	Written explanation annexed		Position transmitted to EC

PRAC membership

Appointed by each Member State:

- 1 member + alternate
- 27 + EEA countries non voting members

Appointed by the European Commission following a public call for expressions of interest:

- 1 patient organisations[1] rep + alternate
- 1 healthcare professionals[1] rep + alternate
- 6 members to ensure relevant expertise available

[1] *Criteria for involvement in EMA activities*

PRAC membership – key points

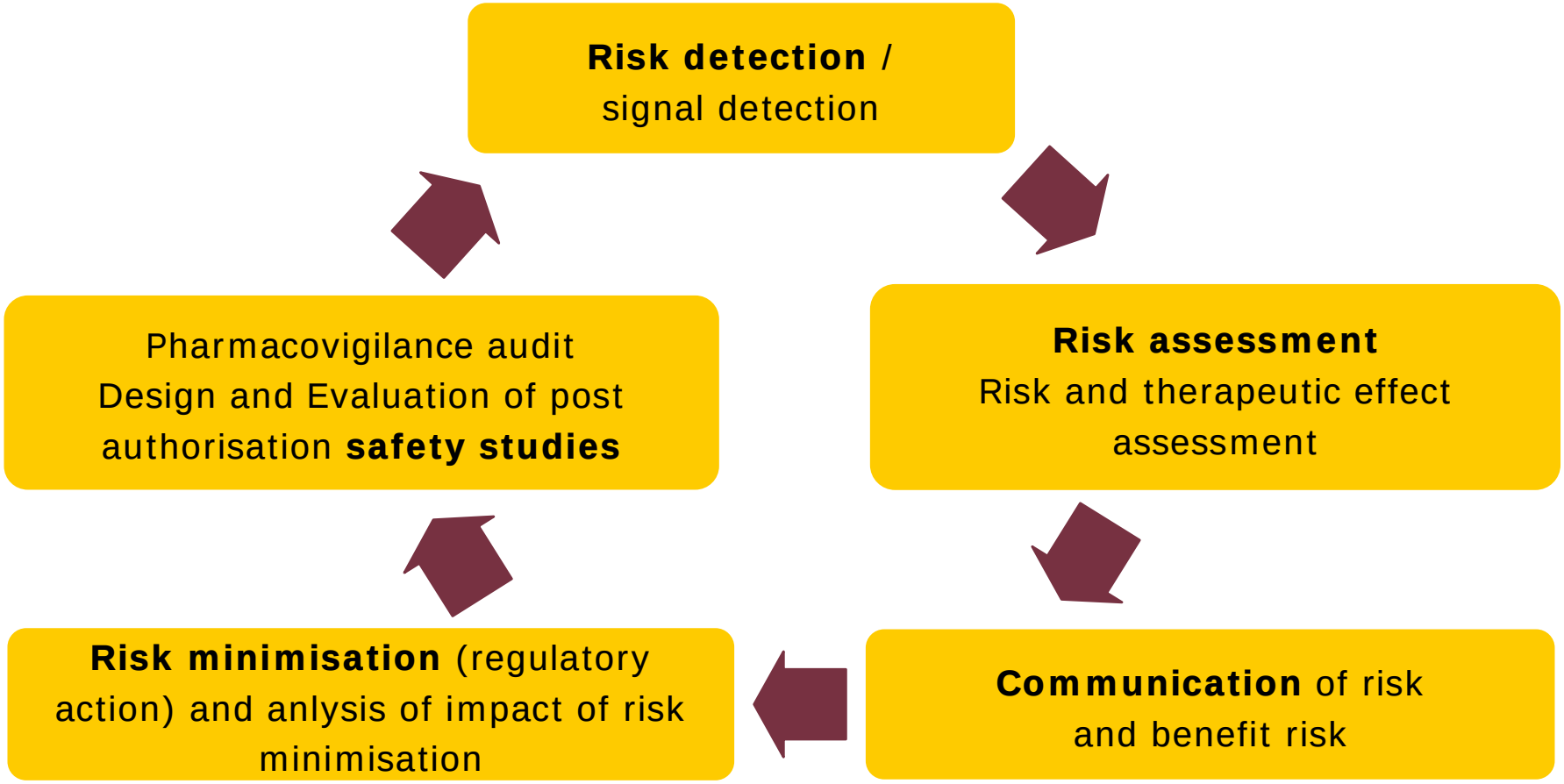
- A Member State may delegate its tasks in the Pharmacovigilance Risk Assessment Committee to another Member State - *guidance*
- Members appointed for 3-year term, which may be prolonged once and thereafter renewed - *guidance*
- Chairman – 3-year term, which may be prolonged once
- Member States shall liaise with the Management Board and the Commission in order to ensure that the final composition of the Committee covers the scientific areas relevant to its tasks - *guidance*

Pharmacovigilance Risk Assessment Committee

Appointment of Members

The members and alternate members of the Pharmacovigilance Risk Assessment Committee shall be appointed on the basis of their **relevant expertise in pharmacovigilance matters and risk assessment** of medicinal products for human use, in order to guarantee the highest levels of **specialist qualifications** and a **broad spectrum of relevant expertise**

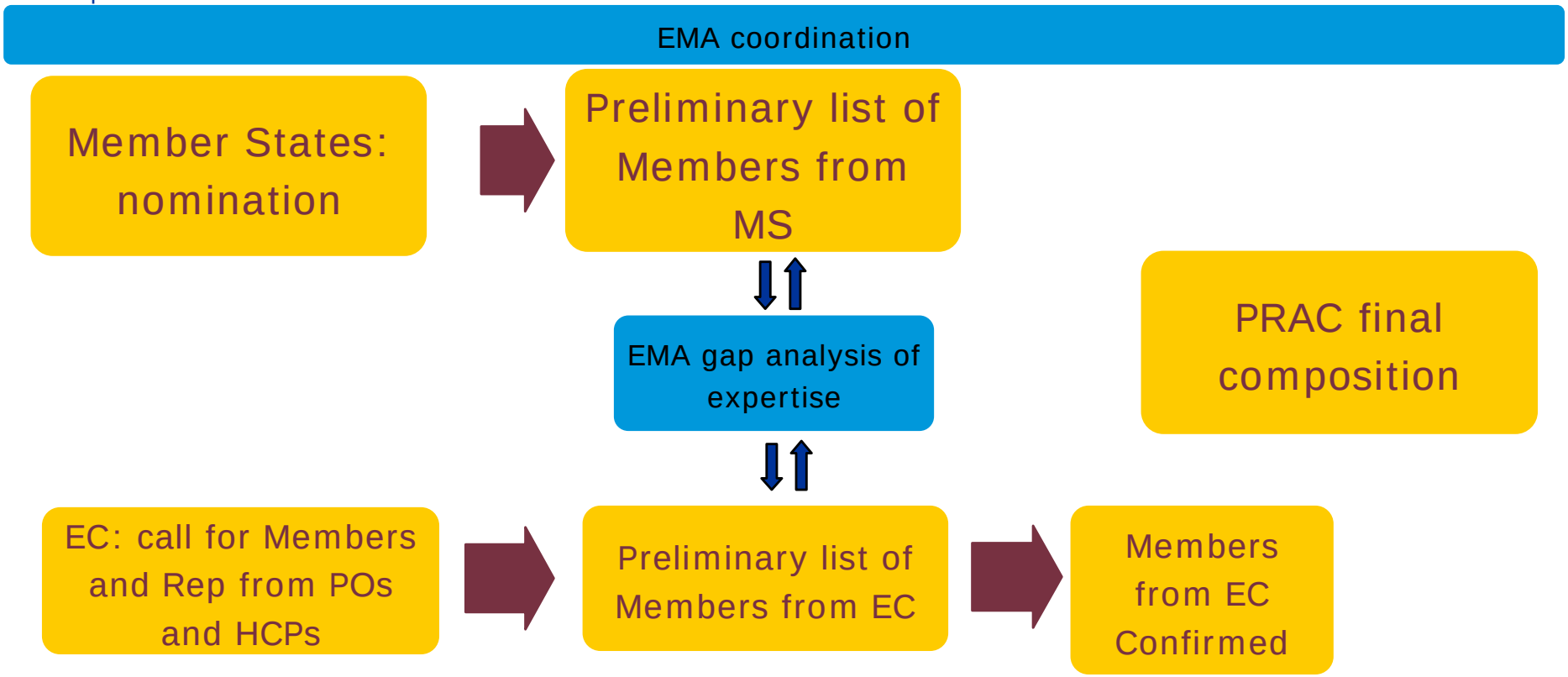
PRAC membership expertise – Core areas



PRAC membership expertise – Additional (specialised) Areas

- Drug safety in pregnancy and lactation
- Drug utilisation studies
- Medication errors leading to ADRs
- Pharmacogenetics and safety of medicines
- PhV in special populations (paediatrics, elderly)
- PhV of biological and biosimilar substances
- PhV and quality defects
- PhV of Vaccines
- Specialised clinical areas for Adverse Drug Reactions

Proposed nomination flow and timelines



Proposed procedure for Implementation: summary

- Q3 – Q4 2011 – Launch of Commission Expression of interest
- Q1 2012 – Appointment of members and alternates by Member States
- Q2 2012 Liaison with Management Board and Commission on composition of PRAC
- 1st Meeting of PRAC: July 2012

PRAC and Transparency

Regulation EU 1235/2010 states that in order to increase transparency as regards as pharmacovigilance issues a European medicines web portal should be created and maintained by the Agency in collaboration with Members States and the Commission

Agenda & Minutes

Assessments

Decisions

Opinions
Agreements
Positions

Recommendations

Available to the public