EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementation of the new pharmacovigilance legislation: update on status

Patients/Consumers Working Party (PCWP) and
Healthcare Professionals Working Group (HCPWG)
Joint Meeting
European Medicines Agency, London

24 September 2012

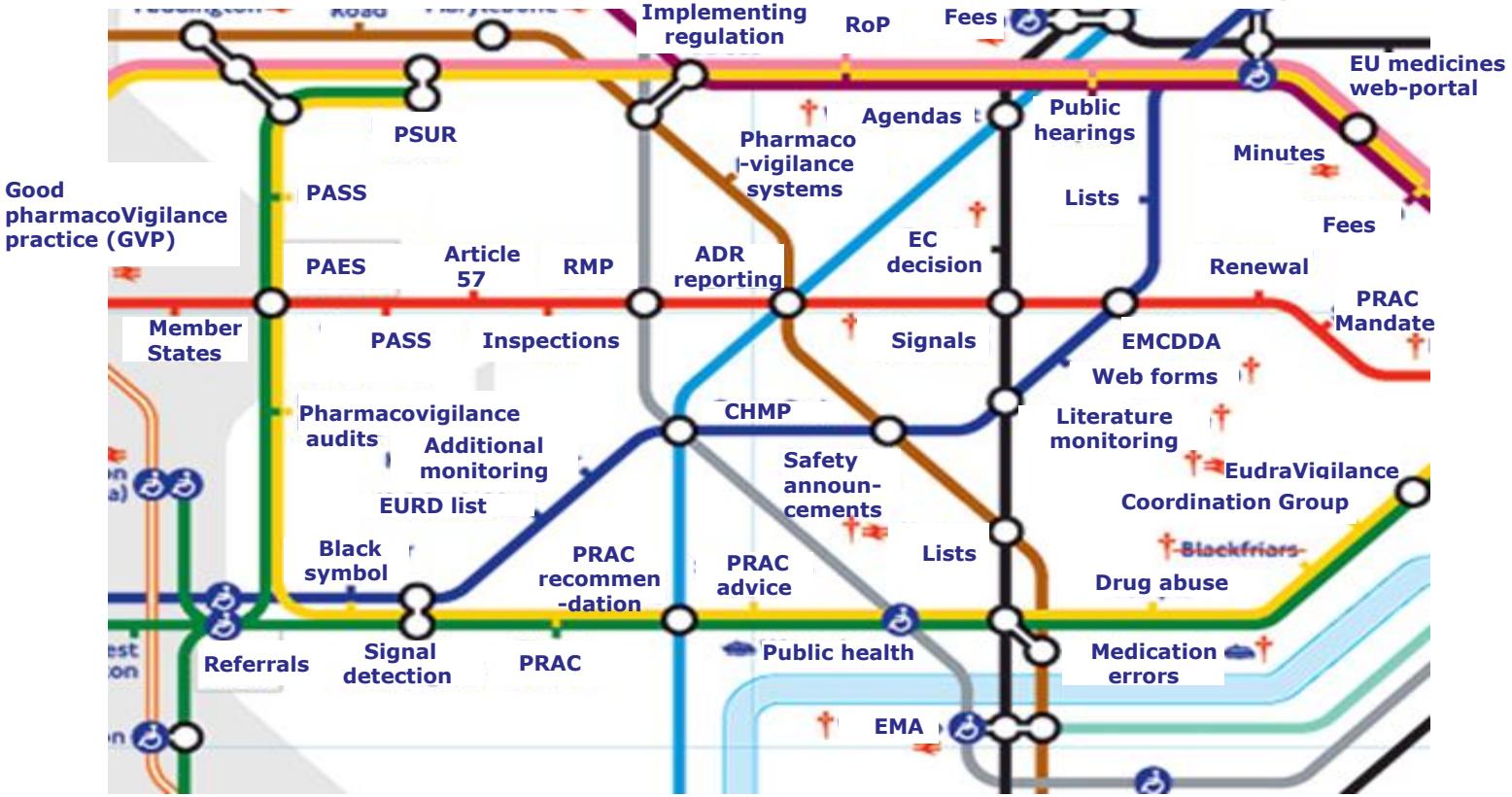
Presented by: Franck Diafouka,
Project 00305 Manager, Pharmacovigilance and Risk Management Sector

An agency of the European Union

Content

- Major achievements
- Next steps
- Conclusion

Implementation journey….



Major achievements

- Input to EC Implementing Regulation (EU) No 520/2012 published on 19/06/2012.
- 11 Good pharmacoVigilance Practice (GVP) modules drafted:
  - 7 adopted (first wave)
  - 2 to be adopted (comments currently being addressed)
  - 2 under public consultation (until 21st September).
- Other guidance documents (under preparation e.g. Q&A/referrals procedural guidance)
- Questions and Answers (Q&As) on transitional aspects (legal and practical) published on EMA website

Major achievements

- Input to EC Implementing Regulation (EU) No 520/2012 published on 19/06/2012.
- 11 Good pharmacoVigilance Practice (GVP) modules drafted:
  - 7 adopted (first wave)
  - 2 to be adopted (comments currently being addressed)
  - 2 under public consultation (until 21st September).
- Other guidance documents (under preparation e.g. Q&A/referrals procedural guidance)
- Questions and Answers (Q&As) on transitional aspects (legal and practical) published on EMA website

Major achievements

- Input to EC Implementing Regulation (EU) No 520/2012 published on 19/06/2012.
- 11 Good pharmacoVigilance Practice (GVP) modules drafted:
  - 7 adopted (first wave)
  - 2 to be adopted (comments currently being addressed)
  - 2 under public consultation (until 21st September).
- Other guidance documents (under preparation e.g. Q&A/referrals procedural guidance)
- Questions and Answers (Q&As) on transitional aspects (legal and practical) published on EMA website

Major achievements

- Input to EC Implementing Regulation (EU) No 520/2012 published on 19/06/2012.
- 11 Good pharmacoVigilance Practice (GVP) modules drafted:
  - 7 adopted (first wave)
  - 2 to be adopted (comments currently being addressed)
  - 2 under public consultation (until 21st September).
- Other guidance documents (under preparation e.g. Q&A/referrals procedural guidance)
- Questions and Answers (Q&As) on transitional aspects (legal and practical) published on EMA website

Major achievements

- Plan for prioritised implementation of the pharmacovigilance legislation by the European Medicines Agency.
- Format for electronic submission of product information ('Article 57'):
  - Electronic format (made available in June 2011)
  - Publication of revised legal notice and detailed guidance and provision of specific ICT tools (made available in March 2012)
  - Training.
- Gap analysis

Major achievements

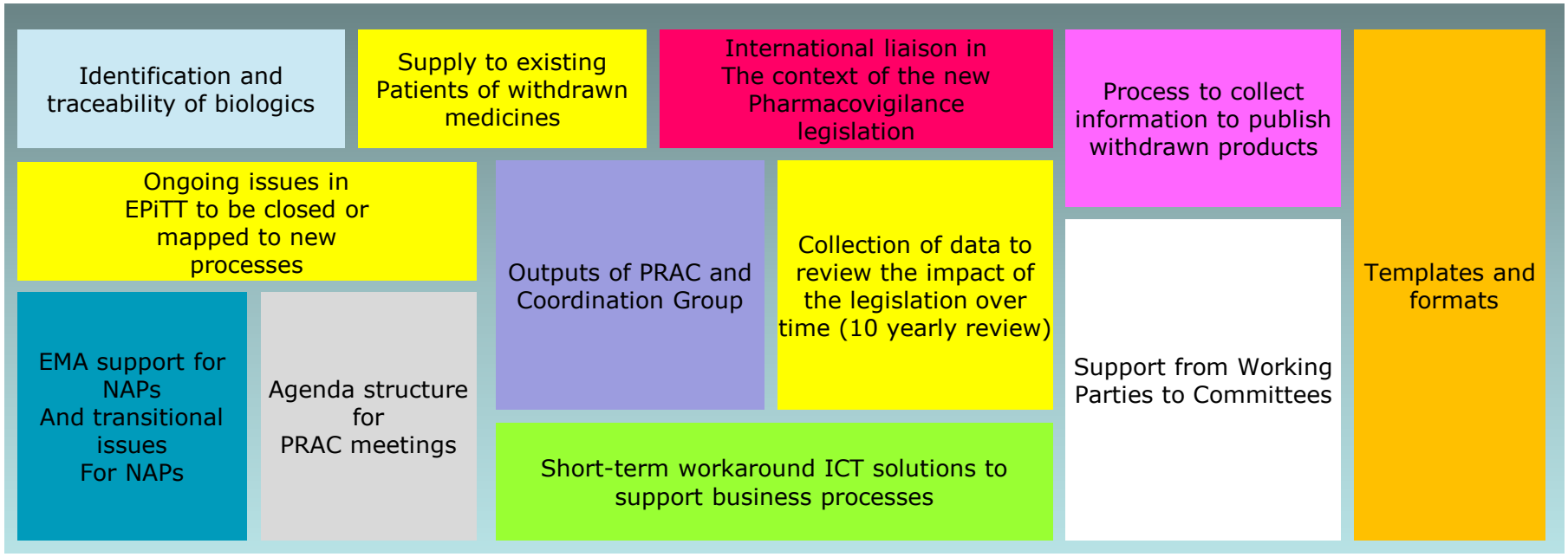
- Plan for prioritised implementation of the pharmacovigilance legislation by the European Medicines Agency.
- Format for electronic submission of product information ('Article 57'):
  - Electronic format (made available in June 2011)
  - Publication of revised legal notice and detailed guidance and provision of specific ICT tools (made available in March 2012)
  - Training.
- Gap analysis

Major achievements

- Plan for prioritised implementation of the pharmacovigilance legislation by the European Medicines Agency.
- Format for electronic submission of product information ('Article 57'):
  - Electronic format (made available in June 2011)
  - Publication of revised legal notice and detailed guidance and provision of specific ICT tools (made available in March 2012)
  - Training.
- Gap analysis

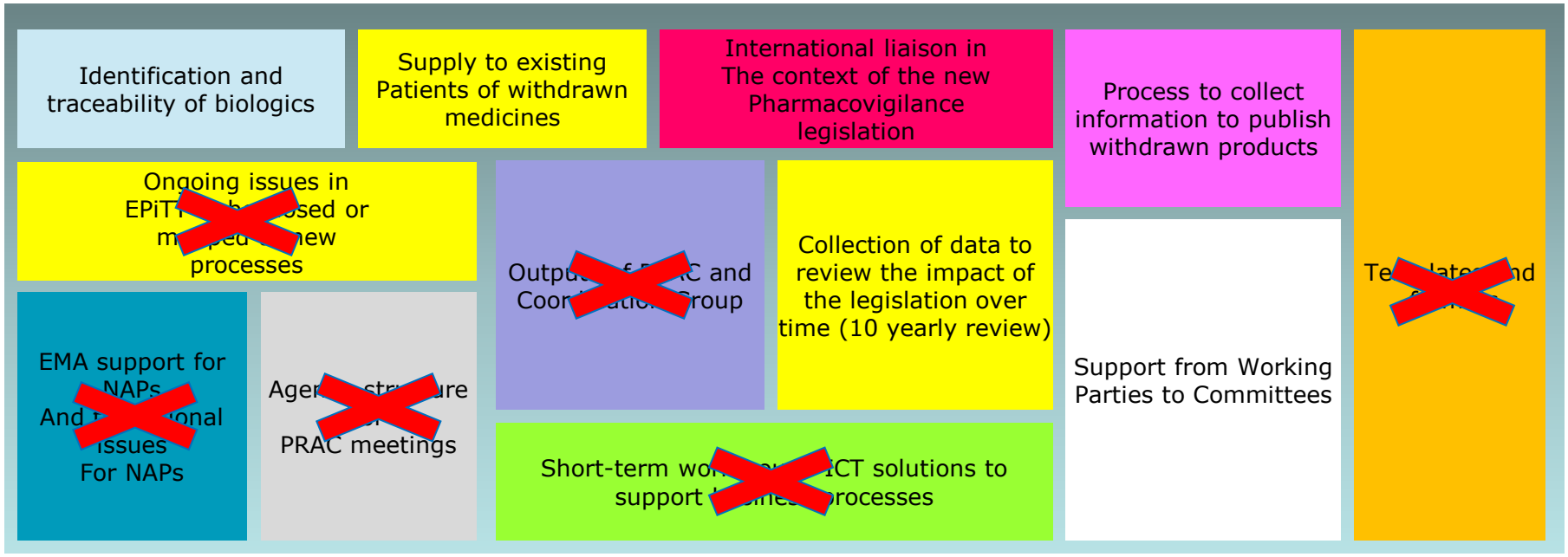
Gap analysis

- No strategic gaps identified – only operational
- Leads and timelines assigned for gap resolution



Gap analysis – status September 12

- No strategic gaps identified – only operational
- Leads and timelines assigned for gap resolution



Major achievements

- Establishment of Training Coordination Group to coordinate pharmacovigilance training within the EU network, in liaison with joint Heads of Medicines Agencies (HMA)/EMA Office of Training Steering Group (OTSG)
- Detailed Business Process Maps to support:
  - future revision of ICT Project Definition Documents
  - on-going development of Standard Operating Procedures (SOPs), Working Instructions (WINs) and Templates.
- EMA website will serve as the EU Medicines Web-portal

Major achievements

- Establishment of Training Coordination Group to coordinate pharmacovigilance training within the EU network, in liaison with joint Heads of Medicines Agencies (HMA)/EMA Office of Training Steering Group (OTSG)
- Detailed Business Process Maps to support:
  - future revision of ICT Project Definition Documents
  - on-going development of Standard Operating Procedures (SOPs), Working Instructions (WINs) and Templates.
- EMA website will serve as the EU Medicines Web-portal

Major achievements

- Establishment of Training Coordination Group to coordinate pharmacovigilance training within the EU network, in liaison with joint Heads of Medicines Agencies (HMA)/EMA Office of Training Steering Group (OTSG)
- Detailed Business Process Maps to support:
  - future revision of ICT Project Definition Documents
  - on-going development of Standard Operating Procedures (SOPs), Working Instructions (WINs) and Templates.
- EMA website will serve as the EU Medicines Web-portal

Major achievements

- Upgrade of EMA corporate website (e.g. publication of safety-related referrals through the PRAC, search tool, RSS feed for agendas and minutes, …)
- Establishment of Pharmacovigilance and Risk Assessment Committee
- Enhanced cooperation with European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
- Preparation of initial lists of European Union Reference Dates (EURD) for Periodic Safety Update Reports and Products under additional monitoring

Major achievements

- Upgrade of EMA corporate website (e.g. publication of safety-related referrals through the PRAC, search tool, RSS feed for agendas and minutes)
- Establishment of Pharmacovigilance and Risk Assessment Committee (PRAC)
- Enhanced cooperation with European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
- Preparation of initial lists of European Union Reference Dates (EURD) for Periodic Safety Update Reports and Products under additional monitoring

Establishment of PRAC

- Nomination of PRAC members (except civil society representatives appointed by the EC).
- Meeting schedule for 2012:
  - Inaugural meeting 19 and 20 July.
  - 3,4,5 September
  - 1,2,3,4 October
  - 29,30,31 October
  - 26,27,28,29 November

Establishment of PRAC

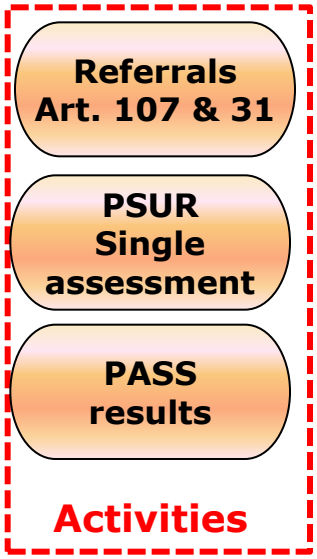
- Principles of meeting schedule: PRAC to take place two-weeks before CHMP and Coordination Group
  - To ensure high quality PRAC outputs
  - To ensure robust scrutiny by CHMP and Coordination Group
  - To facilitate communications
- Rules of Procedure
- Chair and Vice-Chair were elected: June Raine (United Kingdom) and Almath Spooner (Ireland)
- Principles of Rapporteur appointment and Transparency/Communication agreed

Establishment of PRAC

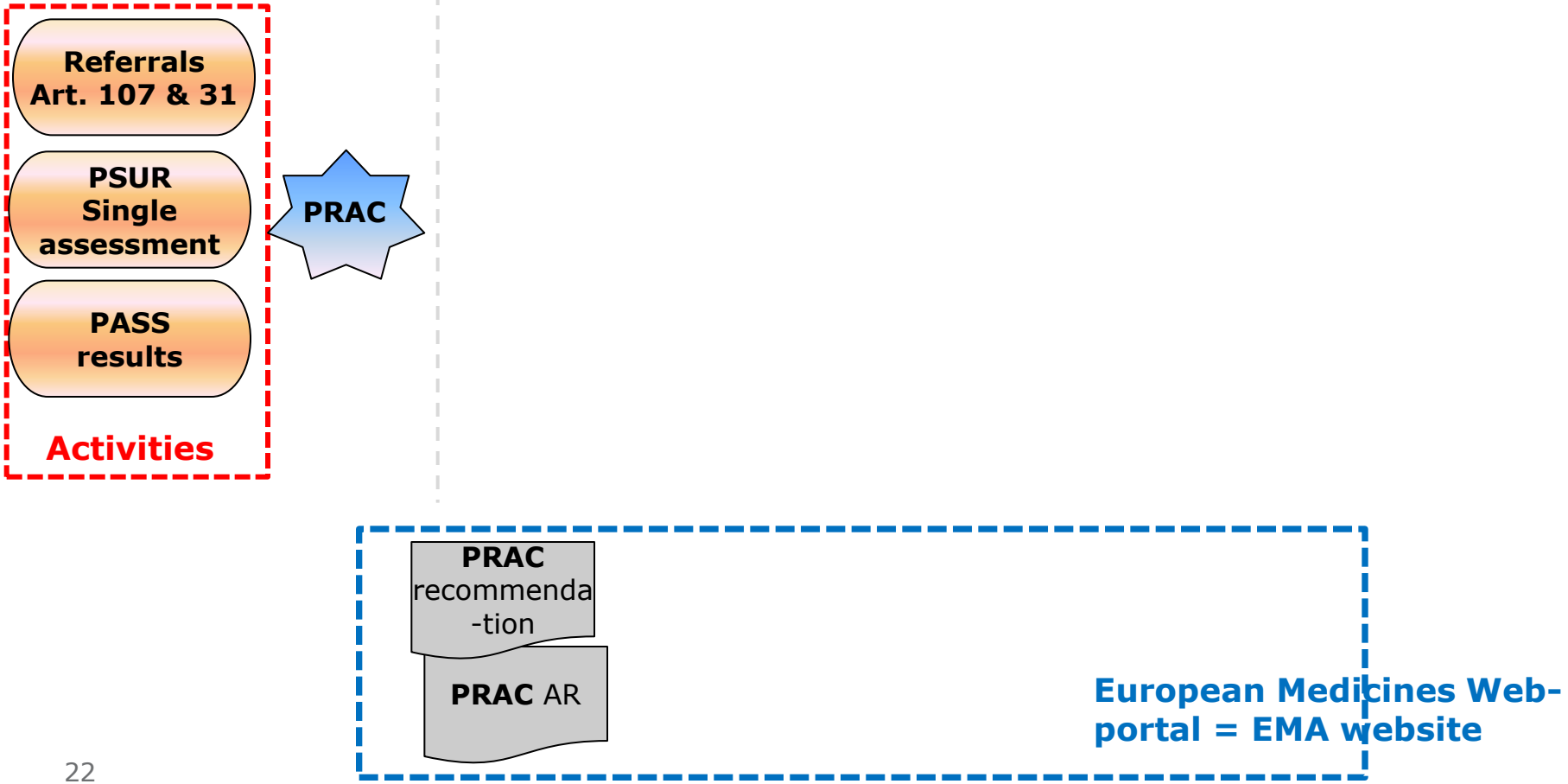
- Definition of PRAC outputs to be handled:
  - with a formal decision-making phase
  - without a formal decision-making phase

PRAC outputs with formal decision-making phase

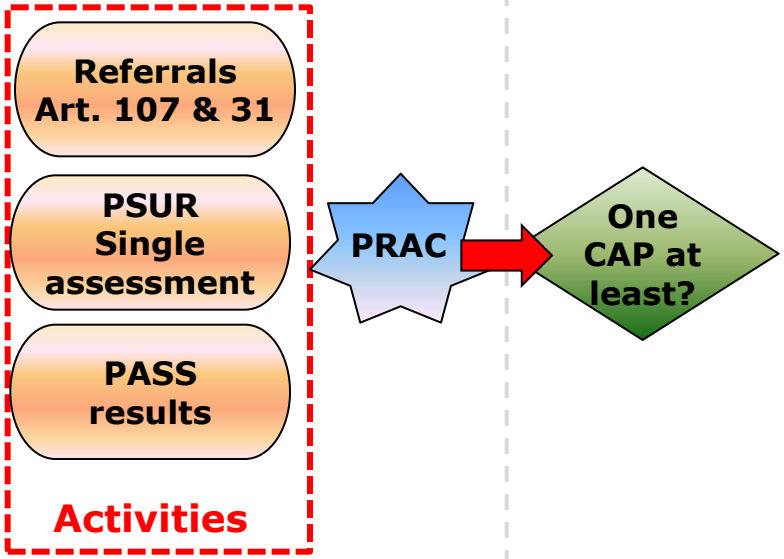
PRAC outputs with formal decision-making phase



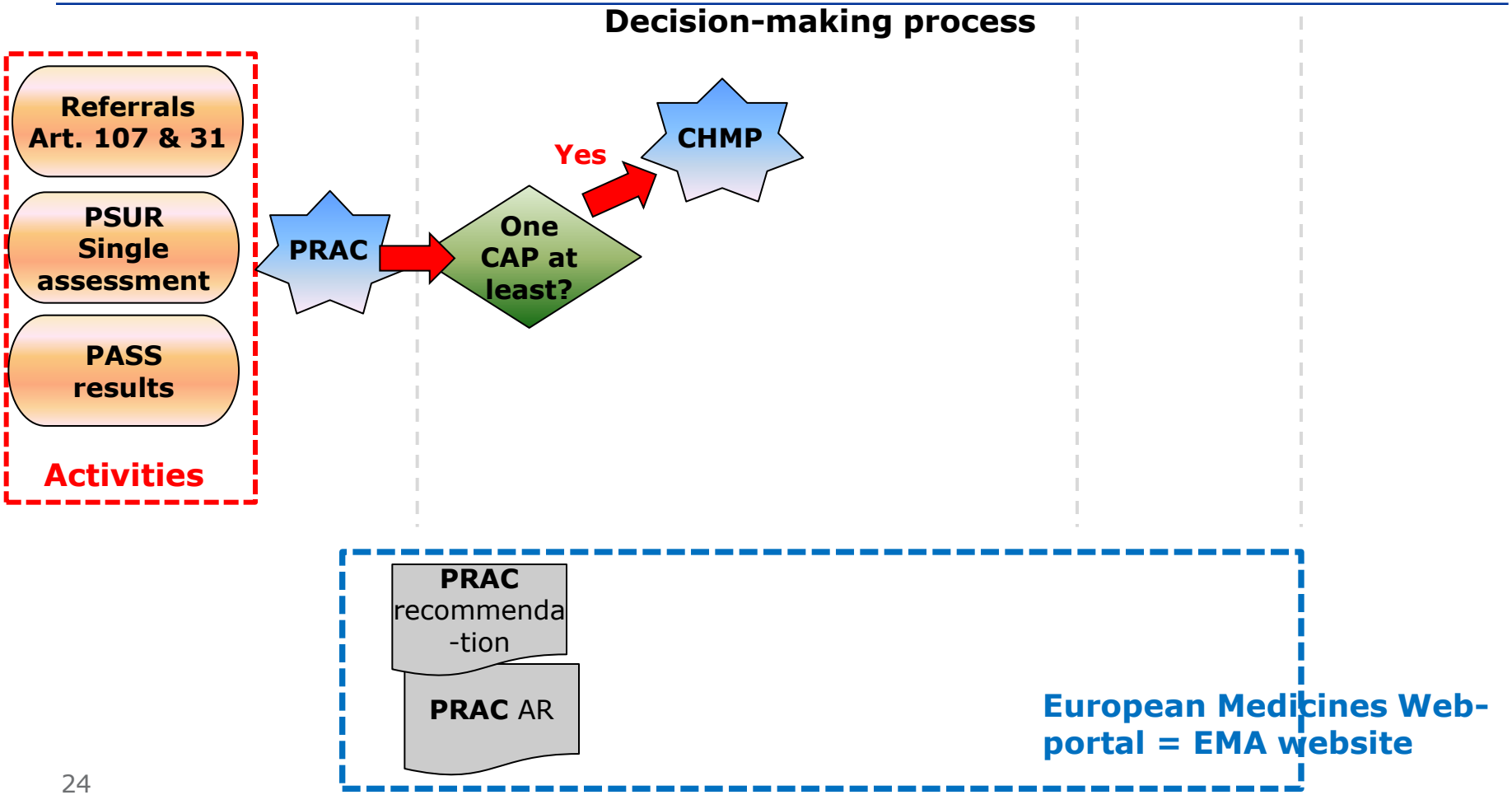
PRAC outputs with formal decision-making phase



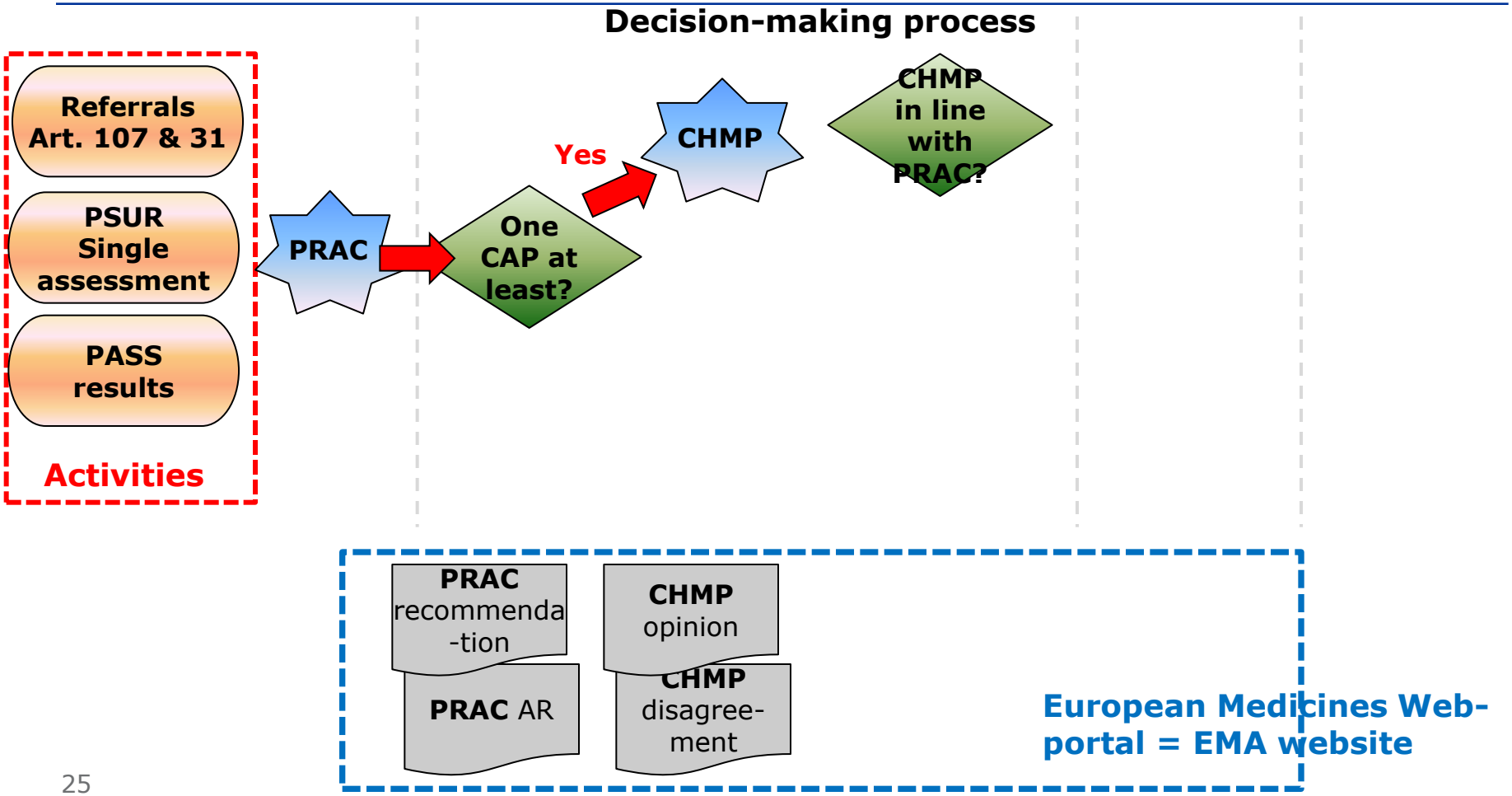
PRAC outputs with formal decision-making phase



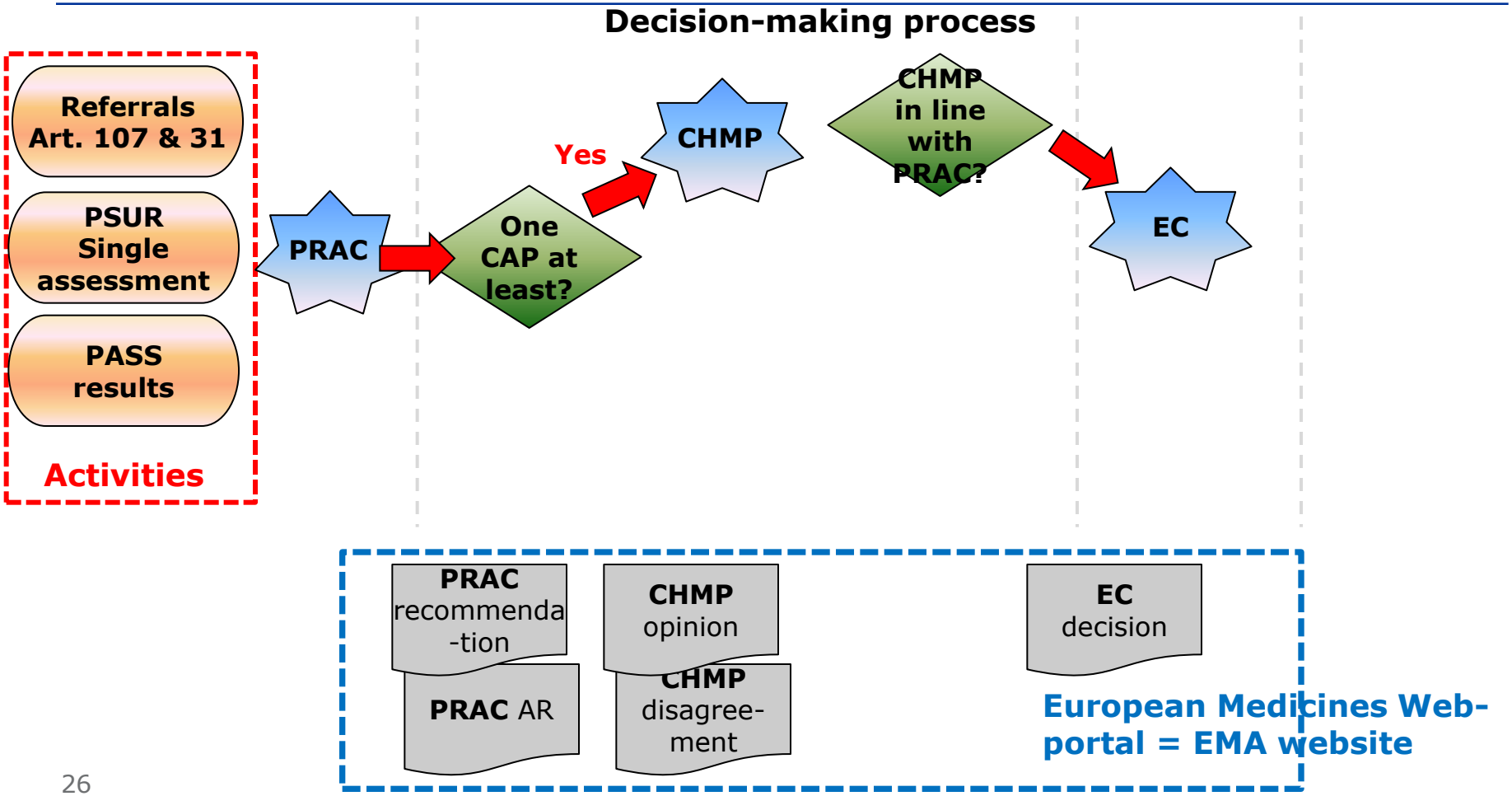
PRAC outputs with formal decision-making phase



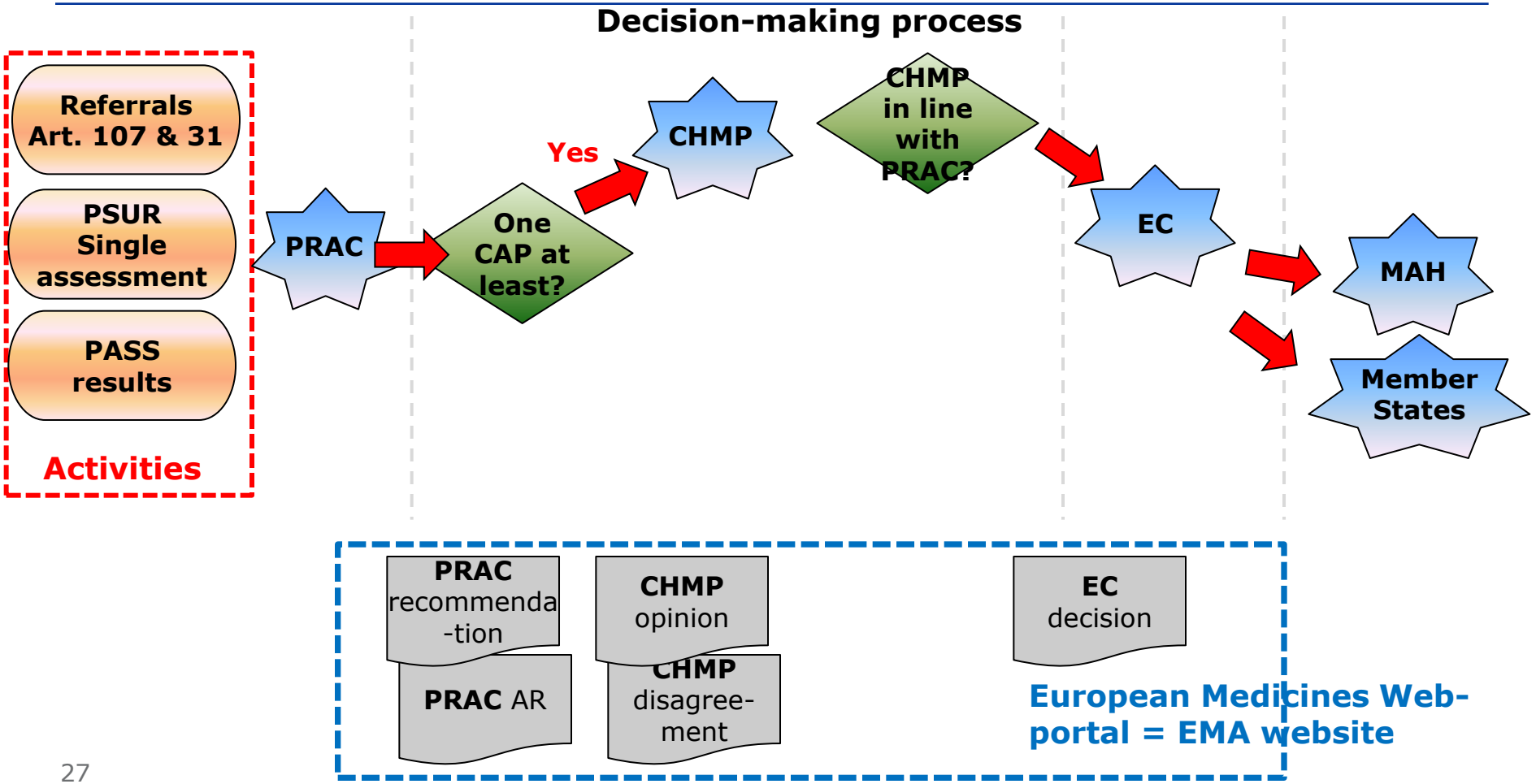
PRAC outputs with formal decision-making phase



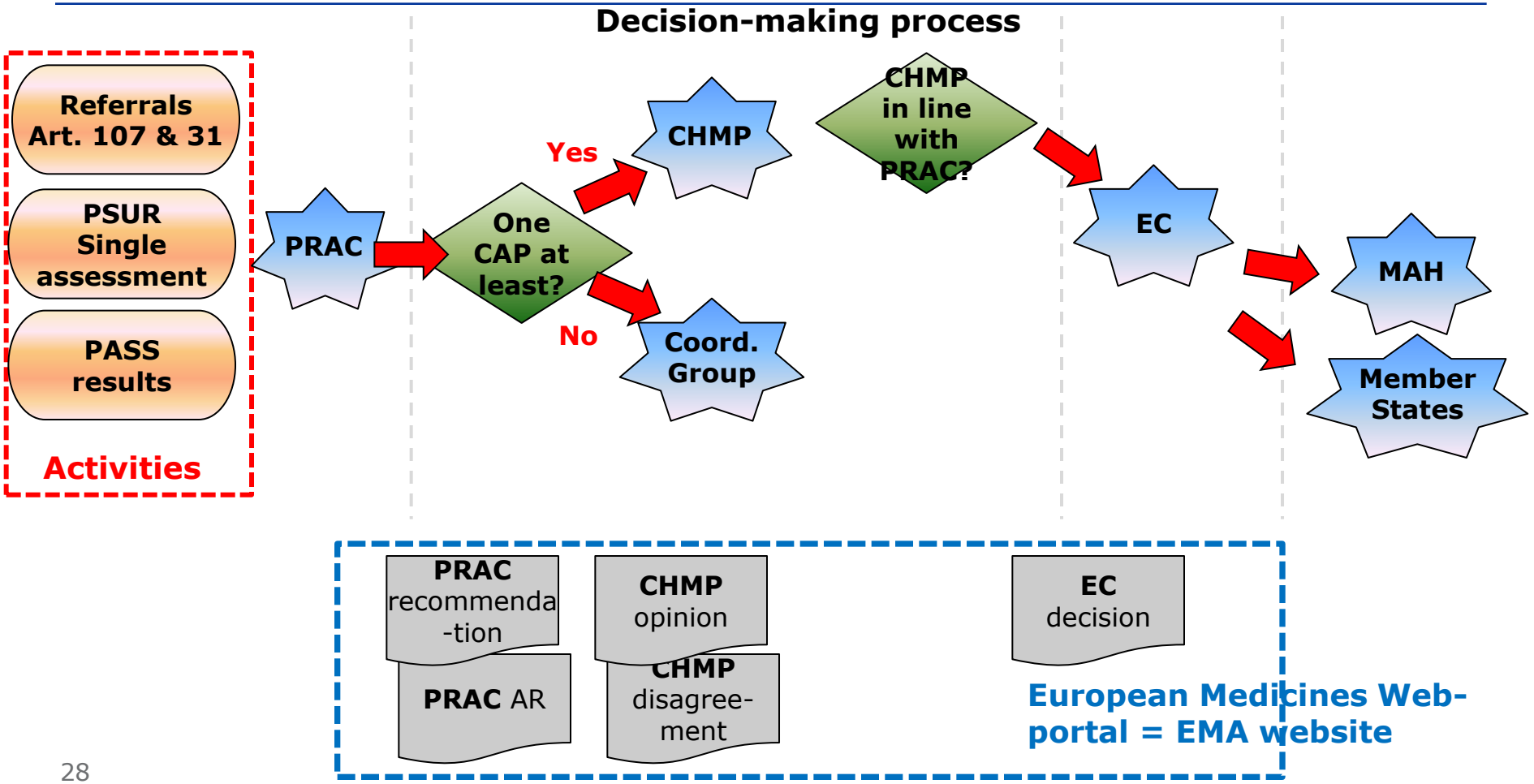
PRAC outputs with formal decision-making phase



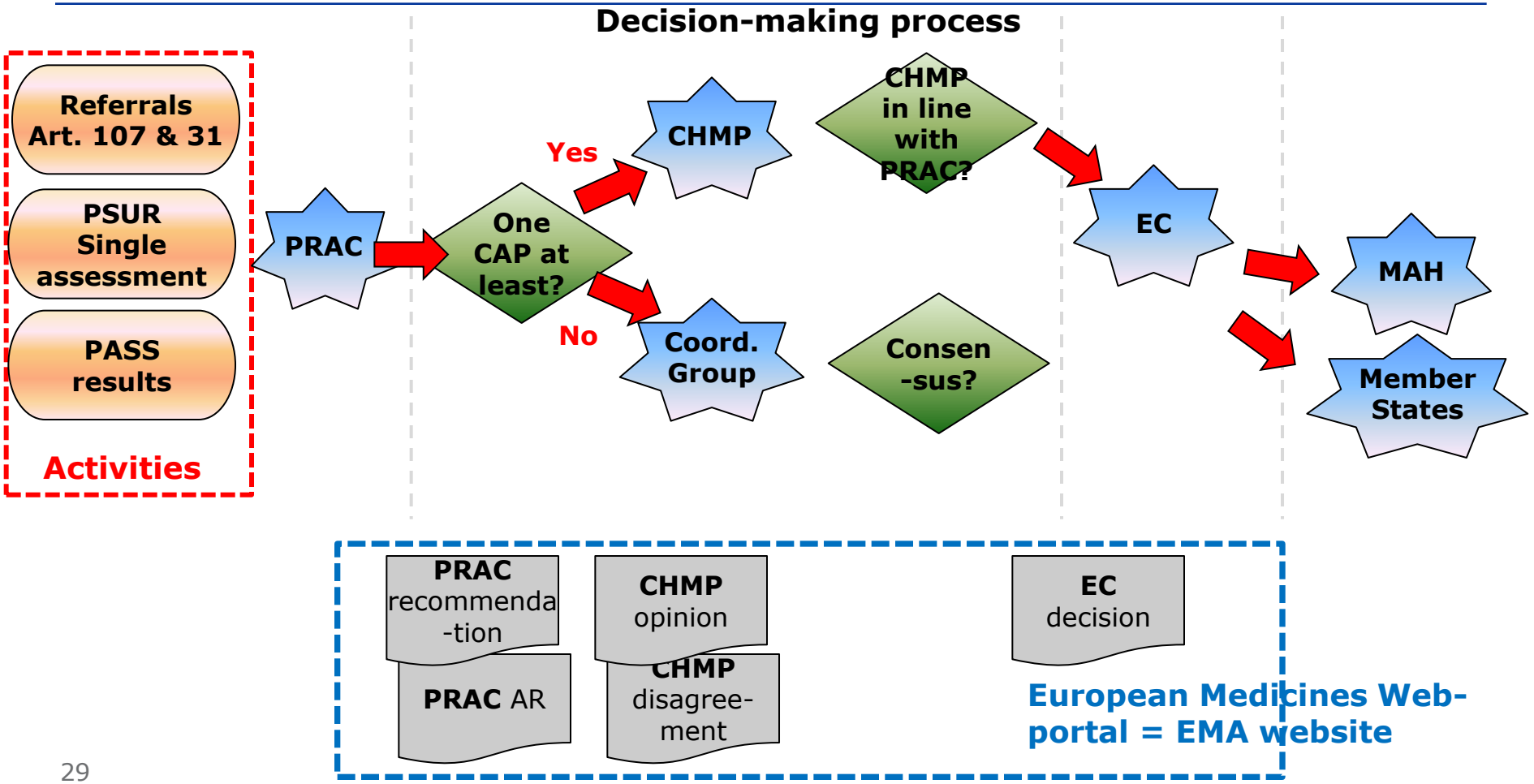
PRAC outputs with formal decision-making phase



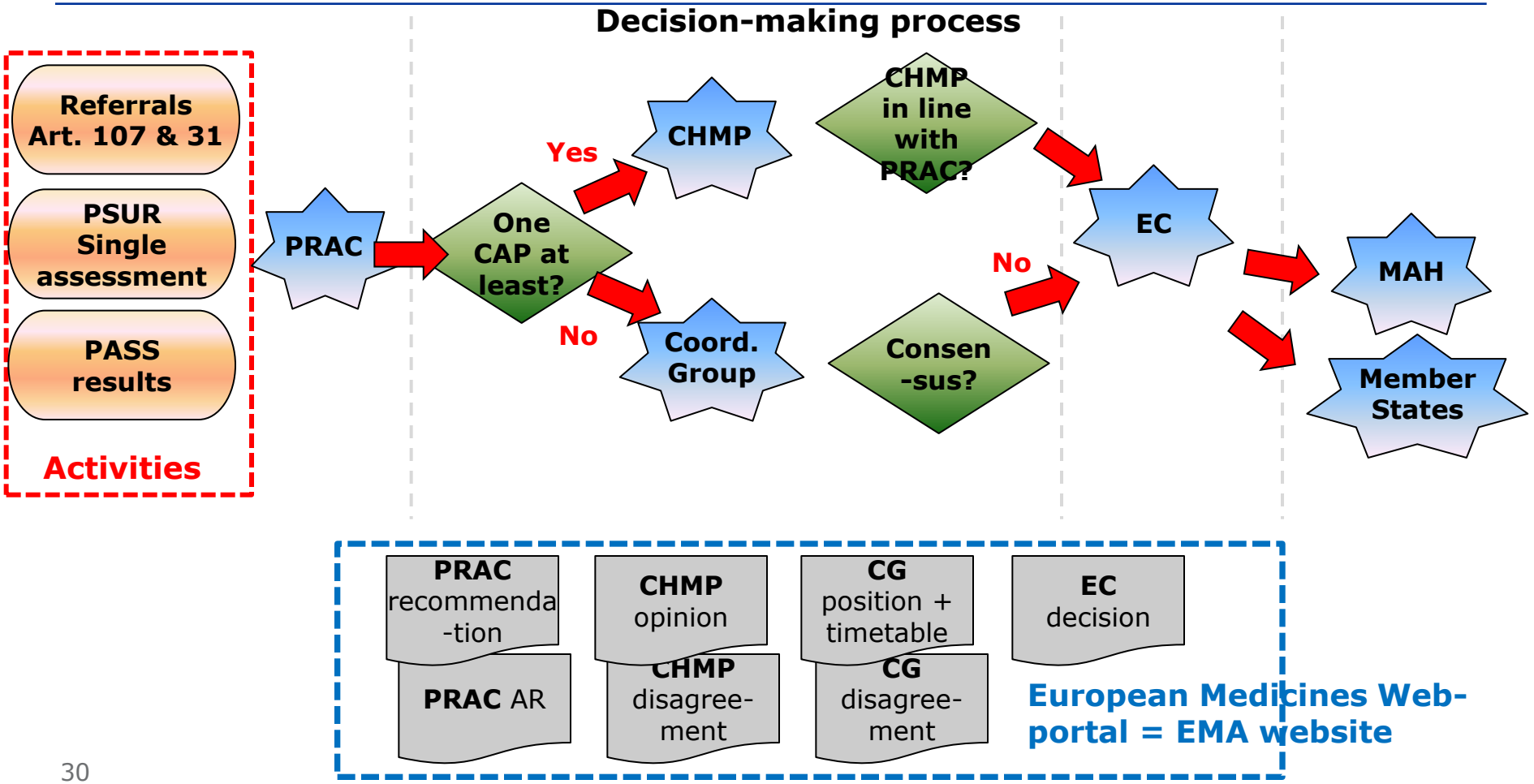
PRAC outputs with formal decision-making phase



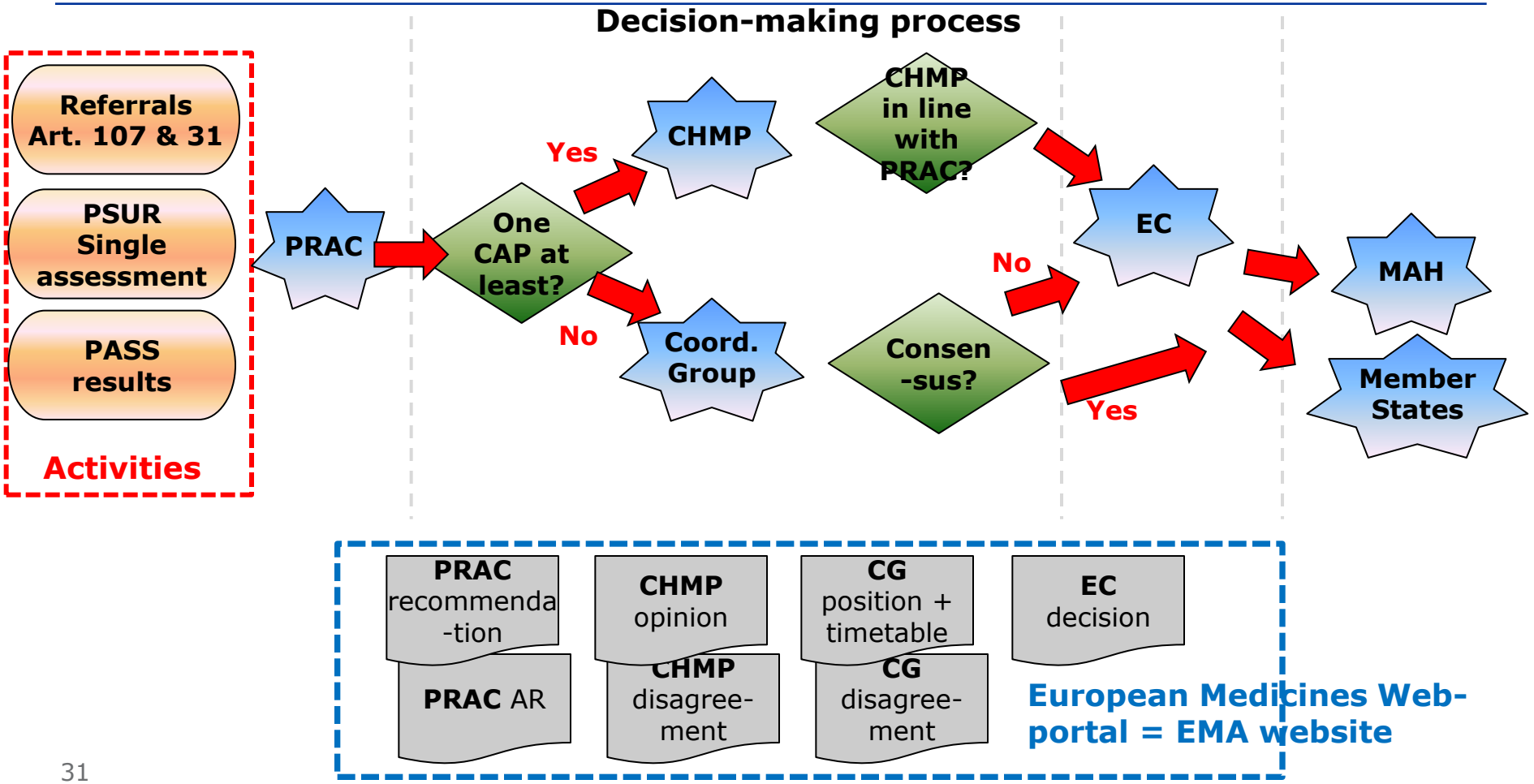
PRAC outputs with formal decision-making phase



PRAC outputs with formal decision-making phase



PRAC outputs with formal decision-making phase



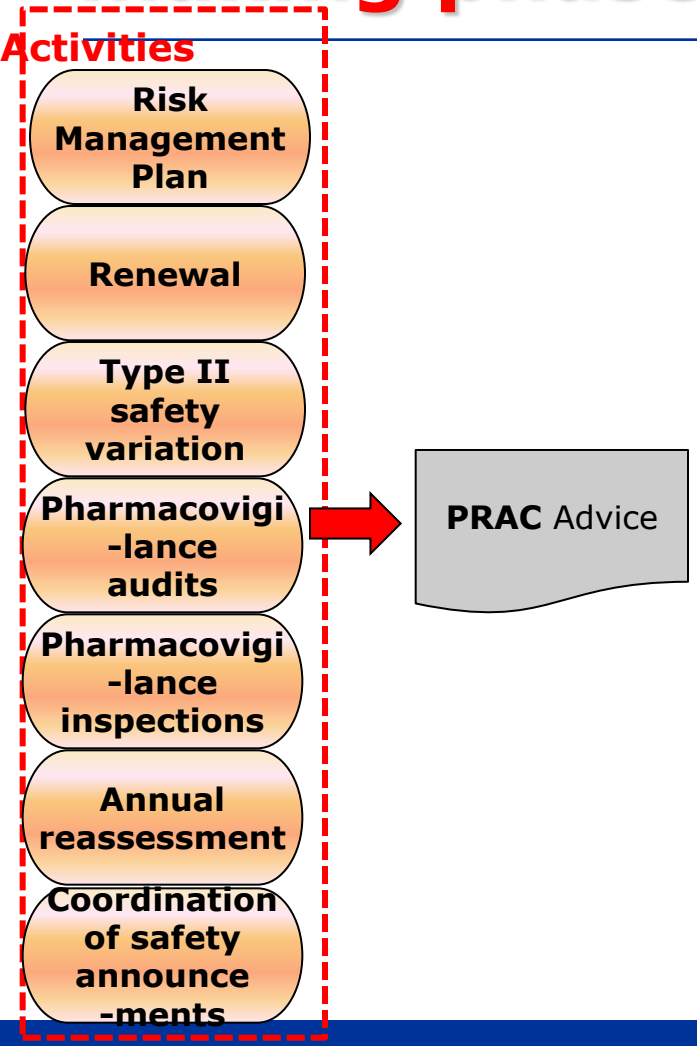
PRAC outputs without formal decision-making phase

PRAC outputs without formal decision-making phase

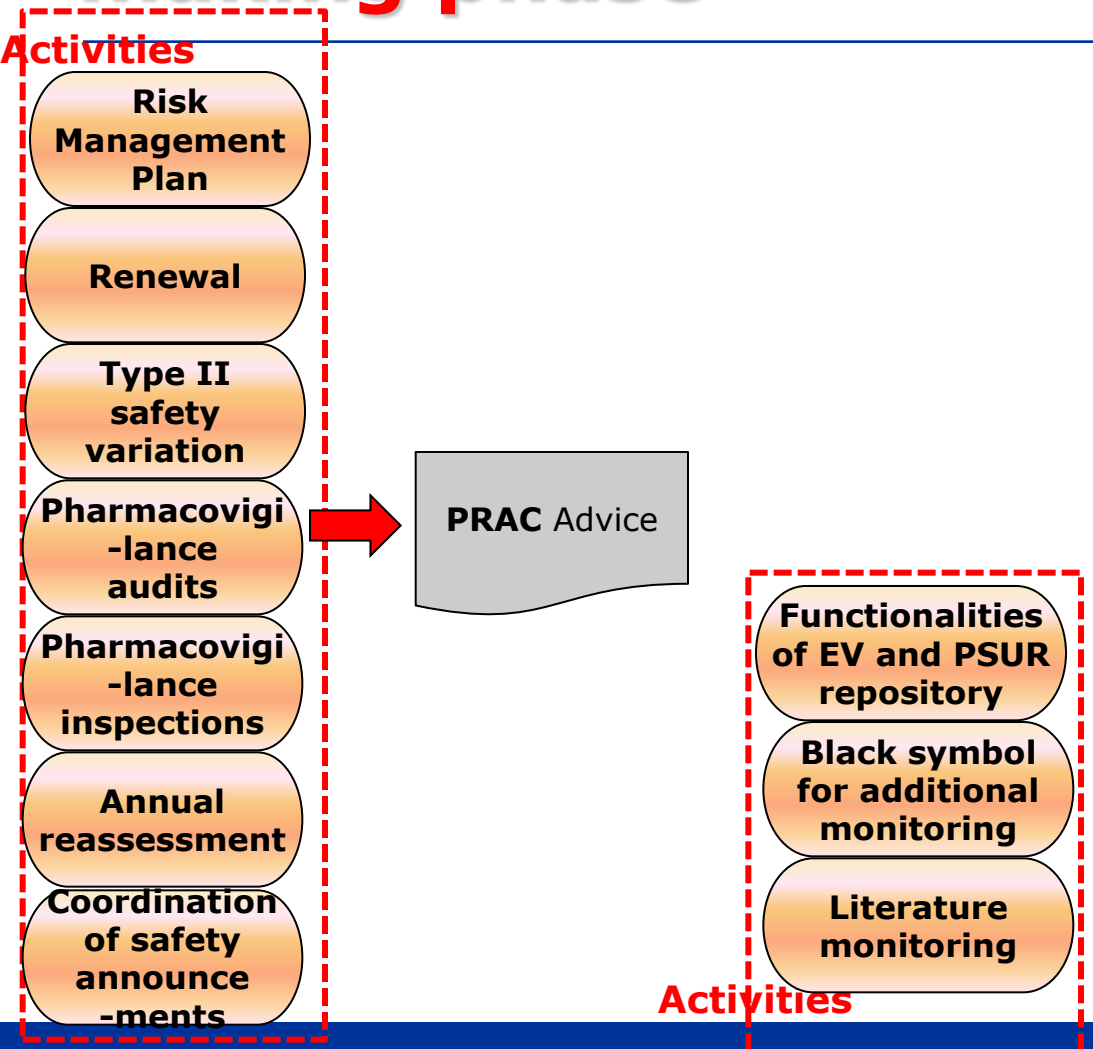
Activities

- Risk Management Plan
- Renewal
- Type II safety variation
- Pharmacovigi-lance audits
- Pharmacovigi-lance inspections
- Annual reassessment
- Coordination of safety announce-ments

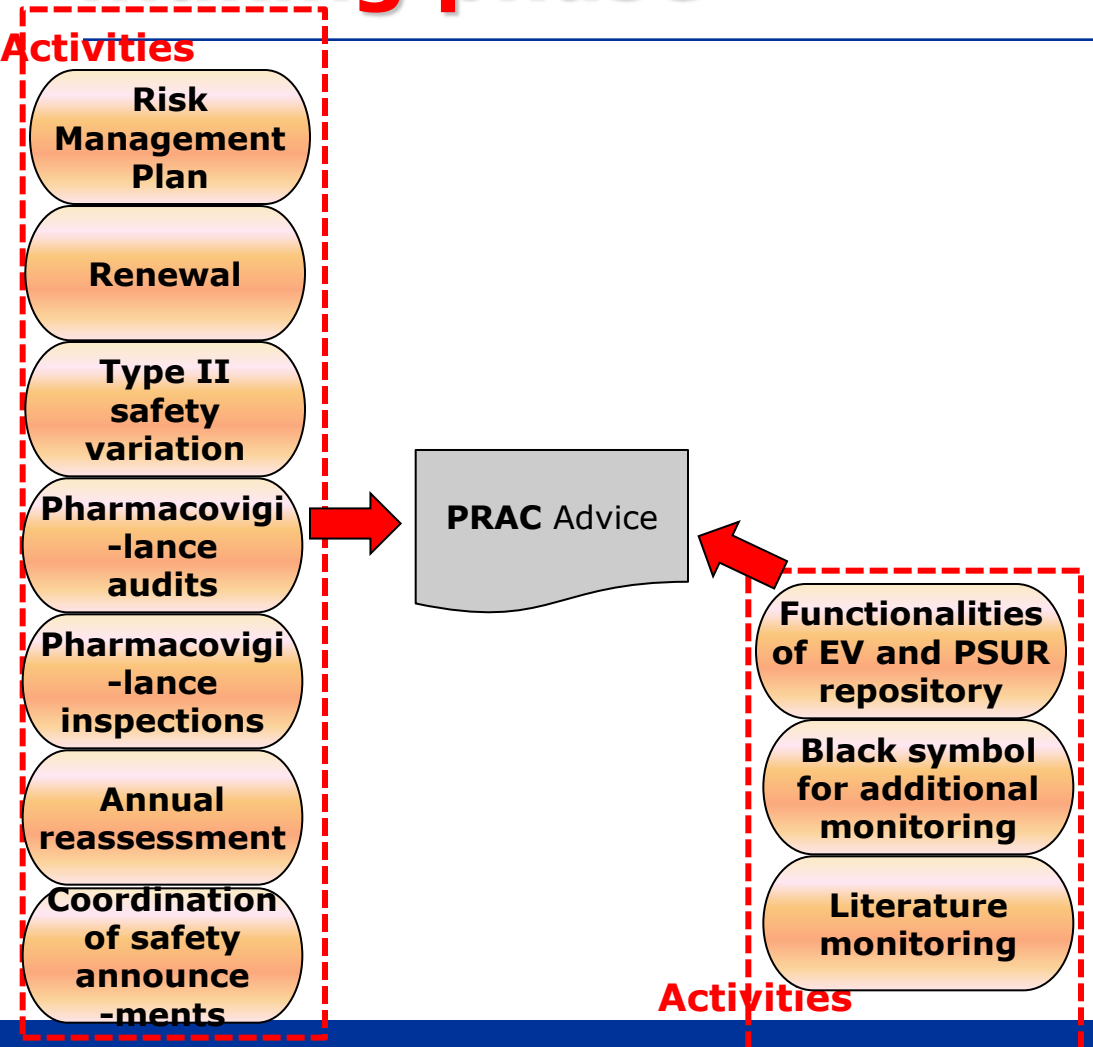
PRAC outputs without formal decision-making phase



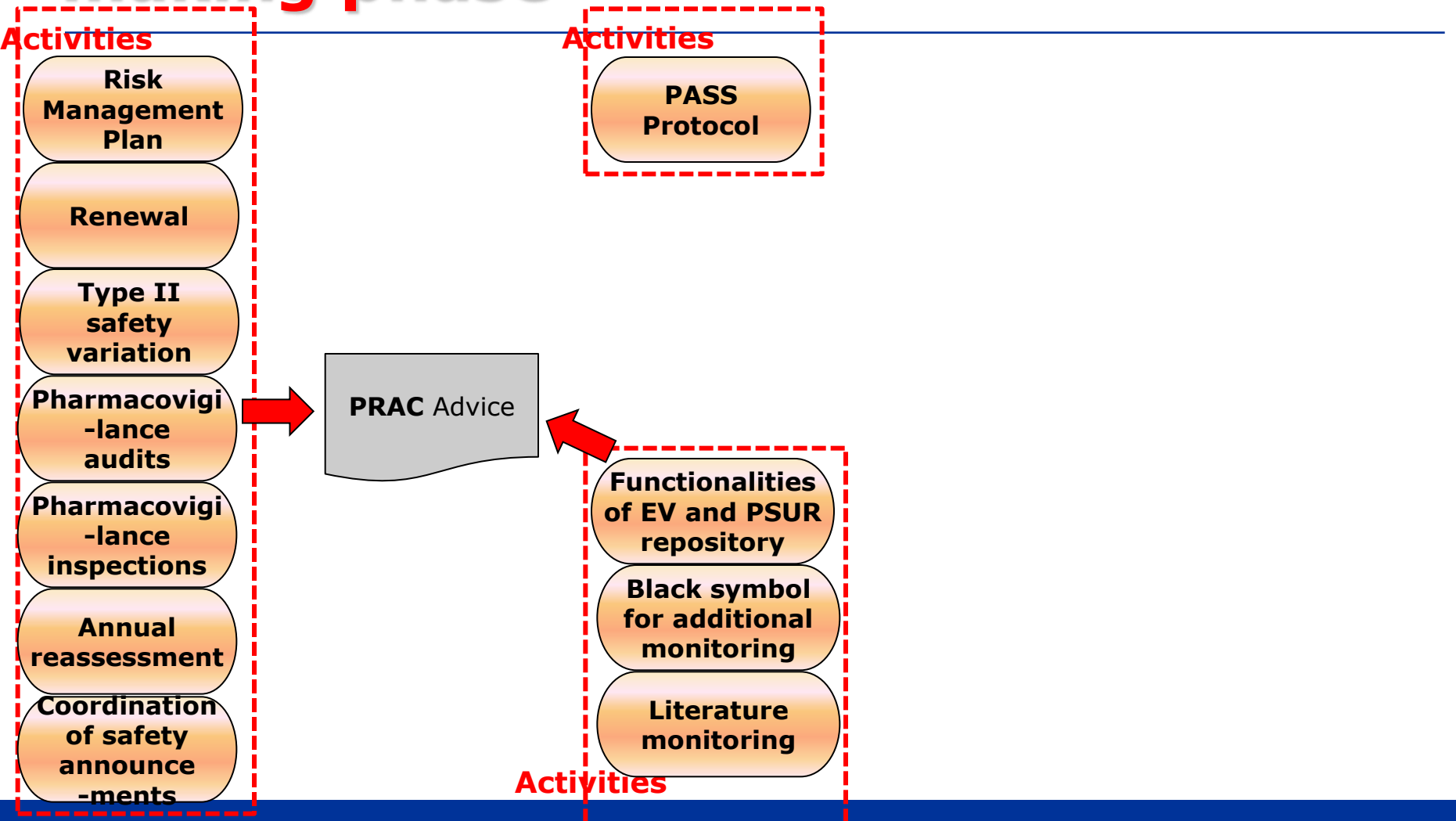
PRAC outputs without formal decision-making phase



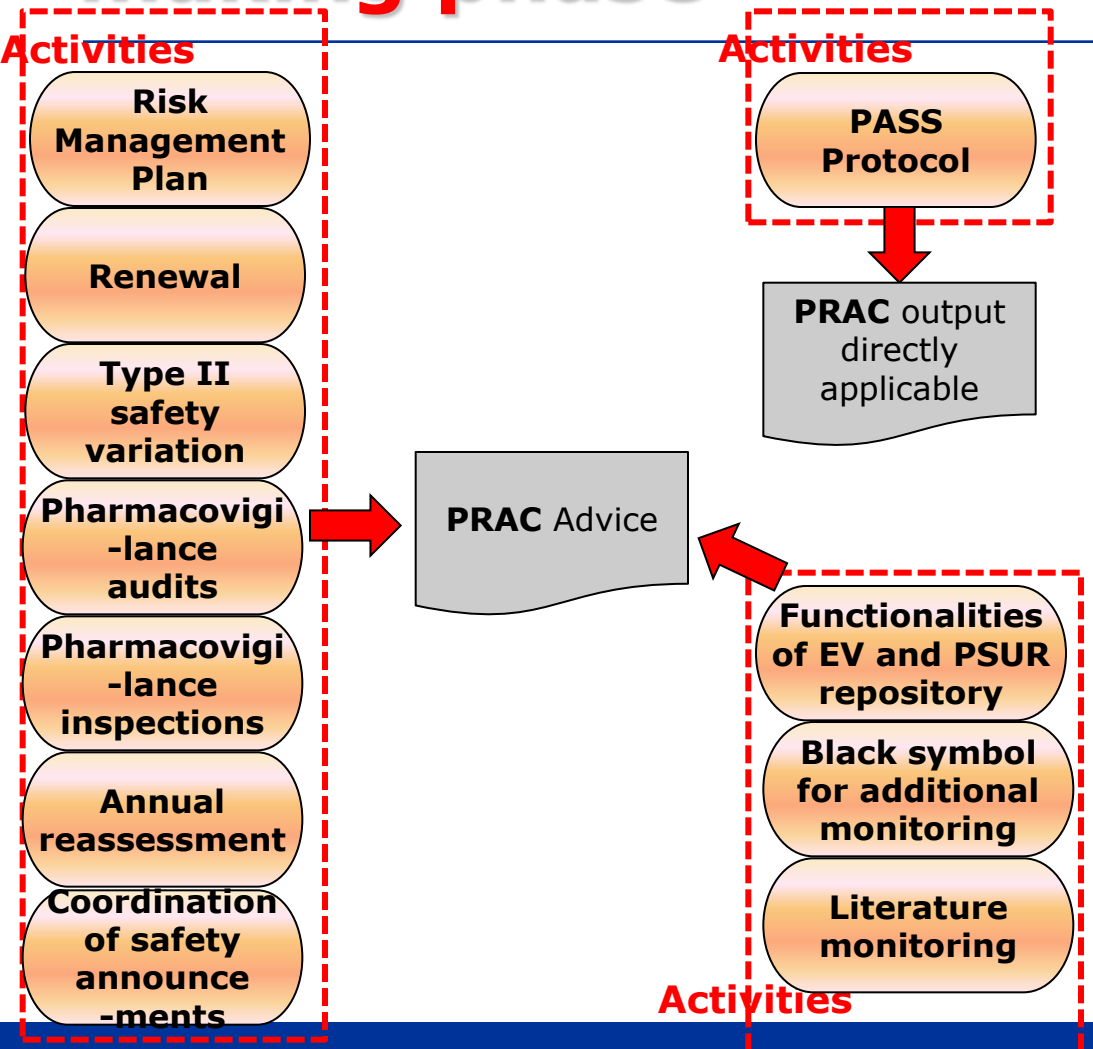
PRAC outputs without formal decision-making phase



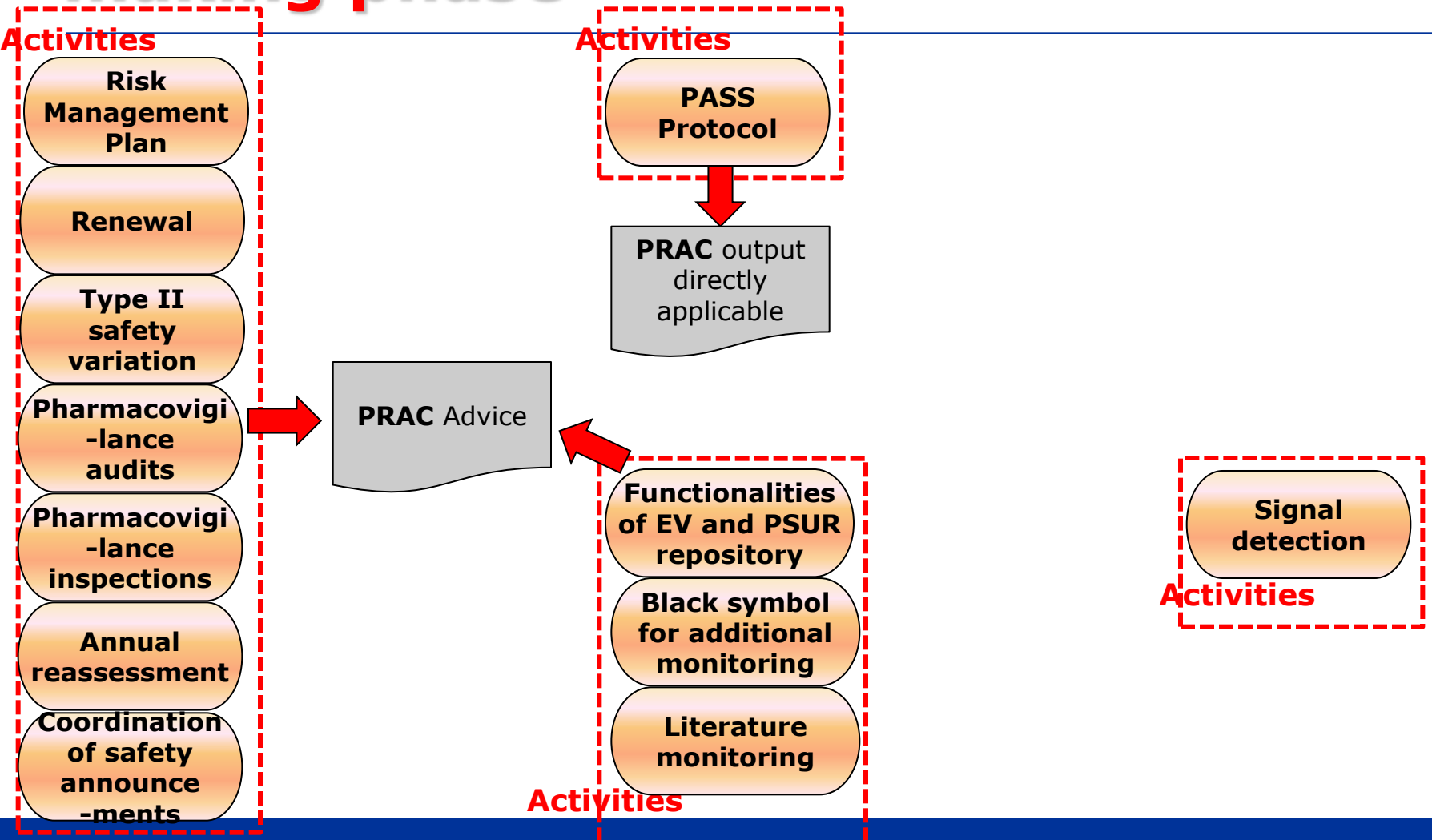
PRAC outputs without formal decision-making phase



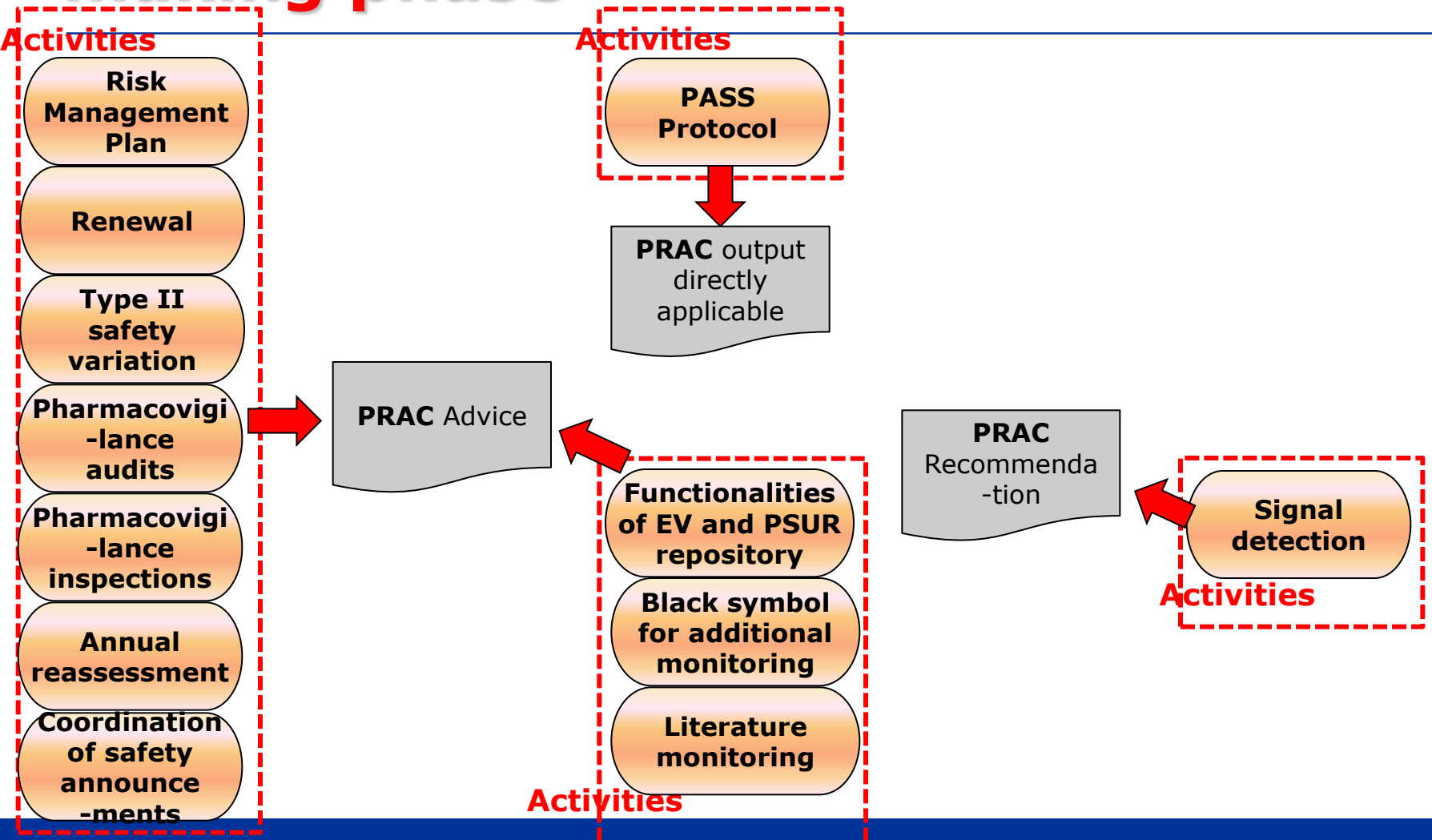
PRAC outputs without formal decision-making phase



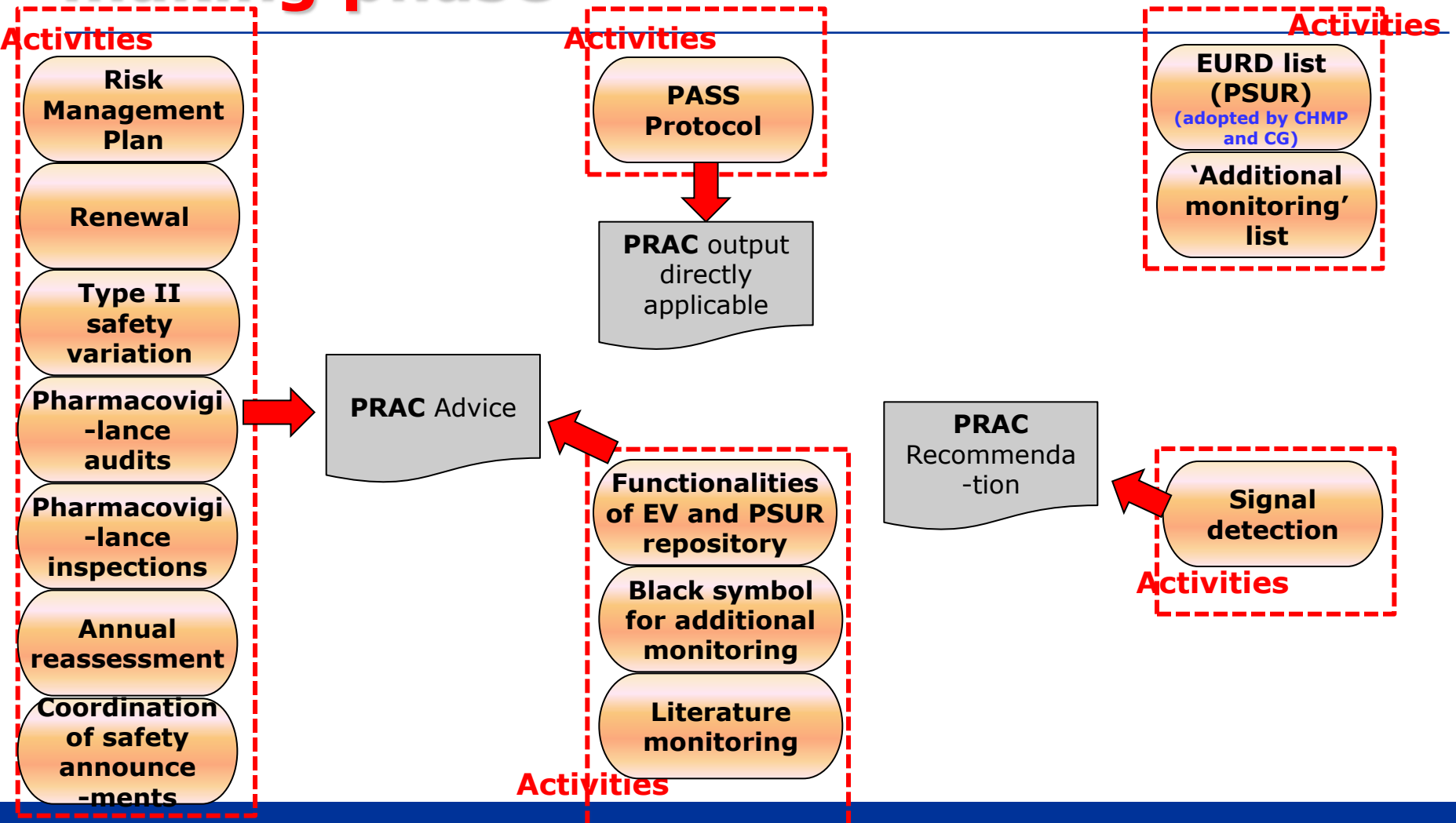
PRAC outputs without formal decision-making phase



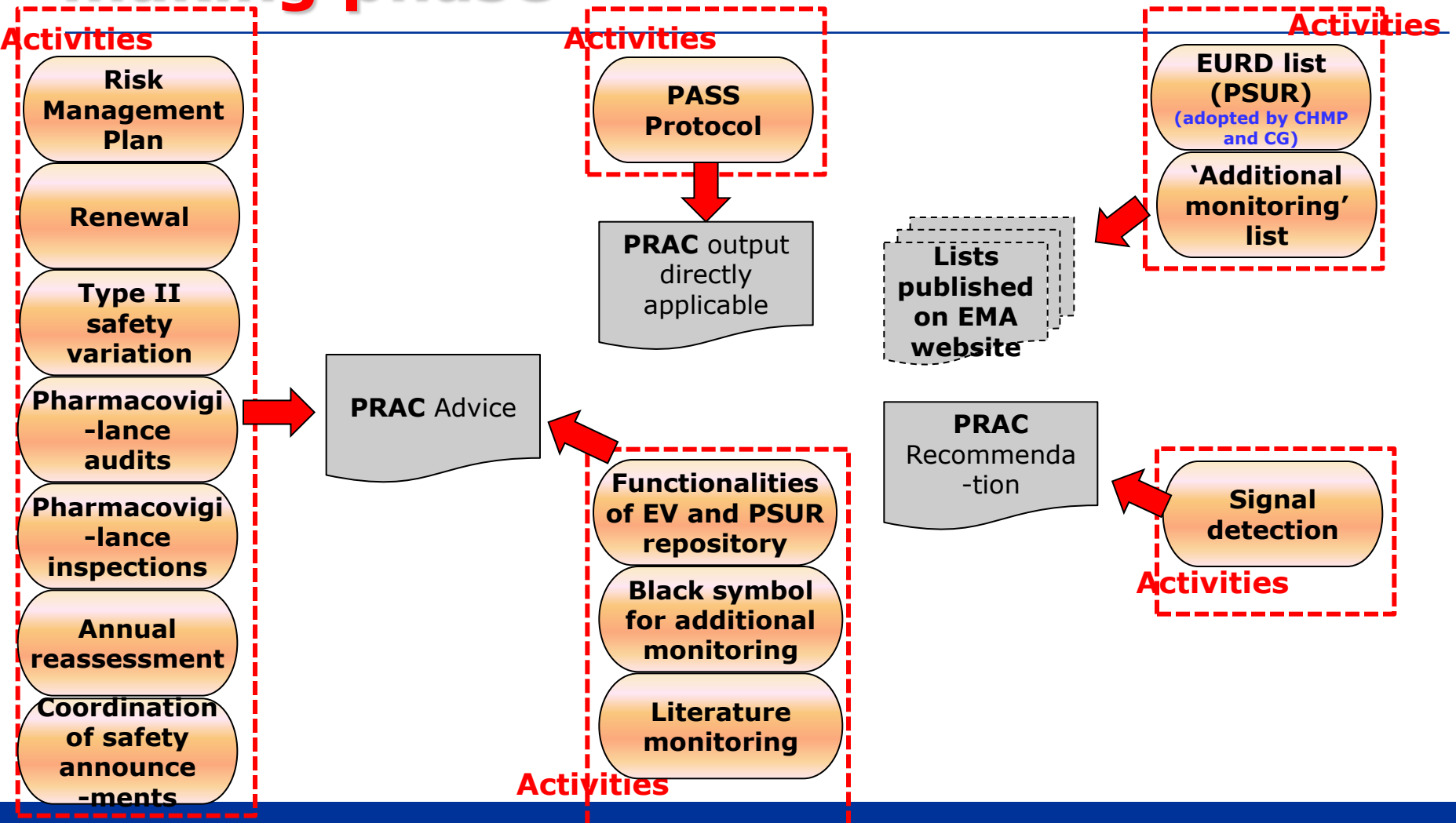
PRAC outputs without formal decision-making phase



PRAC outputs without formal decision-making phase



PRAC outputs without formal decision-making phase



Major achievements

- Upgrade of EMA corporate website (e.g. publication of safety-related referrals through the PRAC, search tool, RSS feed for agendas and minutes)
- Establishment of Pharmacovigilance and Risk Assessment Committee (PRAC)
- Enhanced cooperation with European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
- Preparation of initial lists of European Union Reference Dates (EURD) for Periodic Safety Update Reports and Products under additional monitoring

Enhanced cooperation with EMCDDA

- Article 28c(2): 'The Agency and the EMCDDA shall exchange information that they receive on the abuse of medicinal products including information related to illicit drugs'.
- Working arrangement (first signed in 2010) amended by EMA and EMCDDA Directors to strengthen information-exchange practices.
- More timely response to potential public health threats

Major achievements

- Upgrade of EMA corporate website (e.g. publication of safety-related referrals through the PRAC, search tool, RSS feed for agendas and minutes)
- Establishment of Pharmacovigilance and Risk Assessment Committee (PRAC)
- Enhanced cooperation with European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
- Preparation of initial lists of European Union Reference Dates (EURD) for Periodic Safety Update Reports and Products under additional monitoring

List of European Union Reference Dates

- Adopted by PRAC in September before presentation to CHMP and Coordination Group for agreement.
- Initial list (3,364 substances) to be published on 30th September – becomes binding as of April 2013.
- List will be updated monthly (maintenance process to be finalised).

Major achievements

- Development of proposal for black symbol
- Five Stakeholders meetings held (3 in 2011 and 2 in 2012)
- Enriched governance structure (maintained until end 2012 – to be reviewed)

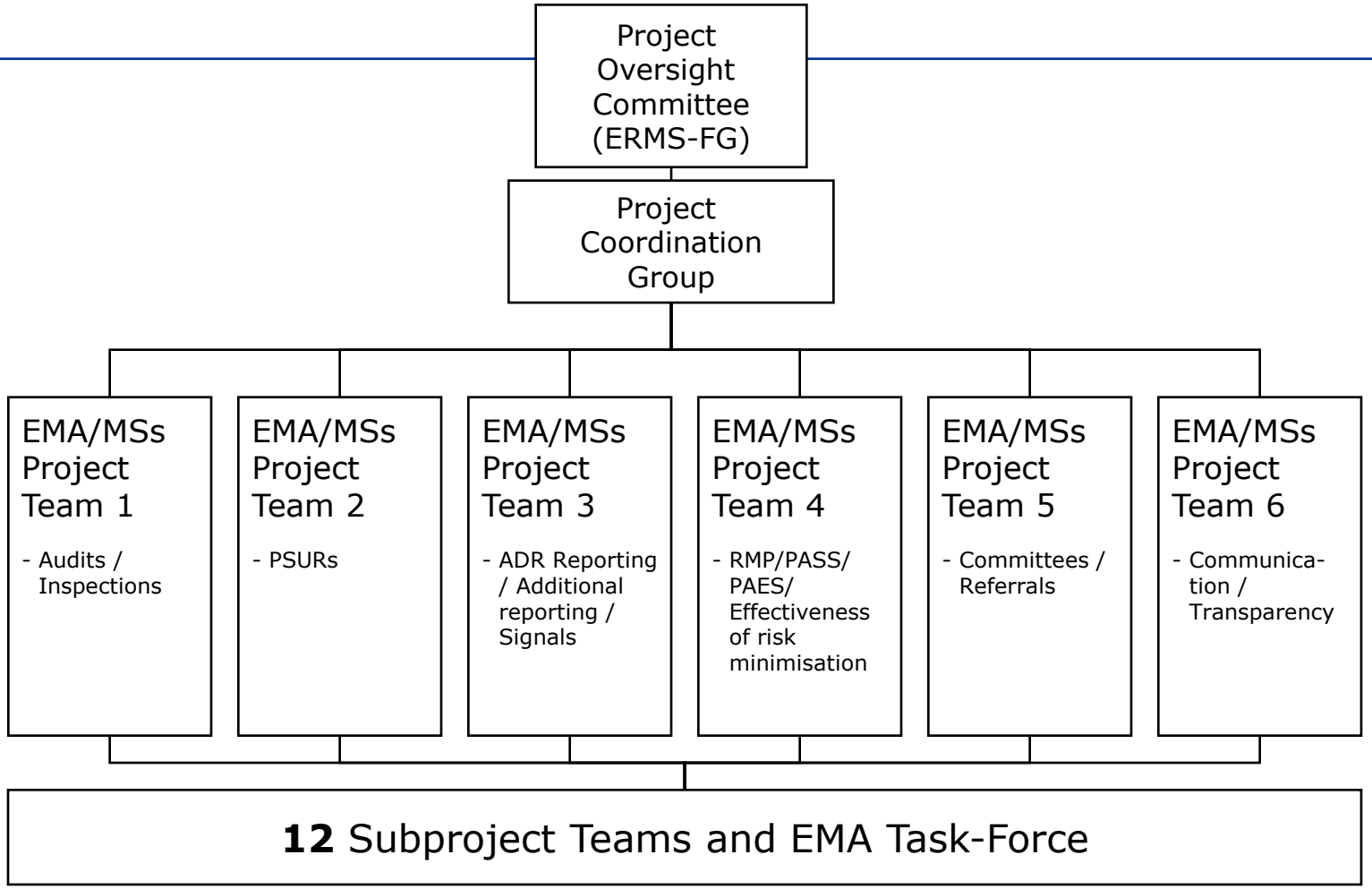
Major achievements

- Development of proposal for black symbol
- Five Stakeholders meetings held (3 in 2011 and 2 in 2012)
- Enriched governance structure (maintained until end 2012 – to be reviewed)

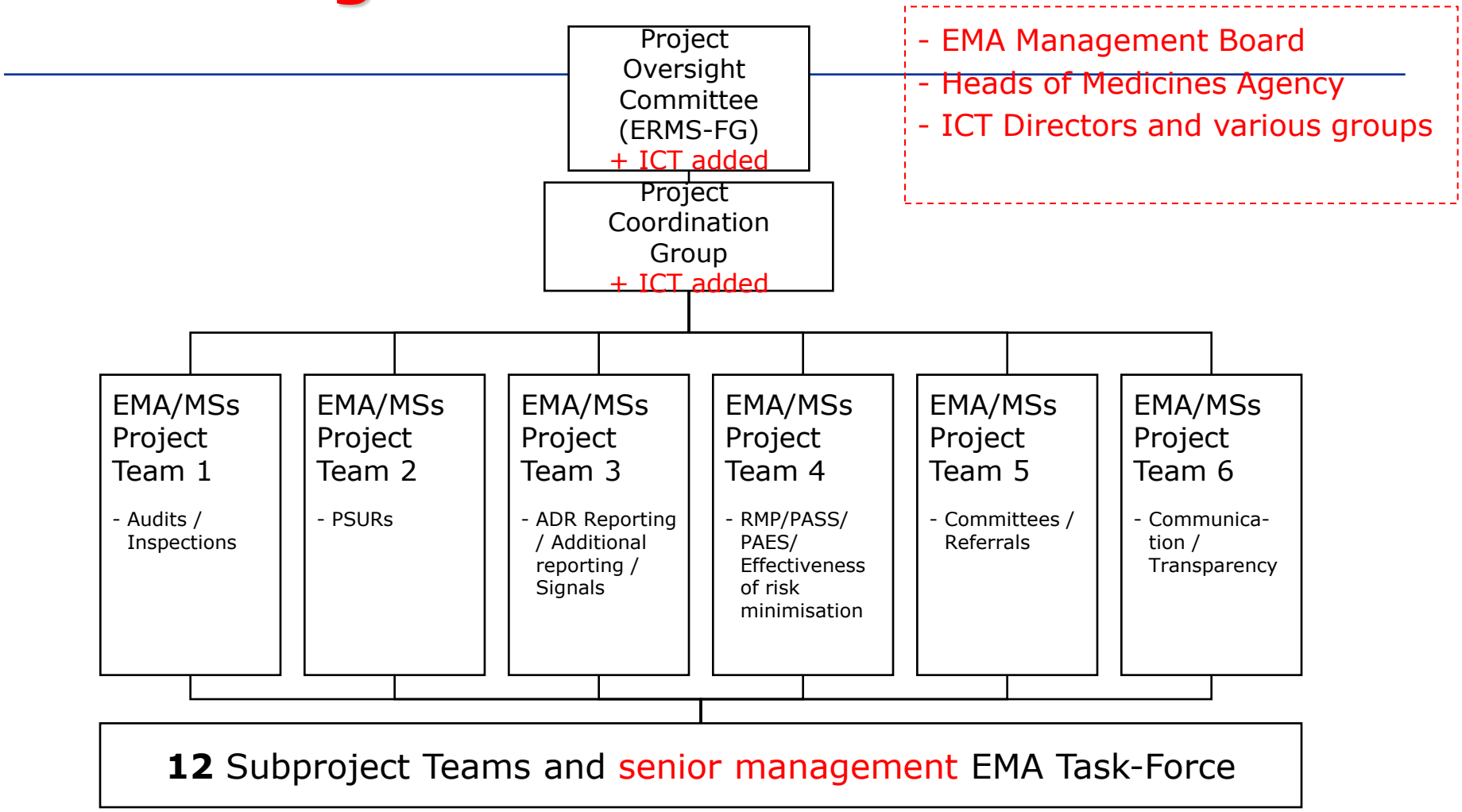
Major achievements

- Development of proposal for black symbol
- Five Stakeholders meetings held (3 in 2011 and 2 in 2012)
- Enriched governance structure (maintained until end 2012 – to be reviewed)

Enriched governance structure



Enriched governance structure



Next steps

- Lessons learnt exercise and gap analysis to be finalised
- Practical aspects of public hearings to be finalised
- SOPs/WINs/Templates being finalised
- Update of fees regulation and pharmacovigilance legislation led by the European Commission
- Sixth Stakeholders forum (8th November)
- Publication of initial lists (e.g. EURD list)
- Finalise prioritised implementation for 2012

Next steps

- Lessons learnt exercise and gap analysis to be finalised
- Practical aspects of public hearings to be finalised
- SOPs/WINs/Templates being finalised
- Update of fees regulation and pharmacovigilance legislation led by the European Commission
- Sixth Stakeholders forum (8th November)
- Publication of initial lists (e.g. EURD list)
- Finalise prioritised implementation for 2012

Next steps

- Lessons learnt exercise and gap analysis to be finalised
- Practical aspects of public hearings to be finalised
- SOPs/WINs/Templates being finalised
- Update of fees regulation and pharmacovigilance legislation led by the European Commission
- Sixth Stakeholders forum (8th November)
- Publication of initial lists (e.g. EURD list)
- Finalise prioritised implementation for 2012

Next steps

- Lessons learnt exercise and gap analysis to be finalised
- Practical aspects of public hearings to be finalised
- SOPs/WINs/Templates being finalised
- Update of fees regulation and pharmacovigilance legislation led by the European Commission
- Sixth Stakeholders forum (8th November)
- Publication of initial lists (e.g. EURD list)
- Finalise prioritised implementation for 2012

Next steps

- Lessons learnt exercise and gap analysis to be finalised
- Practical aspects of public hearings to be finalised
- SOPs/WINs/Templates being finalised
- Update of fees regulation and pharmacovigilance legislation led by the European Commission
- Sixth Stakeholders forum (8th November)
- Publication of initial lists (e.g. EURD list)
- Finalise prioritised implementation for 2012

Next steps

- Lessons learnt exercise and gap analysis to be finalised
- Practical aspects of public hearings to be finalised
- SOPs/WINs/Templates being finalised
- Update of fees regulation and pharmacovigilance legislation led by the European Commission
- Sixth Stakeholders forum (8th November)
- Publication of initial lists (e.g. EURD list)
- Finalise prioritised implementation for 2012

Next steps

- Lessons learnt exercise and gap analysis to be finalised
- Practical aspects of public hearings to be finalised
- SOPs/WINs/Templates being finalised
- Update of fees regulation and pharmacovigilance legislation led by the European Commission
- Sixth Stakeholders forum (8th November)
- Publication of initial lists (e.g. EURD list)
- Finalise prioritised implementation for 2012

Conclusion

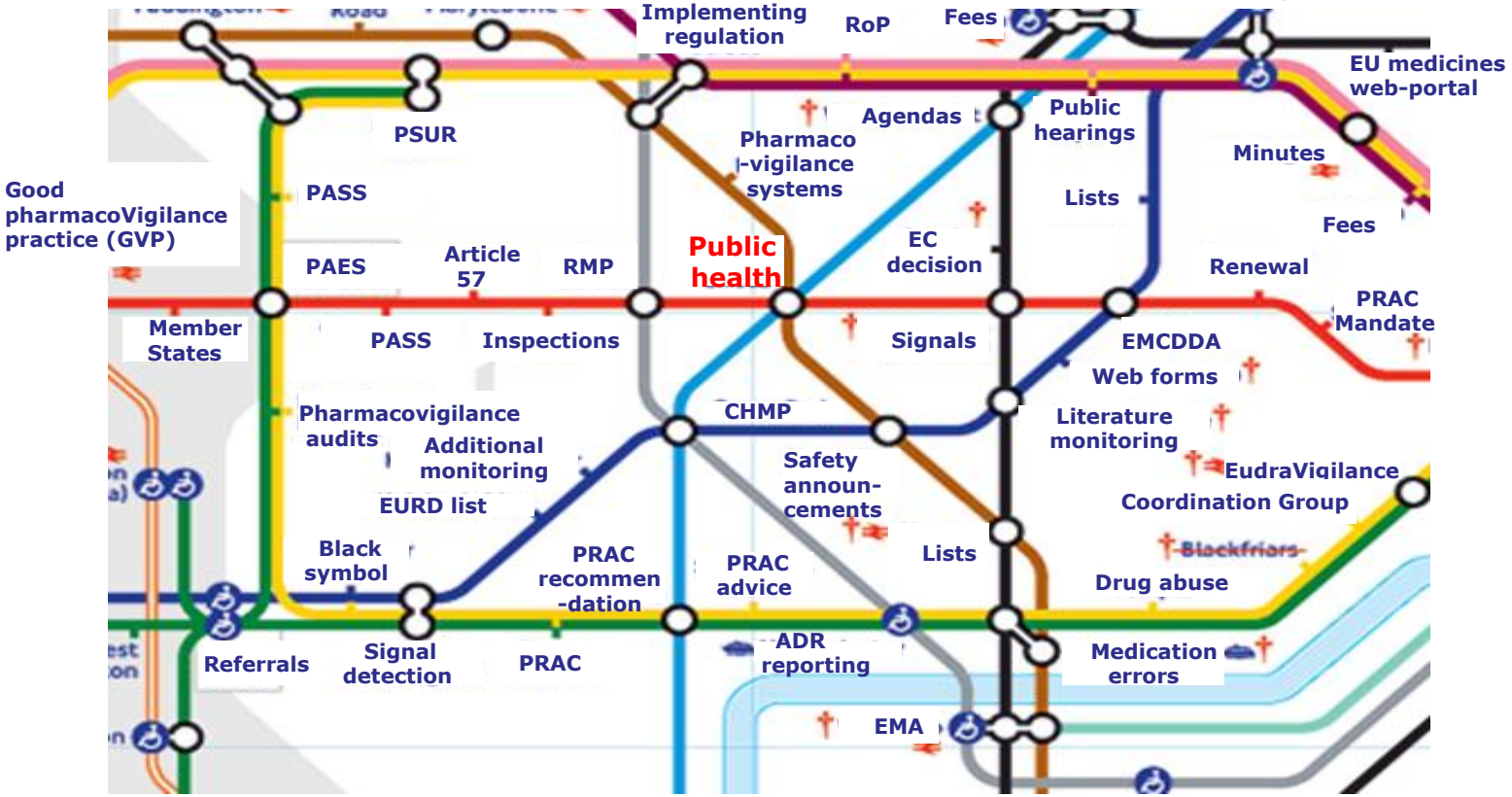
- Biggest change to the EU regulatory framework since 1995
- Funding (and staffing) remains the key risk to system sustainability
- Journey is not over yet but we have a direction of travel: focus on promotion and protection of public health!

Conclusion

- Biggest change to the EU regulatory framework since 1995
- Funding (and staffing) remains the key risk to system sustainability
- Journey is not over yet but we have a direction of travel: focus on promotion and protection of public health!

Conclusion

- Biggest change to the EU regulatory framework since 1995
- Funding (and staffing) remains the key risk to system sustainability
- Journey is not over yet but we have a direction of travel: focus on promotion and protection of public health!

Thank you

PHARMACOVIGILANCE