EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementation of the new pharmacovigilance legislation: planning and processes

Stakeholder Forum

25 May 2012

Presented by: Dr Peter Arlett,
Head, Pharmacovigilance and Risk Management
Patient Health Protection

High Level Objectives

Promote and protect public health by reducing burden of ADRs and optimising the use of medicines:

- Clear roles and responsibilities
- Robust and rapid EU decision-making
- Engage patients and healthcare professionals
- Science based - integrate benefit and risk
- Risk based/proportionate
- Increased proactivity/planning
- Reduced duplication/redundancy
- Increase transparency and provide better information on medicines

Agenda

- Countdown to July 2012
- 2012 implementation
- Beyond 2012
- Categorising the processes
- Points to note

Countdown to July 2012

Countdown to July 2012

Being finalised: implementing regulation; GVP guidance; business processes; transitional measures; rules of procedure; templates…

2 July 2012 – new Pharmacovigilance Regulation applies

21 July 2012 – new Pharmacovigilance Directive applies

19-20 July 2012 – first meeting of the Pharmacovigilance and Risk Assessment Committee (PRAC)

Shared goal to improve the promotion and protection of public health: on-target with implementation

2012 implementation
Prioritisation: EMA MB Dec 2011

- Prioritisation of the implementation
- Criteria for prioritisation:
  - Firstly, public health activities
  - Secondly, transparency and communication activities
  - Thirdly, simplification activities (primarily for pharmaceutical industry)

Implementation of the pharmacovigilance legislation by the EMA in 2012: Collection of key information on medicines (1/2)

1. Risk Management Plans:

- Establishment and operation of new procedure for requesting and assessing RMP. On target July 2012

2. Periodic Safety Update Reports:

- Operation of new procedures related to PSURs for CAPs On target July 2012
- Development and publication of harmonised birthdates to support PSUR submission On target for adoption in September 2012

Implementation of the pharmacovigilance legislation by the EMA in 2012: Collection of key information on medicines (2/2)

3. Post-Authorisation Safety and Efficacy Studies

- Implementation of the PASS procedure for protocols approval and results management for CAPs On target July 2012
- Consultation on PAES See Commission presentation

4. Electronic submission of core medicine information by MAHs ('Article 57'): product information already being received

5. Reporting by patients:

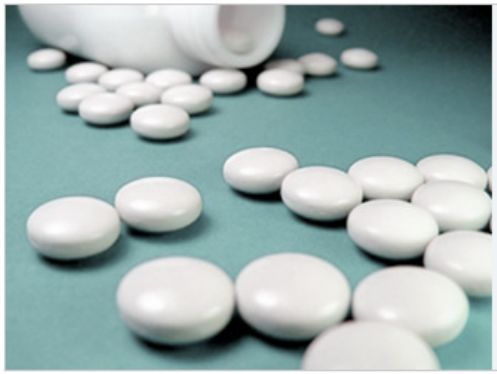
- 2012: cooperation with Member States to provide information to patients on direct reporting. On target to agree core data fields for use by Member States by July 2012

Implementation of the pharmacovigilance legislation by the EMA in 2012: Better analysis and understanding of data and information (1/2)

1. EudraVigilance and signal detection:

- Operation of revised signal detection process for CAPs On target July 2012
- Support Member States to operate the new EU signal detection processes for NAPs On target September 2012
- Start of signal management through the Pharmacovigilance and Risk Assessment Committee (PRAC) On target to start July 2012
- Continuation of maintenance work for the current EV system including data quality Ongoing: 46,000 duplicate cases removed last year + 140,000 product / substances entries in ICSRs recoded
- Implementation of web-publishing of adverse reaction data (further to the EV Access Policy) On target May 2012……

Online access to suspected side-effect reports



On this website you can view data on **suspected side-effects** also known as suspected adverse drug reactions for authorised medicines in the European Economic Area (EEA).

This data is presented in a format called a **web report**. Currently the data only relates to medicines approved through the **centralised authorisation procedure**.

Search for a report

Search here for suspected adverse drug reaction reports

News

More news...

How to report a side-effect

Key information

- The information on this website relates to ***suspected* side effects**, i.e. medical events that have been observed following the use of a medicine, but which are **not necessarily related to or caused by the medicine**.
- Information on suspected side effects **should not be interpreted** as meaning that the medicine or the active substance causes the observed effect or is **unsafe to use**. Only a detailed evaluation and scientific assessment of all available data allows for robust conclusions to be drawn on the benefits and risks of a medicine.
- The European Medicines Agency publishes this data so that its stakeholders, including the general public, can access information that European regulatory authorities use to review the safety of a medicine or active substance. **Transparency** is a key guiding principle of the Agency.

Implementation of the pharmacovigilance legislation by the EMA in 2012: Better analysis and understanding of data and information (2/2)

2. Additional monitoring:

– Develop and publish the list of medicines with additional monitoring status. On target October 2012

3. IT systems to support processing and analysis of data:

– Finalisation of business requirements for enhanced IT systems. On target 2012 – pragmatic use of existing systems until budget available

Implementation of the pharmacovigilance legislation by the EMA in 2012: Regulatory action to safeguard public health

1. Scientific committees and decision-making:

- Establishment of new committee (PRAC) and new responsibilities for CMD(h) On target July 2012

2. Strengthening referral procedures:

- Operation of new referral procedure (Urgent Union Procedure) On target July 2012

Implementation of the pharmacovigilance legislation by the EMA in 2012: Communication with stakeholders

1. **Online publishing of information:**

– Publication (on EMA website) of agendas, minutes, assessments, approvals, recommendations, opinions and decisions of PRAC, CMD(h) and CHMP. On target July 2012 for PRAC outputs…..

2. **Coordination of safety messages:**

– Operation of the coordination of Member States' safety announcements for non-CAPs. On target July 2012

3. **Public hearings:**

– Introduction of public hearings in the context of Urgent Union Procedure if appropriate referral in autumn 2012

So….

On target


Resolution 4500x3375 px
Free hi-res JPG file download
www.psdgraphics.com

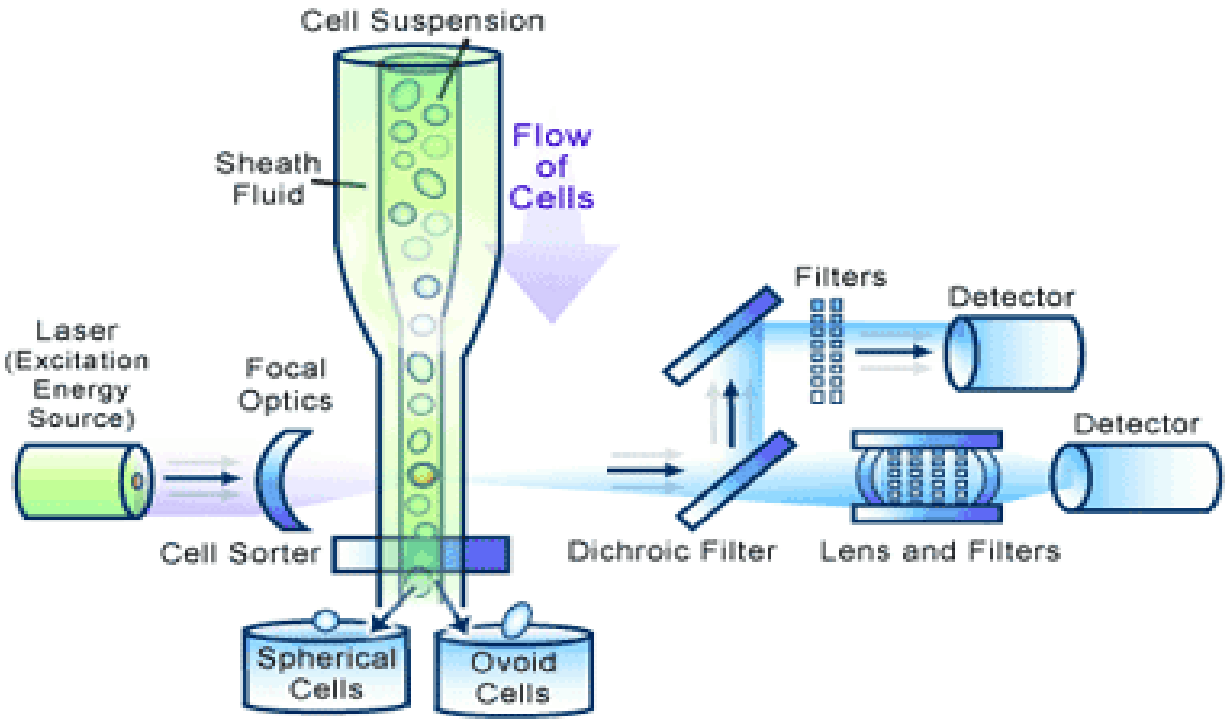
Implementation beyond 2012

- 2013 e.g.
  - –aggregated ADR data published for substances in commonly used nationally authorised products
- 2014 e.g.
  - –New fees for pharmacovigilance
- 2015 all assessment processes at full capacity e.g.
  - –Single assessment procedure for nationally authorised product Periodic Safety Update Reports
- 2016 e.g.
  - –Enhanced EudraVigilance system and centralised EMA reporting
  - –New ISO standards in use for adverse reaction and medicinal product reporting

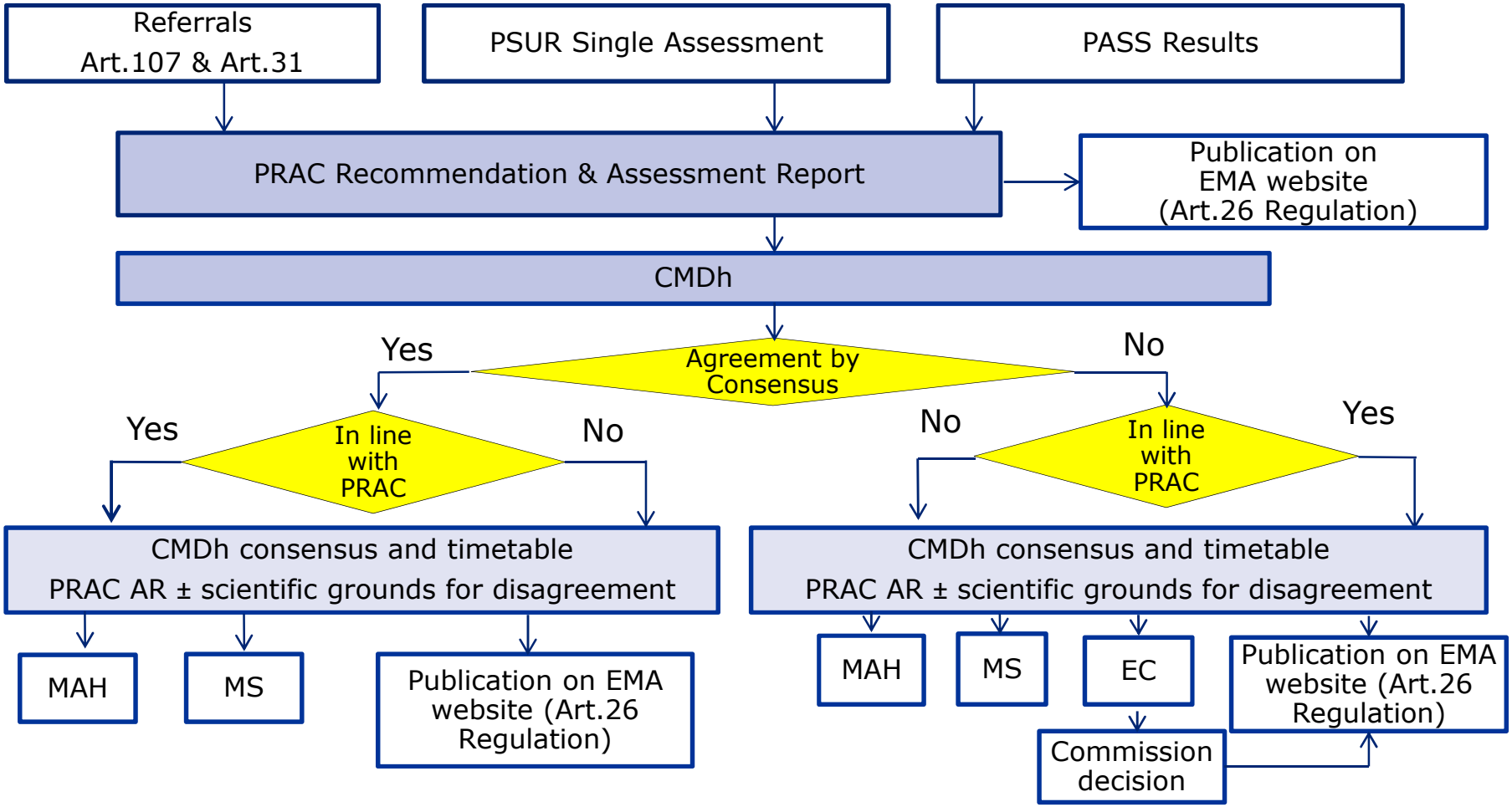
Categorising the business processes

>30 new or amended major processes

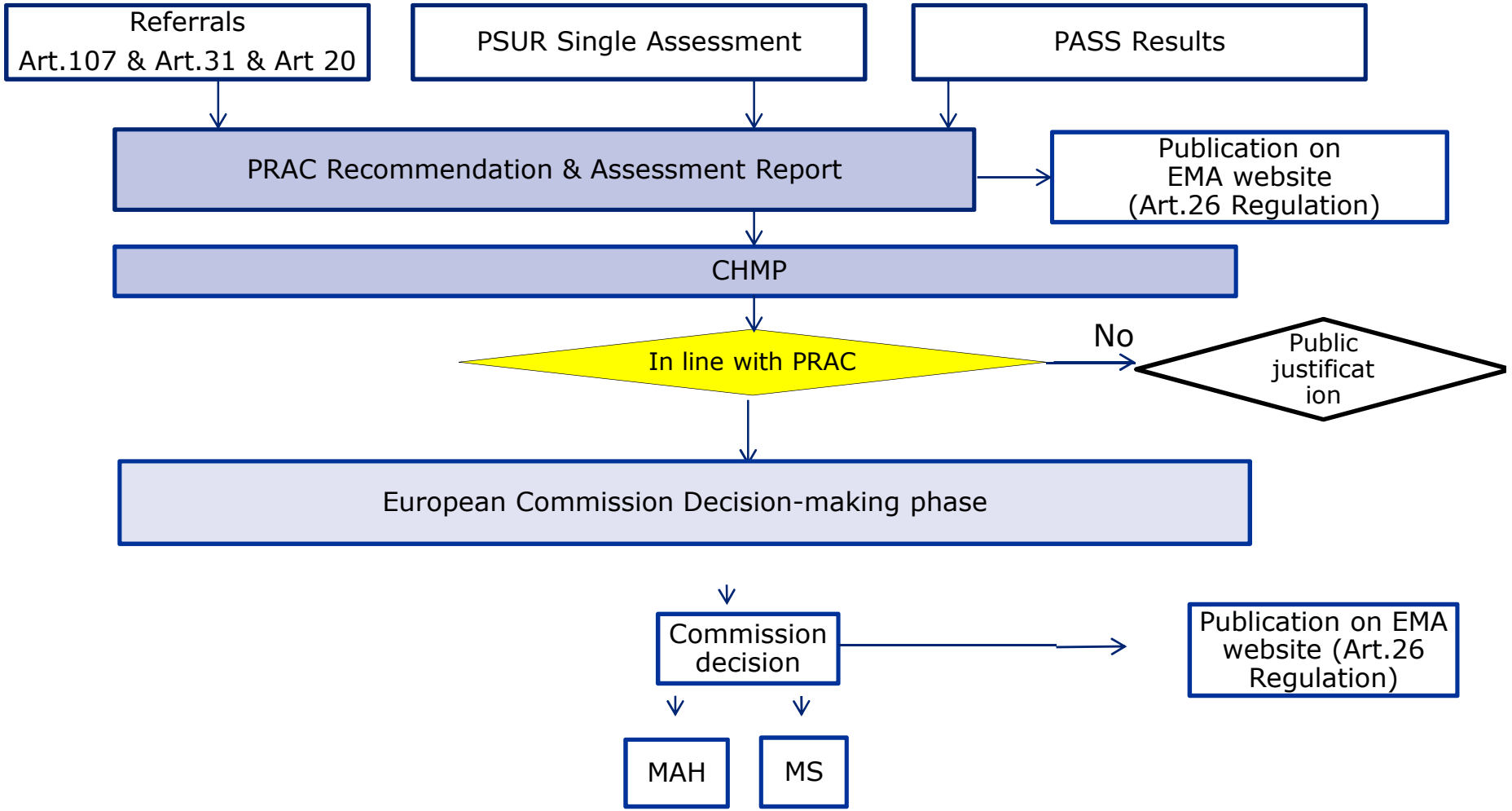
>100 new of amended sub-processes



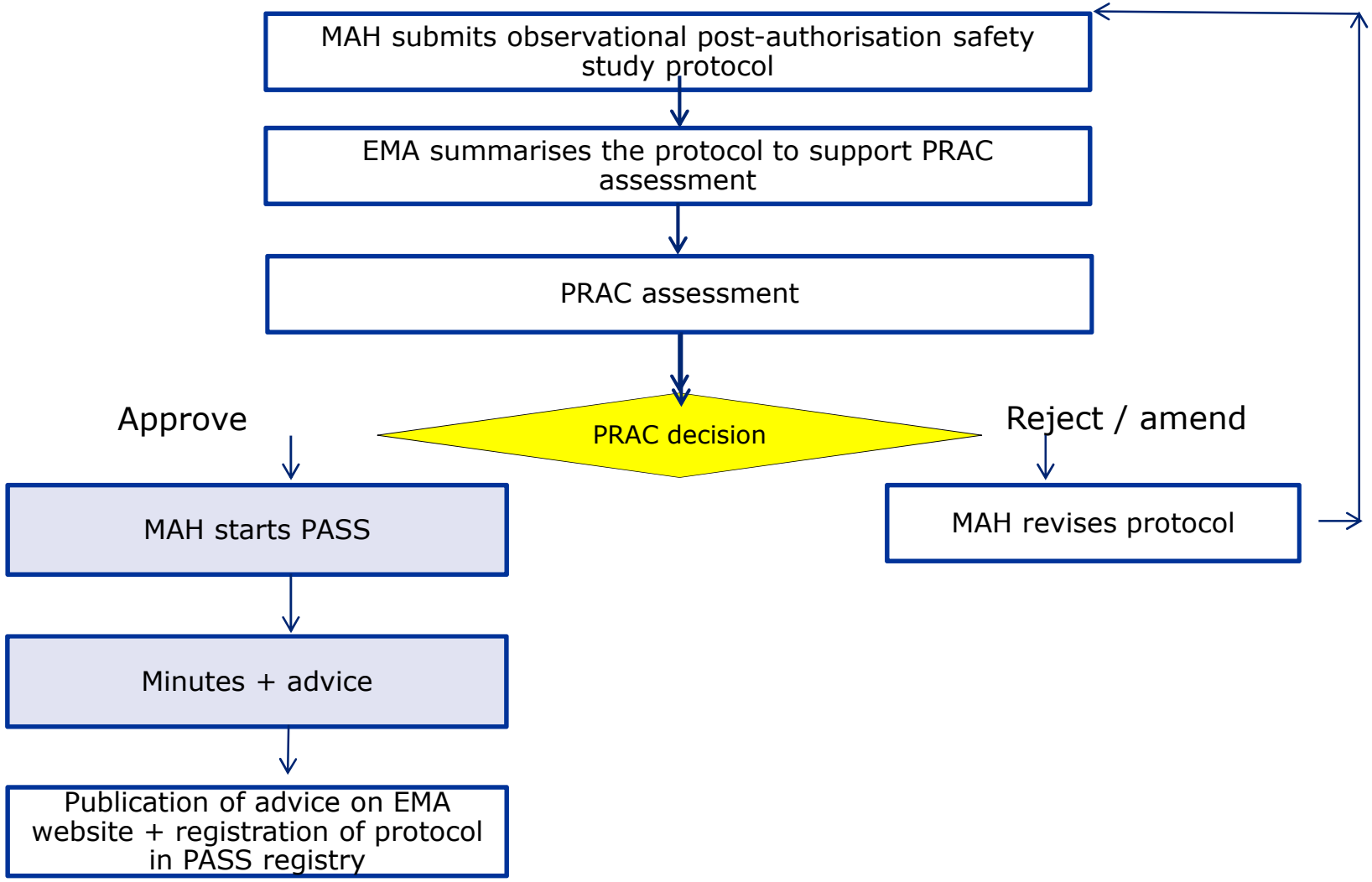
A. Outputs Aa – PRAC Output with formal decision-making phase – NAPs only



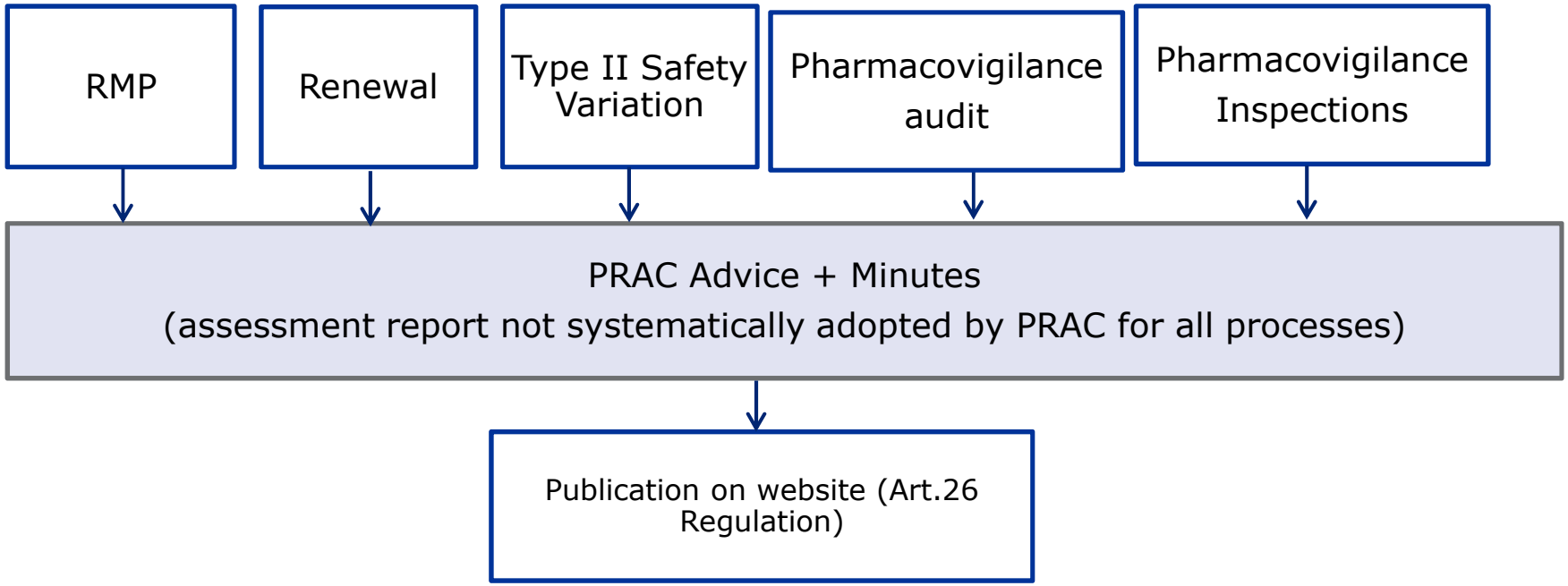
A. Outputs Ab – PRAC Output with formal decision-making phase –includes one or more CAP



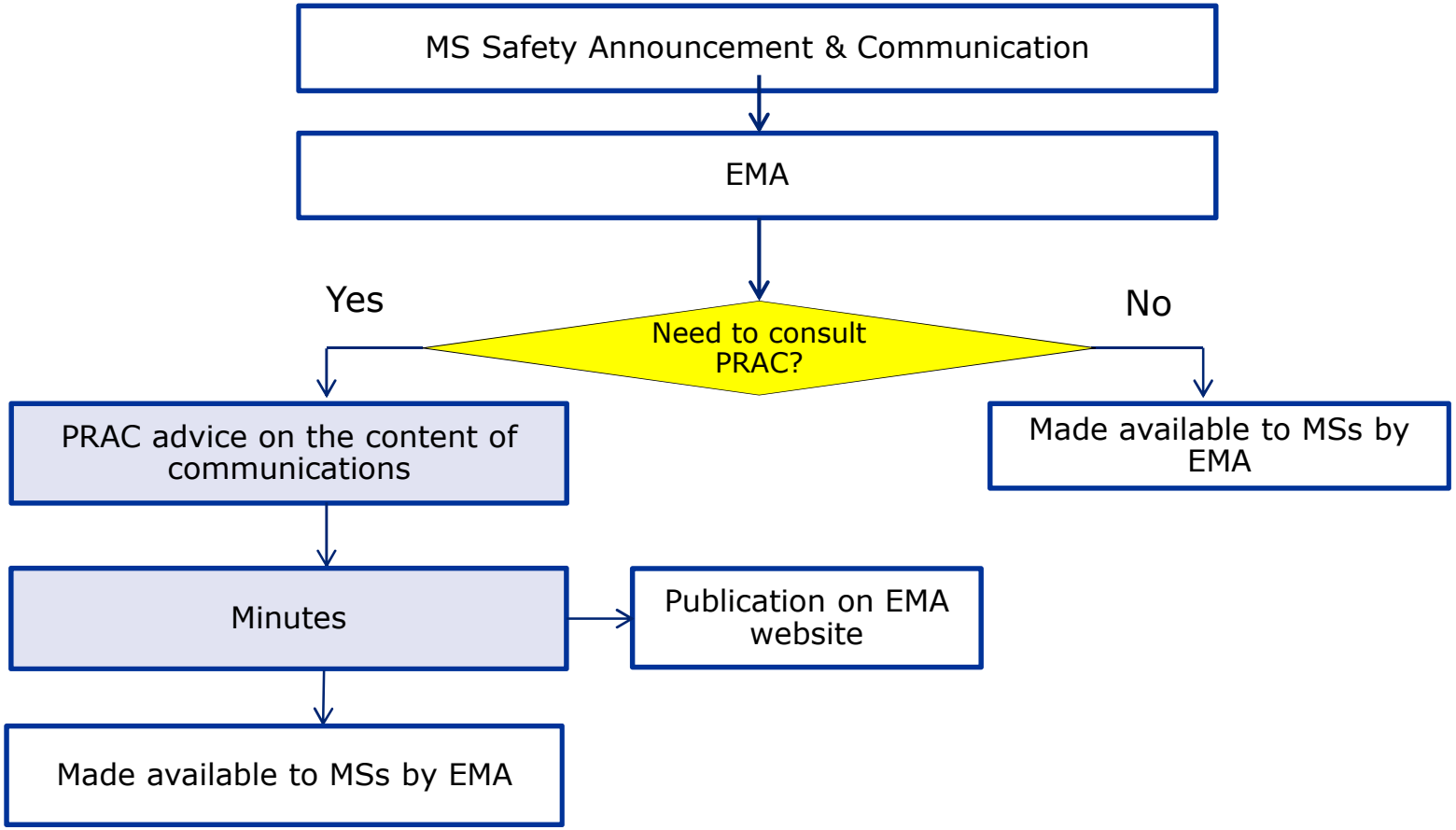
Outputs Ba – PRAC Output without formal decision-making phase: Directly applicable output (PASS protocol)



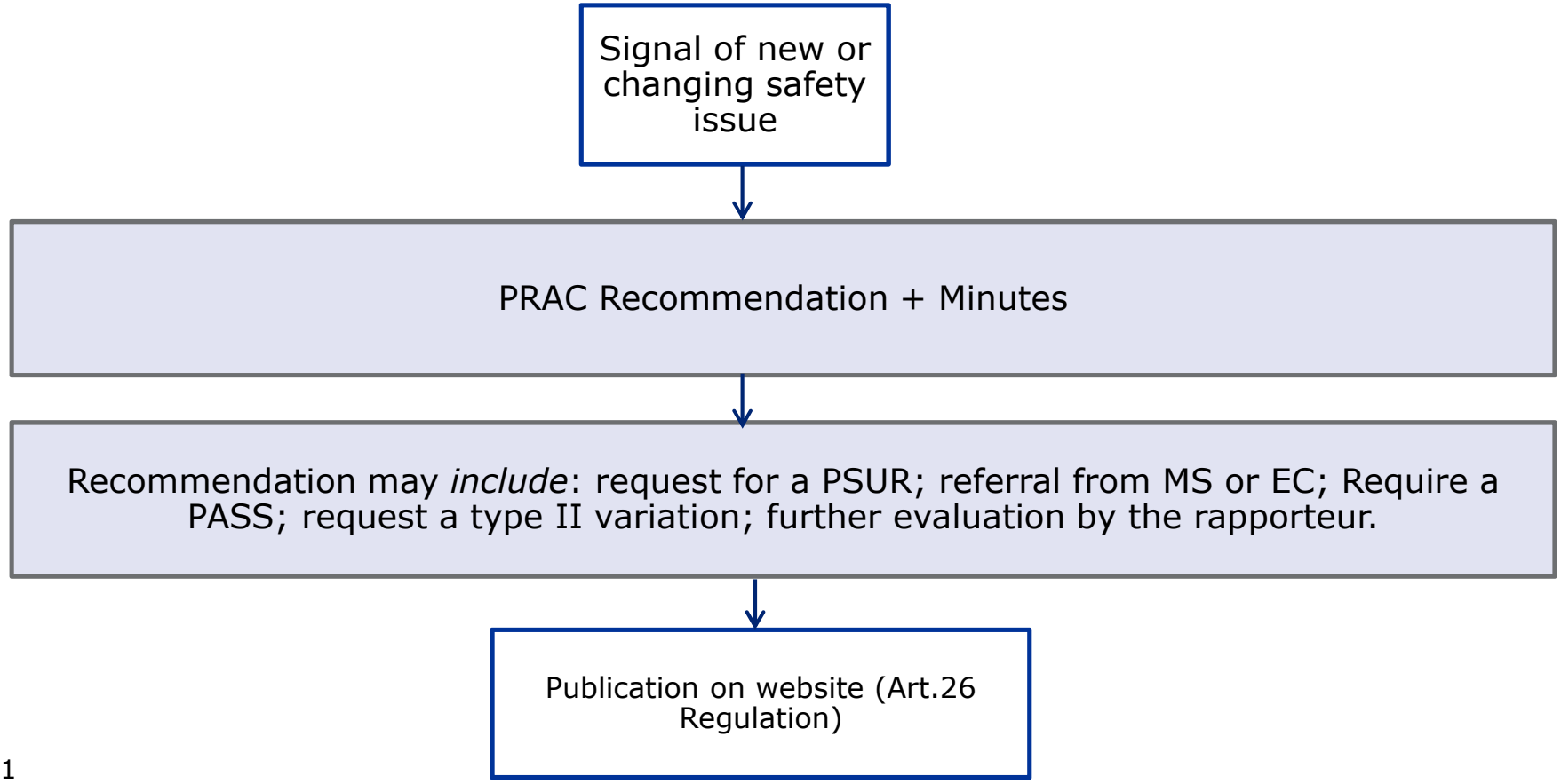
Outputs Bb –PRAC Output without formal decision-making phase: output = advice



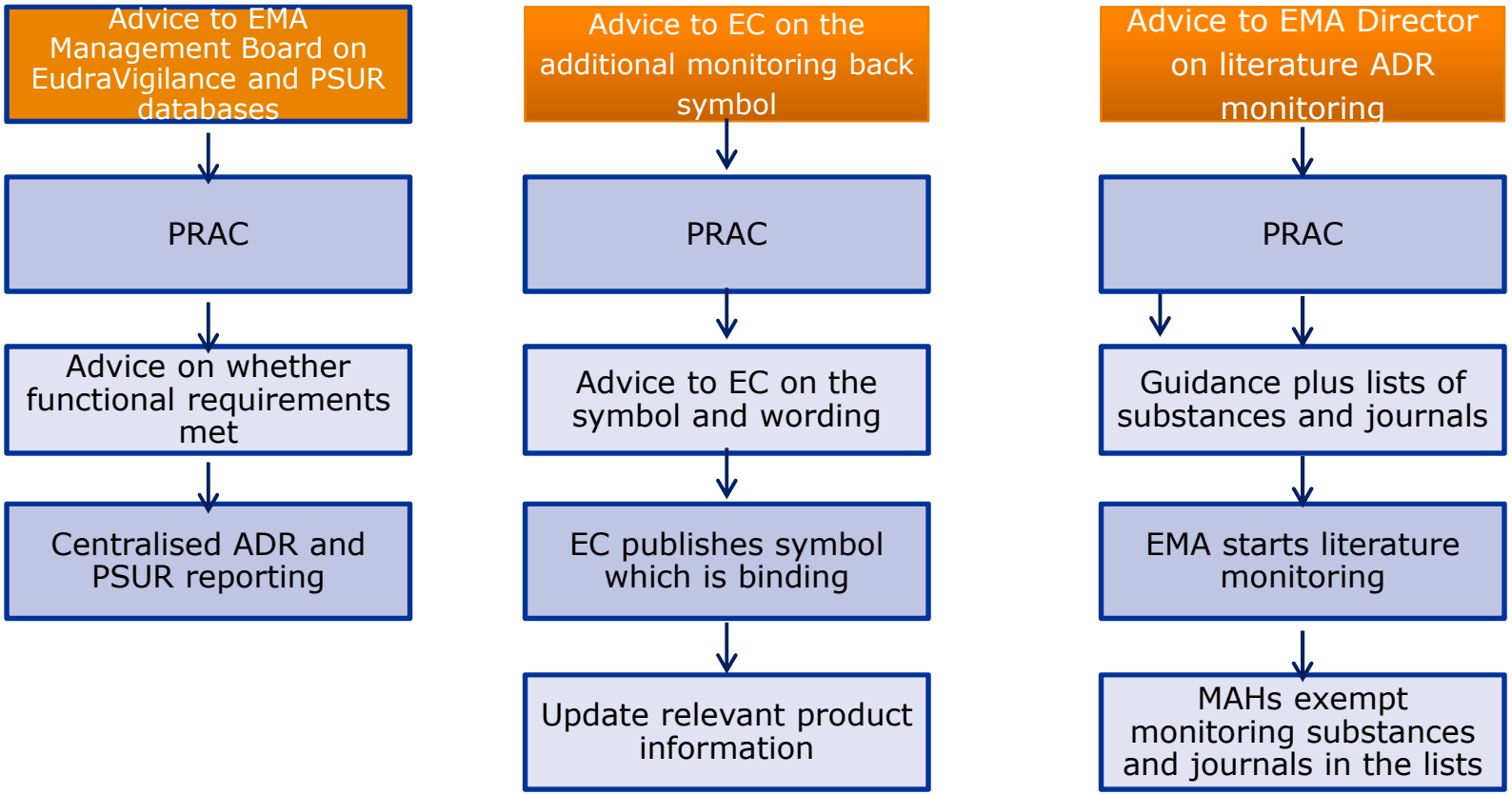
Outputs Bc –PRAC Output without formal decision making phase: output = advice (Safety announcement & communication)



Outputs Bd –PRAC Output without formal decision making phase: output = recommendation (signal management)

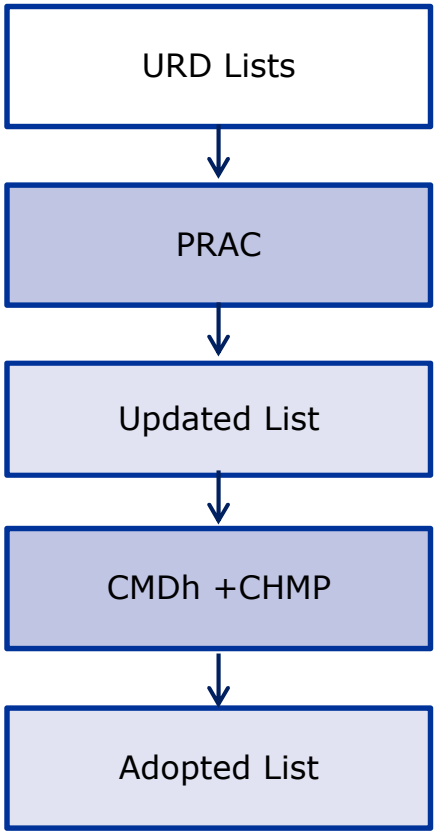


Outputs C – Other PRAC advice (no step through CHMP or CMDh)

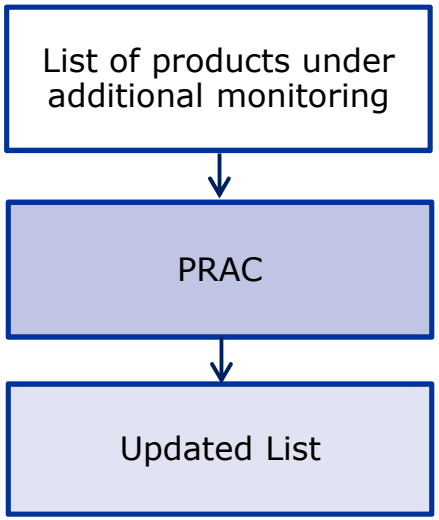


Outputs D – Lists

Da

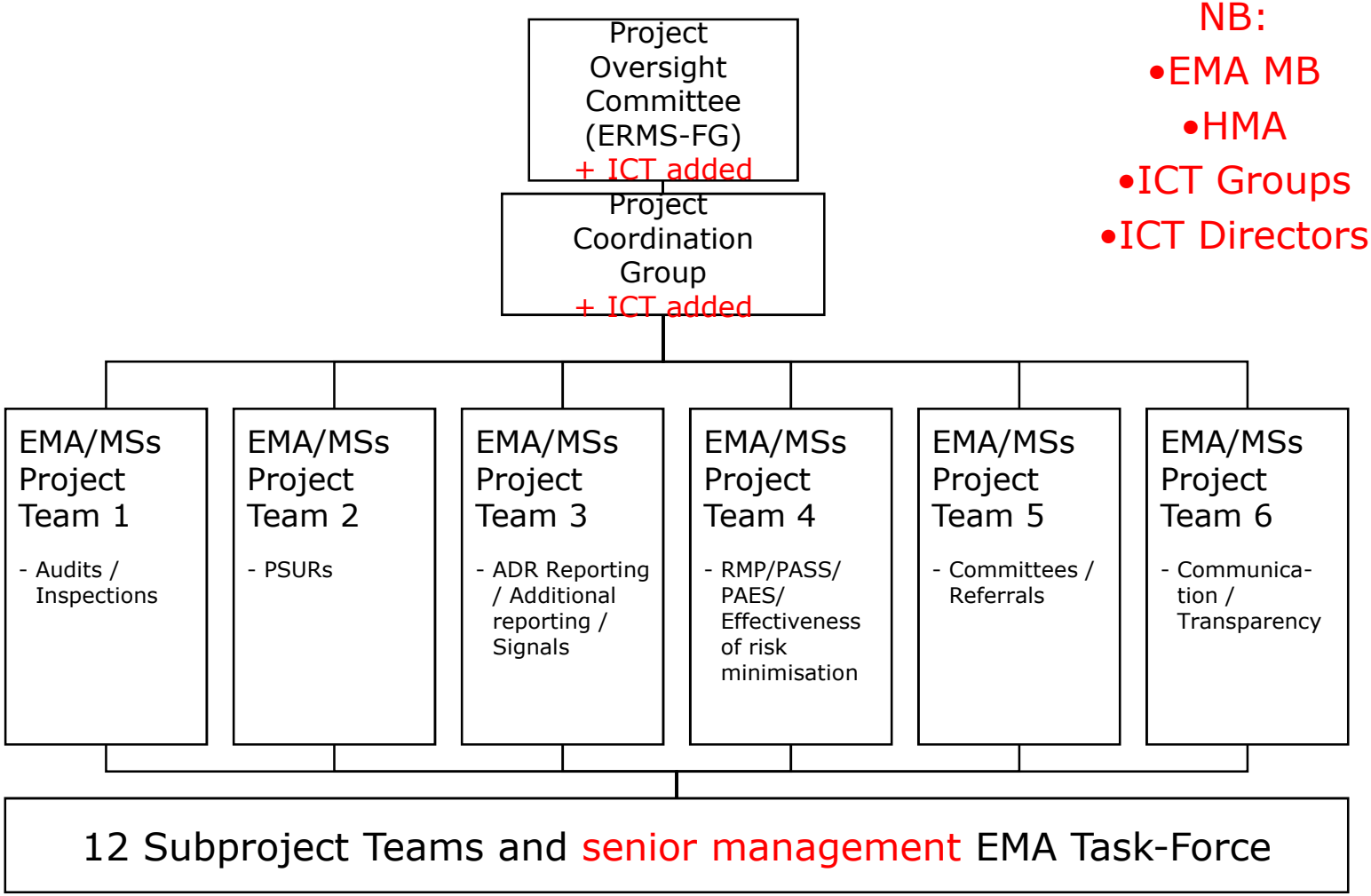


Db



Points to note

Governance structure enhanced 2012



NB:

- EMA MB
- HMA
- ICT Groups
- ICT Directors

Points to note: Gap analysis

April 2012 – Project Coordination Group and ERMS-FG

Finalised gap analysis:

- Conclusion - no critical gaps but small operational gaps identified: e.g.
  - Further elaboration of international strategy needed

Points to note: PSURs + PSUR EURD

Public consultation on the draft EURD lists currently open (until 4 June)

Points to note: Guidance

- Renewal guidance consultation now closed
- Variation classification guidance well advanced
- Referrals – procedural guidance consult July
- GVP first wave – on target for late June publication as final
- GVP - mid June consultations on inspections and additional monitoring
- GVP 3rd quarter – consultations on audit, communications, risk minimisation
- GVP 4th quarter – continuous PhV, patient participation, ?international collaboration

Points to note: Training

- Developing strategy for training to support implementation
- Built around GVP
- Core materials adapted for different stakeholders
- Leveraging existing delivery mechanisms with emphasis on web-based training

Points to note: Training Article 57

- to supplement face to face training - E-learning for industry now available

Points to note: Transitional Q&As

23 May 2003, published:

- Extensive Q&A for practical implementation
- MS ADR reporting requirements
- PSUR submission requirements

PASS notification requirements to come in July

More Q&A possible July (QandA-PV-legislation@ema.europa.eu)*

*Please note that no individual responses will be provided but questions received will be reviewed on a regular basis and form the basis for any further questions and answers updates.

New pharmacovigilance legislation: a marathon and not a sprint for public health