EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Risk Management Plan publications in European Public Assessment Reports

Transparency of Safety Information

8th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines
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Access to Documents
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Background

- Aim to further increase **transparency of safety information** for public/stakeholders;
- RMP **summary already published** in EPARs for all products;
- **Experience with Covid-19 products RMP** publication in EPARs already gained;
- RMPs are requested by companies for **generic products**. Public access will make RMPs readily available;
- **Data on Access To Documents** (ATD) requests showed that the RMP is one of the documents most frequently requested for release (>200 RMPs requested in 2020);
- RMP (main body and Annexes 4 and 6, as single PDF) to **replace the RMP summary** in EPARs.

How the process will be facilitated

Updates of the **Pre- and Post-authorisation guidance** documents (Q&As) to include instructions for preparing a RMP for publication in EPARs.

Update of the **RMP Guidance** for drafting a RMP, and preparing for publication.

Use of the latest RMP template

Short **Guidance to Industry** for quick reference, to omit any **Commercially Confidential Information** (CCI) and anonymise **Protected Personal Data** (PPD)

CCI is identified by the Company, and rarely found in RMPs.

PPD has been identified some times, and mainly:

- In clinical trials data (when interim, or not aggregated)
- In narratives of adverse events, deaths, serious adverse events (SAEs), sensitive populations (HIV patients, immunocompromised etc.)

Which Products

Phased approach

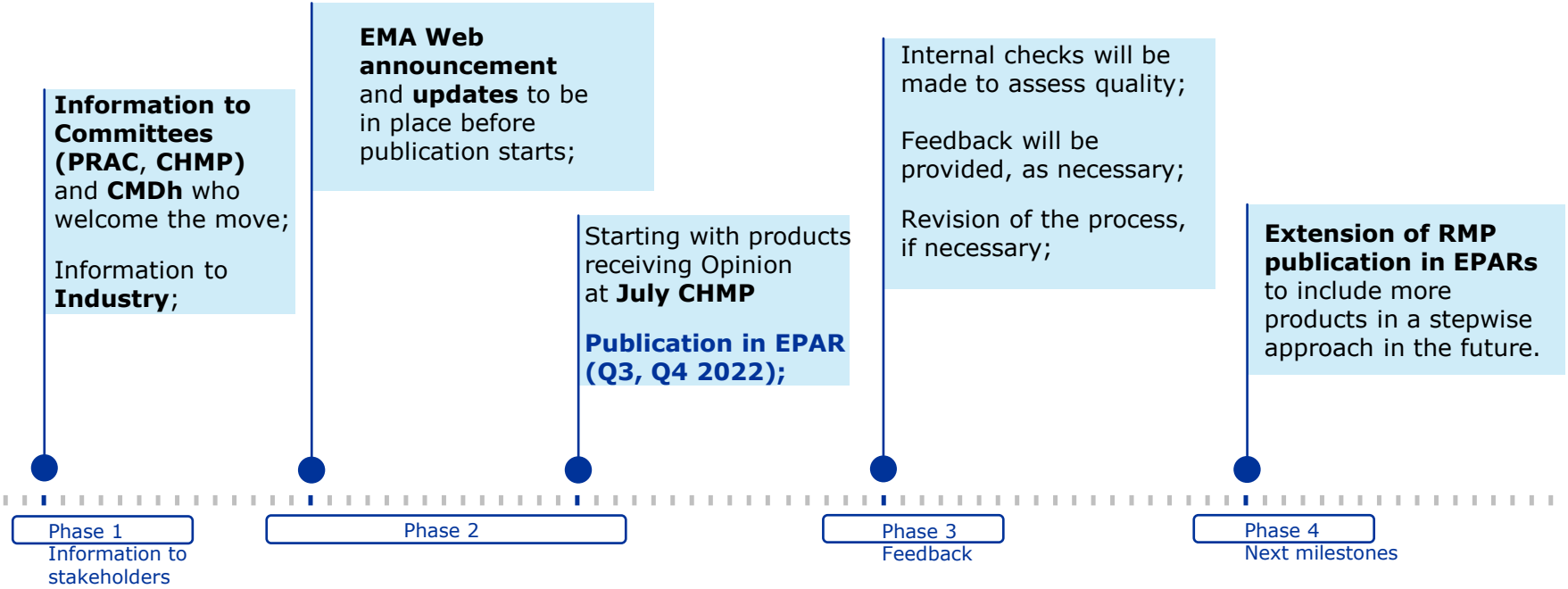
New applications

- **All Covid-19 related product** RMPs (already in place).
- **Newly centrally authorised products (CAPs)**
  new active substance Article 8.3 Directive 2001/83/EC;
  class products of the same new active substance;
  and its fixed-dose combination
  (average 4-5 RMPs/month).
- Once a RMP is published, its updates will be published, too.

Products already authorised

- **Most frequently re-released RMPs for CAPs**
  (ATD released at least twice).
  Approximately 18 CAPs;
  Start publication with ones requested more than 7 times e.g. Gilenya, Revlimid, Xarelto, Zytiga, Exjade);
- Once a RMP is published, its updates will be published, too.

Next phase and timelines



Any questions?

Further information

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