EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PSUR frequencies for active substances with DLP 2025 based on a risk-based approach

19th Industry Stakeholders Platform- Operation of EU Pharmacovigilance

Presented by Marta López Fauqued on behalf of Granularity and Periodicity Advisory Group (GPAG) on 15th November 2024

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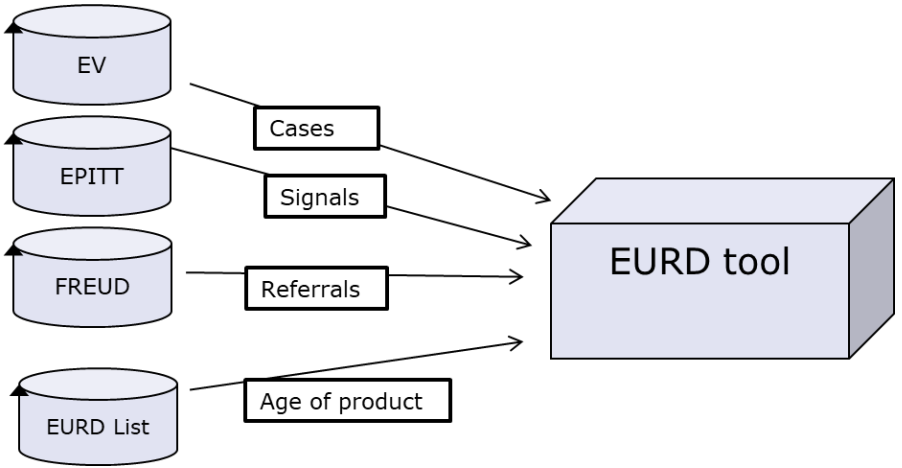
Background

- 17th Industry Stakeholders platform meeting
- EURD list is a comprehensive list of active substances and combinations of active substances contained in medicinal products subject to different marketing authorizations (**> 3,000** active substances)
  - EU reference dates, frequencies for submission of periodic safety update reports (PSURs) and related data lock points (DLPs).
- GVP VII provides risk-based criteria to define the frequency of PSUR submission
- EURD list contained a set of ~ 1,000 entries which PSURs assessments were initially deferred as other active substances were prioritised. These deferred PSUSAs were due in 2025 → PSUSAs have never been evaluated by PRAC

EURD tool

- Project leaded by **Granularity and Periodicity Advisory Group (GPAG)**, who provides advice to the **Pharmacovigilance Risk Assessment committee (PRAC)**

- **Statistical tool** to support decision making for determining PSUR frequencies of EURD List entries centered on on readily available safety-relevant data



Update

- All impacted substances have received a new Data Lock Point and a new frequency for the first PSUSA
- Implementation in EURD List started in 2023 - different phases
- Update will be completed in the next EURD list update
- Details on the methodology used to determine the PSUR frequency have been published in a peer review publication: Frontiers | Predicting the submission frequency of periodic safety update reports: development and application of the EURD tool

Reminders

- Reporting period:
  - A PSUR has been previously submitted in EU (e.g. national level): from the DLP of that PSUR until the DLP mentioned in the EURD list.
  - A PSUR has not been previously been submitted in EU: all data since launch of the product until the DLP mentioned in the EURD list.

  → It is acknowledged that the reporting period for the first PSUR will cover a longer period than the one indicated by the PSUR frequency.
- MAHs can propose and justify a new PSUR frequency with their upcoming submission for LMS assessment
- The EURD list is a dynamic document frequently updated in response to regulatory changes and to improve clarity on the scope of each procedure
- It is the responsibility of the marketing authorisation holder to check regularly the list of EU reference dates and frequency of submission

Any questions?

Further information

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