EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 3 - 6 July 2023

News 07/07/2023

At its monthly meeting, EMA's safety committee (PRAC) carried out its broad range of responsibilities, which cover all aspects of the risk management of the use of medicines: assessment of safety signals, risk management plans, periodic safety update reports and post-authorisation safety studies.

The Committee did not start or conclude any referral procedures. More information on all safety reviews currently under evaluation is provided in the 'Ongoing referrals' table. Information on all topics discussed by the PRAC is available in the agenda below.

Agenda

Agenda of the PRAC meeting 3-6 July 2023 (PDF/613.16 KB) (new)

Draft

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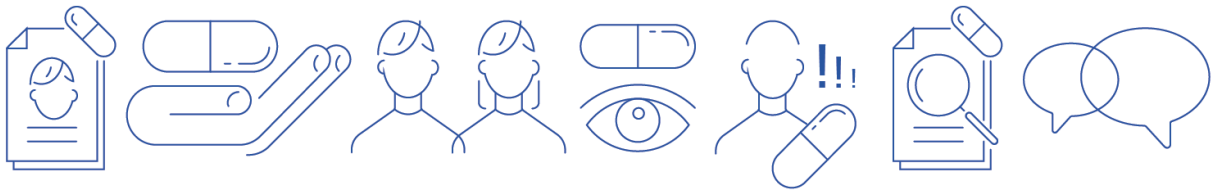
PRAC statistics: July 2023

PRAC statistics

July 2023



7 Safety signals

- 6 Started
- 1 Ongoing/concluded

78 Periodic safety update reports (PSURs) single assessments

- 50 Recommendations for centrally authorised medicines only
- 25 Recommendations for nationally authorised medicines only
- 3 Recommendations for PSURs including both centrally and nationally authorised medicines

56 Risk management plans (RMPs) for centrally authorised medicines

- 8 RMPs reviewed for new medicines
- 48 RMPs reviewed for authorised medicines

30 Post-authorisation safety studies (PASSs)

- 3 Protocols for imposed studies reviewed
- 16 Protocols for non-imposed studies reviewed
- 2 Results from imposed studies reviewed
- 9 Results from non-imposed studies reviewed

0 Referrals

- 0 Started
- 0 Ongoing/concluded

Direct healthcare professional communications (DHPCs)

PRAC minutes | PRAC recommendations on safety signals | Outcomes of PSUSAs

PRAC statistics: July 2023 (PDF/537.5 KB) (new)

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Glossary:

- **Safety signal assessments**. A safety signal is information which suggests a new potentially causal association, or a new aspect of a known association between a medicine and an adverse event that warrants further investigation. Safety signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. More information can be found under 'Signal management'.
- **Periodic safety update reports**, abbreviated as PSURs, are reports prepared by the marketing authorisation holder to describe the worldwide safety experience with a medicine in a defined period after its authorisation. PSURs for medicinal products that contain the same active substance or the same combination of active substances but have different marketing authorisations and are authorised in different EU Member States, are jointly assessed in a single assessment procedure. More information can be found under 'Periodic safety update reports: questions and answers'.
- **Risk management plans**, abbreviated as RMPs, are detailed descriptions of the activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicines. Companies are required to submit an RMP to EMA when applying for a marketing authorisation. RMPs are continually updated throughout the lifetime of the medicine as new information becomes available. More information is available under 'Risk-management plans'.
- **Post-authorisation safety studies**, abbreviated as PASSs, are studies carried out after a medicine has been authorised to obtain further information on its safety, or to measure the effectiveness of risk-management measures. The PRAC assesses the protocols (aspects related to the organisation of a study) and the results of PASSs. More information can be found under 'Post-authorisation safety studies'.
- **Referrals** are procedures used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral related to safety of medicines, the PRAC is requested by a Member State or the European Commission to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the EU. More information can be found under referral procedures.
- **Summary safety reports** have been introduced as part of the enhanced safety monitoring of COVID-19 vaccines. Marketing authorisation holders are required to submit these reports to EMA, starting on a monthly basis. Their submission complements the submission of PSURs. For more information see EMA's pharmacovigilance plan for COVID-19 vaccines.

Ongoing referrals

Procedure
Topiramate – Article-31 referral

Status
Under evaluation

Update

PRAC continued its assessment

Procedure
Pseudoephedrine-containing medicinal products - Article - 31 referral

Status
Under evaluation

Update
PRAC continued its assessment

Procedure
Hydroxyprogesterone-containing medicinal products – Article-31 referral

Status
Under evaluation

Update
PRAC continued its assessment

Related content

- Hydroxyprogesterone-containing medicinal products: Article 31 referrals
- Pseudoephedrine-containing medicinal products: Article 31 referrals
- Topiramate: Article 31 referrals

- Pharmacovigilance Risk Assessment Committee (PRAC): 3-6 July 2023
- PRAC: Agendas, minutes and highlights

Related documents

Abbreviations used in EMA human medicines scientific committees and CMDh documents, and in relation to EMA's regulatory activities (PDF/255.03 KB) (updated)

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