EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 25-28 September 2023

News 29/09/2023

New safety information for Omega-3-acid ethyl esters

The PRAC agreed to add atrial fibrillation (irregular, rapid contraction of the heart) as a common side effect to the product information for medicines containing omega-3-acid ethyl esters. These medicines are indicated for the treatment of hypertriglyceridaemia, when a modification of diet and lifestyle alone are not sufficient to bring down levels of triglyceride, a type of fat, in the blood. Hypertriglyceridemia is a risk factor for coronary artery disease. Patients on these medications often have other conditions such as cardiovascular diseases and diabetes.

During a Periodic Safety Update Single Assessment (PSUSA) procedure, the PRAC considered systematic reviews and meta-analyses of randomised controlled clinical trials which highlighted a dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors treated with omega-3-acid ethyl esters compared to placebo. The observed risk is highest with a dose of 4 g/daily. If atrial fibrillation develops, treatment should be permanently discontinued.

The PRAC agreed to recommend an update to the product information to inform healthcare professionals and patients of the risk of atrial fibrillation. A Direct Healthcare Professional Communication (DHPC) will be sent shortly to provide doctors with further details.

Once adopted, this DHPC will be forwarded to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh). Following the CMDh opinion, the DHPC will be disseminated to healthcare professionals by the marketing authorisation holder, according to an agreed communication plan, and published on the Direct healthcare professional communications page and in national registers in EU Member States.

Agenda

Agenda of the PRAC meeting 25-28 September 2023 (PDF/507.29 KB) (new)

Draft

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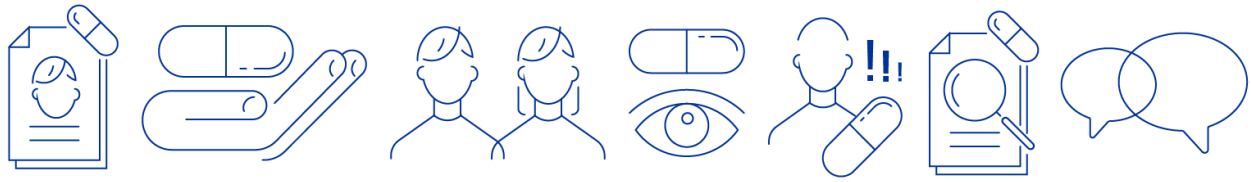
PRAC statistics: October 2023

PRAC statistics

October 2023



8 Safety signals

- 5 Started
- 3 Ongoing and concluded

89 Periodic safety update reports (PSURs) single assessments

- 62 Recommendations for centrally authorised medicines only
- 25 Recommendations for nationally authorised medicines only
- 2 Recommendations for PSURs including both centrally and nationally authorised medicines

43 Risk management plans (RMPs) for centrally authorised medicines

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

42 Post-authorisation safety studies (PASSs)

- 4 Protocols for imposed studies reviewed
- 26 Protocols for non-imposed studies reviewed
- 3 Results from imposed studies reviewed
- 9 Results from non-imposed studies reviewed

2 Referrals

- 0 Started
- 2 Ongoing and concluded

Direct healthcare professional communications (DHPCs)
PRAC minutes | PRAC recommendations on safety signals | Outcomes of PSUSAs

EMA

PRAC statistics: October 2023 (PDF/529.42 KB) (new)

First published: 29/09/2023

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
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

- Pharmacovigilance Risk Assessment Committee (PRAC): 25-28 September 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)

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