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SCIENCE MEDICINES HEALTH

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News announcement

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

New safety information for Omega-3-acid ethyl esters

The PRAC recommended 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.

The recommendation is the outcome of a Periodic Safety Update Single Assessment (PSUSA). The PRAC considered systematic reviews and meta-analyses of randomized 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 now recommends 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.

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