



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency concludes on use of celecoxib in familial adenomatous polyposis

Celecoxib not to be used off-label following Onsenal withdrawal

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has finalised its review of the use of the COX-2 inhibitor celecoxib in the reduction of the number of adenomatous intestinal polyps in familial adenomatous polyposis (FAP). The CHMP concluded that existing evidence of safety and efficacy does not support the use of celecoxib in FAP patients.

This review follows Pfizer's voluntary withdrawal of the marketing authorisation of its celecoxib-containing orphan medicine, Onsenal, which had been authorised for use in FAP patients. The reason for the withdrawal was that Pfizer was unable to provide confirmatory data regarding clinical benefit due to slow enrolment in a clinical trial. These data had been requested by the CHMP at the time of granting of the marketing authorisation for Onsenal.

Celecoxib-containing products are currently authorised in the European Union for the treatment of the symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. This review was initiated because of concerns that celecoxib may be used off-label in the FAP indication following the withdrawal of Onsenal.

The CHMP looked at the available data on the use of celecoxib in FAP patients. This included the results from the main study that supported the marketing authorisation for Onsenal, an ongoing study with celecoxib, post-marketing safety data and data from the published literature.

The CHMP concluded that the benefit of celecoxib in FAP patients had not been sufficiently demonstrated and did not outweigh the increased risk of cardiovascular and gastrointestinal side effects, which would result from high dose and long-term treatment used in FAP patients.

This CHMP opinion will be communicated to the EU Member States, so that they can take appropriate action at national level.



Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The review of celecoxib was conducted in the context of a formal review, initiated at the request of the European Commission under Article 5(3) of Regulation (EC) No 726/2004.
3. A question-and-answer document on this review is available on the Agency's website.
4. The public statement on the withdrawal of the marketing authorisation of Onsenal is available on the Agency's website.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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