27 th May 2011

Circular No. P05/2011

Dear Healthcare Professional,

Re: European Medicines Agency concludes its evaluation on use of celecoxib in familial adenomatous polyposis.

Conclusion: Celecoxib is not to be used off-label

Pfizer voluntary withdrew the marketing authorisation of its celecoxib-containing orphan medicine, Onsenal, which had been authorised for use in Familial Adenomatous Polyposis 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.

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. This review was initiated because of concerns that celecoxib may be used off-label in the FAP indication following the withdrawal of Onsenal.

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has finalised its review on 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.

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The CHMP concluded that the benefit of celecoxib in FAP patients had not been sufficiently demonstrated and would 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.

Celecoxib-containing products are currently authorised in Malta for the treatment of the symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. Onsenal was authorised in Malta but had never been marketed.

The Medicines Authority has participated in the discussions held at the EMA and is in agreement with the full **press release** issued by the EMA, attached here for your perusal. A **question-and-answer** document with more information about the outcome of this assessment is also available.

Healthcare professionals are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis

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