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Human Medicines Development and Evaluation

Public statement on

Onsenal (celecoxib)

Withdrawal of the marketing authorisation in the European Union

On 17 October 2003 the European Commission issued a marketing authorisation under exceptional circumstances valid throughout the European Union for the medicinal product Onsenal (celecoxib) for the reduction of the number of adenomatous intestinal polyps in familial adenomatous polyposis, as an adjunct to surgery and further endoscopic surveillance.

A marketing authorisation under exceptional circumstances may be granted if the applicant is unable to provide comprehensive data on the efficacy and safety of the medicine for which authorisation is being sought, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data. Therefore, it will normally be subject to specific obligation(s) during its life-cycle.

At the time of marketing authorisation for Onsenal, the applicant was given a specific obligation to provide further data on its efficacy and safety.

The marketing authorisation holder (MAH) for Onsenal was Pfizer Limited. The European Commission was notified by a letter dated 10 March 2011 of the MAH's decision to voluntarily withdraw the marketing authorisation for Onsenal. The reason given was that the MAH has not yet been able to provide the additional data required to fulfil its specific obligation, as a result of slow enrolment in an ongoing clinical trial.

Onsenal was marketed in all EU countries except for Bulgaria, Hungary, Malta, Romania and Slovenia.

At the time of the withdrawal, Onsenal was undergoing the 8th annual reassessment by the CHMP. On the basis of the documentation submitted, the CHMP was of the view that the specific obligation necessary to maintain the marketing authorisation had not been fulfilled. The CHMP, therefore, requested supplementary information to be provided in order to confirm that the benefits associated with the use of Onsenal in the treatment of familial adenomatous polyposis still outweigh its risks.

On 28 March 2011 the European Commission issued a decision to withdraw the marketing authorisation for Onsenal.

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Pursuant to this decision the European Public Assessment Report for Onsenal will be updated to reflect that the marketing authorisation is no longer valid.