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Press Office

Press release

Novartis withdraws its marketing authorisation application for Joicela (lumiracoxib)

The European Medicines Agency has been formally notified by Novartis of its decision to withdraw its application for a centralised marketing authorisation for the medicine Joicela (lumiracoxib), 100 mg film-coated tablets. Joicela was intended to be used for symptomatic relief in the treatment of osteoarthritis of the knee and hip in patients who are non-carriers of the DQA1*0102 allele.

The application for the marketing authorisation for Joicela was submitted to the Agency on 3 December 2009. At the time of the withdrawal it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that its decision to withdraw the application was based on its inability to address the CHMP's request to provide additional data within the timeframe allowed in the centralised procedure.

More information about Joicela and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the Agency's website after the next CHMP meeting on 16 – 19 May 2011.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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