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Questions and answers

Withdrawal of the marketing authorisation application for Joicela (lumiracoxib)

On 15 April 2011, Novartis officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Joicela for the symptomatic relief in the treatment of osteoarthritis of the knee and hip in patients who are not carriers of the DQA1*0102 allele.

What is Joicela?

Joicela is a medicine that contains the active substance lumiracoxib. It was to be available as film-coated tablets.

What was Joicela expected to be used for?

Joicela was expected to be used to relieve the symptoms of osteoarthritis (swelling and pain in the joints) of the knee and hip in adults who are not carriers of a gene variant called 'DQA1*0102'.

DQA1*0102 is thought to increase the risk of liver toxicity in patients taking Joicela.

How is Joicela expected to work?

The active substance in Joicela, lumiracoxib, is a selective 'non-steroidal anti-inflammatory drug' (NSAID) that belongs to the group 'cyclo-oxygenase 2 (COX-2) inhibitors'. It blocks the COX-2 enzyme, resulting in a reduction in the production of prostaglandins, substances that are involved in the inflammation process. By reducing the production of prostaglandins, Joicela helps to reduce the symptoms of inflammation, such as pain, seen in osteoarthritis.

What did the company present to support its application?

The effects of Joicela were first tested in experimental models before being studied in humans.

Joicela was compared with celecoxib (another medicine used in osteoarthritis) and placebo (a dummy treatment) in three main studies. Two of the studies involved 3,235 patients with knee osteoarthritis while the third study involved 1,262 patients with hip osteoarthritis. The studies looked at measurements of pain and disease activity after 13 weeks of treatment.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after 'day 181'. This means that the CHMP had evaluated the documentation provided by the company and formulated a list of questions. After the CHMP had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What was the recommendation of the CHMP at that time?

Based on the review of the data and the company's response to the CHMP's lists of questions, the CHMP had some concerns and was of the provisional opinion that Joicela could not have been approved for the symptomatic treatment of osteoarthritis (swelling and pain in the joints) of the knee and hip in adults who are not carriers of DQA1*0102.

At the time of the withdrawal, the CHMP was of the view that the benefits of Joicela did not outweigh its risks, particularly its risk of liver toxicity. The Committee was not convinced that screening patients for the DQA1*0102 gene variant sufficiently reduced this risk.

What were the reasons given by the company for withdrawing the application?

The letter from the company notifying the Agency of the withdrawal of the application is available under the tab 'All documents'.

What consequences does this withdrawal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that no clinical trials or compassionate use programmes are currently on-going with Joicela.