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Press Office

Press release

Astellas Pharma Europe B.V. withdraws its applications for an extension of the indication for Qutenza (capsaicin)

The European Medicines Agency has been formally notified by Astellas Pharma Europe B.V. of its decision to withdraw its application for an extension of the therapeutic indication for the centrally authorised medicine Qutenza (capsaicin), 179 mg cutaneous patch.

On 06 May 2011, Astellas Pharma Europe B.V. submitted an application to extend the marketing authorisation for Qutenza to all adult patients with exclusion of patients with pain caused by diabetes. At the time of the withdrawal, the application was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

Qutenza was first authorised in the European Union on 5 May 2009 and it is currently indicated for the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain.

In its official letter, the company stated that it decided to withdraw the application based on the CHMP's view that the data provided do not allow the Committee to conclude on a positive benefit-risk balance.

Qutenza continues to be authorised in the currently approved indication.

More information about Qutenza and the state of the scientific assessment at the time of the 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 16-19 April 2012 CHMP meeting.

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.

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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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