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Press Office

Press release

Novartis Europharm Ltd withdraws its applications for an extension of the indication for Exelon and Prometax (rivastigmine)

The European Medicines Agency has been formally notified by Novartis Europharm Ltd of its decision to withdraw its applications for an extension of the therapeutic indication for the centrally authorised medicines Exelon and Prometax (rivastigmine), 4.6 mg/24 h and 9.5 mg/24h transdermal patches.

On 30 March 2011, Novartis Europharm Ltd submitted an application to extend the marketing authorisations for Exelon and Prometax transdermal patches to include a new indication for the symptomatic treatment of mild to moderately severe dementia in patients with idiopathic Parkinson's disease. At the time of the withdrawal, the application was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

Exelon was first authorised in the European Union on 12 May 1998 and its duplicate Prometax was first authorised on 4 December 1998. The transdermal patches are currently indicated for the symptomatic treatment of mild to moderately severe Alzheimer's dementia.

In its official letter, the company stated that it decided to withdraw the application after the CHMP indicated that in order to conclude a favourable approval additional data was required, which could not be generated within the timeframe allowed in the centralised procedure.

Both medicines continue to be authorised in the currently approved indications.

More information about Exelon and Prometax 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.

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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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