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Press Office

Press release

Warner Chilcott UK Ltd withdraws its application for an extension of indication for Intrinsa

The European Medicines Agency (EMA) has been formally notified by Warner Chilcott UK Ltd of its decision to withdraw its application for an extension of indication for the centrally authorised medicine Intrinsa (testosterone) transdermal patch.

On 10 August 2009, Procter & Gamble Pharmaceuticals UK Ltd submitted an application to extend the marketing authorisation for Intrinsa to include the treatment of hypoactive sexual desire disorder in menopausal women. At the time of withdrawal, the application was under review by the EMA's Committee for Medicinal Products for Human Use (CHMP).

Intrinsa was first authorised in the European Union on 28 July 2006. It is currently authorised for the treatment of hypoactive sexual desire disorder in women who have had their uterus (womb) and both ovaries removed. It is used in patients already taking an oestrogen (a female sex hormone).

In its official letter, the company stated that the withdrawal of the application was based upon commercial considerations.

Intrinsa continues to be authorised for the currently approved indication.

More information about Intrinsa 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 EMA website in due course.

Notes

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. The marketing authorisation for Intrinsa has been transferred from Procter and Gamble Pharmaceuticals UK Ltd to Warner Chilcott UK Ltd.
3. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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