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Human Medicines Development and Evaluation

Public statement

Intrinsa (testosterone)

Withdrawal of the marketing authorisation in the European Union

On 28 July 2006 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Intrinsa (testosterone). Intrinsa is approved for the treatment of hypoactive sexual desire disorder (HSDD) in bilaterally oophorectomised and hysterectomised (surgically induced menopause) women receiving concomitant estrogen therapy.

The Marketing Authorisation Holder (MAH) responsible for Intrinsa was Warner Chilcott UK Ltd. The European Commission was notified by letter dated 13 March 2012 of the MAH's decision to voluntarily withdraw the marketing authorisation for Intrinsa for commercial reasons.

On 25 May 2012 the European Commission issued a decision to withdraw the marketing authorisation for Intrinsa. Pursuant to this decision the European Public Assessment Report for Intrinsa will be updated to reflect that the marketing authorisation is no longer valid.

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