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Questions and answers

Withdrawal of the application for a change to the marketing authorisation for Intrinsa (testosterone)

On 22 September 2010, Warner Chilcott Pharmaceuticals UK Limited officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a change to the marketing authorisation for Intrinsa, to extend treatment to all postmenopausal women with hypoactive sexual desire disorder.

What is Intrinsa?

Intrinsa is a transdermal patch (a patch that delivers a medicine across the skin). The patch releases 300 micrograms of the active substance testosterone over 24 hours.

Intrinsa has been authorised since July 2006. It is already used to treat women with hypoactive sexual desire disorder (HSDD, a lack of sexual thoughts and sexual desire) who have had their womb and both ovaries surgically removed. These women will also be receiving treatment with an oestrogen (a female sex hormone).

What was Intrinsa expected to be used for?

Intrinsa was expected to be used to treat HSDD in postmenopausal women with or without hormone treatment. This was to incude all women who have been through the menopause and not only those who are 'surgically postmenopausal' as result of having had their womb or ovaries removed.

How is Intrinsa expected to work?

Intrinsa is expected to work in the same way as it does in women who have had their womb and both ovaries surgically removed.

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The active substance in Intrinsa, testosterone, is a natural sex hormone produced in men and, to a lesser extent, in women. Low testosterone levels have been linked to low sexual desire and to reduced sexual thoughts and arousal. The amount of testosterone in the blood is reduced after the menopause. In postmenopausal women, Intrinsa was expected to release testosterone through the skin into the bloodstream to produce testosterone levels that match the levels seen before the menopause.

What did the company present to support its application?

The company presented results of four studies in a total of 2,245 women with HSDD. Some of the women had their womb and both ovaries surgically removed while others were postmenopausal women who had not had their womb or ovaries removed. They were given either Intrinsa or placebo (a dummy treatment). The main measure of effectiveness was based on how frequently the women had 'satisfying sexual episodes'.

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

The application was withdrawn after 'day 90'. This means that the CHMP had evaluated the documentation provided by the company and formulated two lists of questions. After the CHMP had assessed the company's responses to the 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, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Intrinsa could not have been approved for use in all postmenopausal women who have HSDD. The CHMP noted that there was insufficient long-term data on the safety of the medicine in this larger group of patients and was therefore of the opinion that the medicine's benefits in these women did not outweigh its risks.

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 there are no consequences for patients currently in clinical trials or compassionate use programmes with Intrinsa. If you are in a clinical trial or compassionate use programme and need more information about your treatment, contact the doctor who is giving it to you.

What is happening with Intrinsa for its existing indication?

There are no consequences on the use of Intrinsa in the treatment of HSDD in women who have had their womb and both ovaries removed.

The full European Public Assessment Report for Intrinsa can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.