24 June 2010
EMA/351712/2010
EMEA/H/C/001237

Questions and answers

Withdrawal of the marketing authorisation application for Brilence (bazedoxifene)

On 21 May 2010, Wyeth Europa Ltd officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Brilence, for the treatment of osteoporosis in postmenopausal women.

What is Brilence?

Brilence is a medicine that contains the active substance bazedoxifene. It was to be available as tablets (20 mg).

This medicine was intended to be the same as Conbriza, which is already authorised in the European Union (EU). The company that makes Conbriza has agreed that its scientific data can be used for Brilence ('informed consent').

What was Brilence expected to be used for?

Brilence was expected to be used for the treatment of osteoporosis (a disease that makes bones fragile) in women who have been through the menopause. It was to be used in women who are at risk of fracture (broken bones).

How is Brilence expected to work?

Osteoporosis happens when not enough new bone grows to replace the bone that is naturally broken down. Gradually, the bones become thin and fragile, and more likely to break (fracture). Osteoporosis is more common in women after the menopause, when the levels of the female hormone oestrogen fall: oestrogen slows down bone breakdown and makes the bones less likely to fracture.

The active substance in Brilence, bazedoxifene, is a selective oestrogen receptor modulator (SERM). Bazedoxifene acts as an 'agonist' of the oestrogen receptor (a substance that stimulates the receptor for oestrogen) in some tissues in the body. Bazedoxifene has the same effect as oestrogen in the bone.

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What did the company present to support its application?

As Brilence was an informed consent product, the company referred to the results of the studies that had been used for the marketing authorisation application of Conbriza.

How far into the evaluation was the application when it was withdrawn?

The CHMP had received the initial documentation provided by the company. However, the company had not provided information on the commercial partner that would have marketed the medicine if it had been approved.

What was the recommendation of the CHMP at that time?

At the time of the withdrawal, the CHMP had no scientific concerns and was of the provisional opinion that Brilence could have been approved.

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 here.

What consequences does this withdrawal have for patients in clinical trials or compassionate use programmes?

There are no clinical trials or compassionate use programmes using Brilence. Patients who would have received Brilence can be treated with Conbriza, which is identical to Brilence and is not affected by this withdrawal.