



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 January 2011
EMA/24587/2011
EMA/H/C/002097

Questions and answers

Refusal of the marketing authorisation for Fampyra (fampridine)

On 20 January 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Fampyra, intended to be used to improve the walking ability of adult patients with multiple sclerosis.

The company that applied for authorisation is Biogen Idec Ltd. It may request a re-examination of the opinion within 15 days of receipt of notification of this negative opinion.

What is Fampyra?

Fampyra is a medicine that contains the active substance fampridine. It was to be available as prolonged-released tablets.

What was Fampyra expected to be used for?

Fampyra was expected to be used to improve the walking ability of adult patients with multiple sclerosis. Multiple sclerosis is a disease of the nerves, in which inflammation destroys the protective sheath around the nerves.

How is Fampyra expected to work?

For the muscles to contract, electrical impulses have to be transmitted along the nerves to the muscles. This transmission of electrical impulses is impaired when the protective sheaths around the nerves are damaged.

The active substance in Fampyra, fampridine, is a potassium channel blocker. It acts on damaged nerves, where it was expected to prevent charged potassium particles from leaving the nerve cells.



This is expected to have the effect of allowing the electrical impulse to continue travelling along the nerves to stimulate the muscles.

What did the company present to support its application?

The effects of Fampyra were first tested in experimental models before being studied in humans. Because fampridine is well known as a potassium channel blocker, the company also used data from the scientific literature.

The company presented results of two main studies comparing Fampyra with placebo in 540 patients with multiple sclerosis. The patients were treated for nine or 14 weeks. The main measure of effectiveness was based on how fast they could walk along a 25-foot (about 7.5 metres) path.

What were the CHMP's main concerns that led to the refusal?

The CHMP was not convinced that Fampyra's small effect on the walking speed was a meaningful benefit for patients. The effect on speed could not be linked to meaningful improvements such as better coordination, balance or stamina or increased range of action.

The Committee was of the view that the medicine's uncertain benefits did not outweigh its side effects which included pain, dizziness, paraesthesia (unusual sensations like pins and needles) and problems with balance, as well as symptoms similar to those of multiple sclerosis that could impair the patient's ability to walk. The Committee also noted the lack of adequate long-term data on the medicine's benefits and safety as well as data on some groups of patients, such as the elderly and patients with epilepsy or heart problems.

The CHMP concluded that the benefits of Fampyra did not outweigh its risks and recommended that it be refused marketing authorisation.

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

The company informed the CHMP that there are no consequences for patients currently included in clinical trials or compassionate use programmes with Fampyra. The trials and programmes will continue as planned. 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.