19 May 2011
EMA/CHMP/396600/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Fampyra

fampridine

On 19 May 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Fampyra, 10mg prolonged-release tablet, intended to improve walking of adult patients suffering from multiple sclerosis with walking disability. The applicant for this medicinal product is Biogen Idec Ltd.

The active substance of Fampyra is fampridine, a potassium channel blocker, ATC code: N07XX07. By blocking potassium channels, Fampyra reduces the leakage of ionic current through these channels, thereby prolonging repolarization and thus enhancing action potential formation in demyelinated axons and neurological function. Presumably, by enhancing action potential formation, more impulses might be conducted in the central nervous system.

The benefit observed with Fampyra was its ability to improve walking, as measured by a Timed 25 Foot Walk Test and 12-item Multiple Sclerosis Walking Scale (a patient reported outcome measure).

The most common side effects observed were urinary tract infection, insomnia, anxiety, dizziness, headache, balance disorder, paraesthesia, tremor, dyspnoea, pharyngolaryngeal pain, nausea, vomiting, constipation, dyspepsia, back pain and asthenia.

A pharmacovigilance plan for Fampyra will be implemented as part of the marketing authorisation.

The approved indication is: “Fampyra is indicated for the improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS 4-7)”.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Fampyra and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional[2].

2 A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage