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Questions and answers

Refusal of the marketing authorisation for sumatriptan Galpharm 50 mg tablets

(sumatriptan)

On 21 July 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 Sumatriptan Galpharm, intended for the relief of migraine attacks in people who have been diagnosed with migraine.

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

What is Sumatriptan Galpharm?

Sumatriptan Galpharm is a medicine that contains the active substance sumatriptan. It was to be available as 50 mg tablets.

Sumatriptan Galpharm was developed as a 'generic medicine'. This means that sumatriptan was intended to be similar to a 'reference medicine' already authorised in the European Union called Imigran. For more information on generic medicines, see the question-and-answer document here.

Sumatriptan Galpharm was to be made available without prescription whereas its reference medicine Imigran is available on prescription only.

What was Sumatriptan Galpharmexpected to be used for?

Sumatriptan Galpharm was expected to be used to relieve migraine attacks in people who had been diagnosed with migraine.

How is Sumatriptan Galpharm expected to work?

Sumatriptan Galpharm was expected to work in the same way as the reference medicine, Imigran. The active substance in Sumatriptan Galpharm and Imigran, sumatriptan, works by mimicking the action of

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the neurotransmitter 5-hydroxytryptamine (serotonin) in the brain. Neurotransmitters are chemicals that allow nerve cells to communicate with one another. Migraine attacks occur when the level of 5-hydroxytryptamine in the brain becomes low. This leads to a widening of blood vessels in the brain which can lead to a migraine attack. Sumatriptan will help blood vessels to return to their normal size. This will stop the symptoms of migraine: headache, sickness and sensitivity to light.

What did the company present to support its application?

Because Sumatriptan Galpharm was developed as a generic medicine, the company presented the results of a study carried out to investigate whether it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

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

Although Sumatriptan Galpharm has been shown to be bioequivalent to Imigran the CHMP considered that Sumatriptan Galpharm in the non prescription setting was not approvable. This was because lack of medical supervision and monitoring of the patient would increase the risk for cerebrovascular (brain) and cardiovascular (heart) side effects and potential misuse. In addition the CHMP felt that Sumatriptan Galpharm in the non prescription setting is not appropriate because migraine as a condition changes over time as well as the patients cardiovascular and cerebrovascular status and monitoring is therefore essential. The CHMP felt that the measures proposed by the company to reduce these risks were insufficient.

The CHMP was therefore of the opinion that the benefits of making the medicine available without prescription did not outweigh its risks. Therefore the CHMP recommended that Sumatriptan Galpharm be refused marketing authorisation.