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Questions and answers

Refusal of the marketing authorisation for Sumatriptan Galpharm 50 mg tablets

Outcome of re-examination

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 Healthcare Ltd.

The applicant requested a re-examination of the negative opinion. After considering the grounds for this request, the CHMP re-examined the initial opinion, and confirmed the refusal of the marketing authorisation on 17 November 2011.

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 intended to be similar to a 'reference medicine' already authorised in the European Union called Imigran.

Sumatriptan Galpharm was to be made available without prescription.

What was Sumatriptan Galpharm expected 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 the neurotransmitter 5-hydroxytryptamine (serotonin) in the brain. Neurotransmitters are chemicals

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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?

The company presented the results of a study carried out to investigate whether it is 'bioequivalent' to the reference medicine and data in support of its use in the non-prescription setting. 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?

In July 2011, the CHMP was concerned that Sumatriptan Galpharm in the non-prescription setting was not approvable. This was because a lack of medical supervision and monitoring of the patient would increase the risk for cerebrovascular (brain) and cardiovascular (heart) side effects and potential misuse and overuse. 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 patient's 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.

Therefore, at that point in time, the CHMP was of the opinion that the benefits of Sumatriptan Galpharm did not outweigh its risks and recommended that it be refused marketing authorisation.

During the re-examination in November 2011, the CHMP's main concerns were not resolved. The additional measures proposed by the company were still considered insufficient. The CHMP also remained concerned about the safety of Sumatriptan Galpharm, in particular the potential for misuse and overuse as well as the risk of misdiagnosis of migraine and lack of medical follow-up when used in the non-prescription setting. The CHMP therefore confirmed its initial negative opinion.