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Questions and answers on Loraxin and associated names (loratadine, 10 mg tablets)

Outcome of a procedure under Article 29 of Directive 2001/83/EC

On 21 June 2012, the European Medicines Agency completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Loraxin. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that it was not possible to show that the benefits of Loraxin outweigh its risks based on the data submitted by the company. The Committee therefore recommended that the marketing authorisation granted in Finland should not be recognised in other Member States of the EU. The marketing authorisation in Finland should also be suspended.

What is Loraxin?

Loraxin is a medicine used to relieve the symptoms of allergic rhinitis (inflammation of the nasal passages caused by an allergy such as hay fever or allergy to dust mites) and long-term idiopathic urticaria (itchy rash). 'Idiopathic' means that the cause of the urticaria is not known.

The active substance in Loraxin, loratadine, is an antihistamine. It works by blocking receptors for histamine, a substance in the body that causes allergic symptoms.

Why was Loraxin reviewed?

Vitabalans Oy submitted an application for Loraxin for mutual recognition, on the basis of an initial authorisation granted by Finland on 31 August 2010. The initial authorisation was based on a well-established use application. This means that the use of the active substance has been well-established in the European Union for over ten years. The company wanted the authorisation to be recognised in the Czech Republic , Denmark, Estonia, Hungary, Lithuania, Latvia, Norway, Poland, Sweden, Slovenia and Slovakia (the 'concerned Member States').

However, the Member States were not able to reach an agreement and the Finnish medicines regulatory agency referred the matter to the CHMP for arbitration on 23 December 2011.

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The grounds for the referral were the concerns of the Swedish and Polish medicines agencies that its safety and benefits could not be ascertained on the basis of the data that were submitted.

What are the conclusions of the CHMP?

For well-established use applications, data from the published literature on medicines with the same active substance are used to show the benefits and safety of a medicine. The CHMP noted that the published data that was submitted with this application were limited, and not sufficient to support this well-established use application for Loraxin. Therefore, the Committee concluded that the benefits of the medicine could not be shown to outweigh its risks and recommended that the marketing authorisation should not be granted in the concerned Member States. In addition, the Committee recommended that the marketing authorisation for Loraxin in Finland should be suspended.

The European Commission issued a decision on 20 December 2012.