European Medicines Agency

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Questions and answers on the referral for Loratadine Sandoz 10 loratadine 10 mg tablets

The European Medicines Agency has completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Loratadine Sandoz 10. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Loratadine Sandoz 10 do not outweigh its risks, and the marketing authorisation granted in the Netherlands cannot be recognised in other Member States of the EU. The marketing authorisation in the Netherlands should also be suspended.
The review was carried out under an 'Article 29' referral[1].

What is Loratadine Sandoz 10?

Loratadine Sandoz 10 is 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 (itching and patches on the skin). 'Idiopathic' means that the cause of the urticaria is not known.
Loratadine is an antihistamine. It works by blocking the receptors that histamine, a substance in the body that causes allergic symptoms, normally attaches to. When the receptors are blocked, histamine cannot have its effect, which leads to a decrease in the symptoms of allergy.
Loratadine Sandoz 10 is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the EU called Clarityne.

Why was Loratadine Sandoz 10 reviewed?

Sandoz B.V. submitted Loratadine Sandoz 10 for mutual recognition on the basis of the initial authorisation granted in the Netherlands on 22 July 2001. The company wanted the authorisation to be recognised in Bulgaria, the Czech Republic, Estonia, France, Hungary, Italy, Latvia, Lithuania, Poland, Romania, Slovenia and Slovakia (the 'concerned Member States'). However, these Member States were not able to reach an agreement and the Dutch medicines regulatory agency referred the matter to the CHMP for arbitration on 31 July 2008.
The grounds for the referral were a disagreement from the Czech Republic and Poland, which were of the opinion that 'bioequivalence' with the reference medicine had not been shown. Two medicines are bioequivalent when they produce the same levels of the active substance in the body. The Czech Republic and Poland argued that the original study presented by the company was not in line with current guidance, and did not show bioequivalence of Loratadine Sandoz 10 and Clarityne.

What are the conclusions of the CHMP?

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP was of the opinion that bioequivalence between Loratadine Sandoz 10 and the reference medicine had not been sufficiently demonstrated. The CHMP therefore concluded that Loratadine Sandoz 10 could not be considered a generic medicine of Clarityne, and therefore that the marketing

[1] Article 29 of Directive 2001/83/EC as amended, referral on the grounds of potential serious risk to public health

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authorisation should not be granted in the concerned Member States. In addition, the Committee also required that the company carried out additional studies to show bioequivalence of Loratadine Sandoz 10 and Clarityne in accordance with the current guidelines. Until the results of these studies are assessed, the marketing authorisation for Loratadine Sandoz 10 in the Netherlands should be suspended.

The Committee noted that this product was previously authorised in a number of other Member States on the basis of the same data. These countries are Austria, Denmark, Finland, Germany, Greece, Norway, Portugal, Spain, Sweden and the United Kingdom. The CHMP recommended that the authorisations in these countries should also be suspended.

The European Commission issued a decision on 6 August 2009.

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