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Questions and answers on Simvastatin Vale and associated names (simvastatin, oral suspension, 20mg/5ml and 40mg/5ml)

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

On 25 March 2013, 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 Simvastatin Vale. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Simvastatin Vale outweigh its risks, and the marketing authorisation can be granted in the United Kingdom and in the following Member States of the EU: Austria, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Portugal, Spain and Sweden as well as Norway.

What is Simvastatin Vale?

Simvastatin Vale is a medicine that contains the active substance simvastatin. It is available as an oral suspension (20mg/5ml and 40mg/5ml).

The active substance in Simvastatin Vale, simvastatin, belongs to a group of medicines called statins, the standard type of medicine used to reduce cholesterol. Simvastatin Vale is used to treat certain forms of hypercholesterolaemia (high blood cholesterol levels) and to reduce the risk of heart disease and death in patients with atherosclerotic cardiovascular disease (where the arteries become narrower due to fatty materials building up on their inside walls) or diabetes.

Simvastatin Vale is a generic medicine based on a 'reference medicine' already authorised in the EU, called Zocor.

Why was Simvastatin Vale reviewed?

Vale Pharmaceuticals Ltd submitted Simvastatin Vale to the United Kingdom's Medicines and Healthcare products Regulatory Agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance the United Kingdom) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance Austria, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Portugal, Spain and Sweden as well as Norway).

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However, the Member States were not able to reach an agreement and the United Kingdom referred the matter to the CHMP for arbitration on 29 January 2013.

The grounds for the referral were concerns about the data submitted to show that Simvastatin Vale is 'bioequivalent' to the reference medicine, Zocor. Two medicines are bioequivalent when they produce the same levels of the active substance in the body. The bioequivalence study submitted in support of the application compared Simvastatin Vale 20mg/5ml with Zocor 20 mg tablets. However, some Member States considered that the higher strength of 40mg/5ml should have been used, in line with the current guideline on the investigation of bioequivalence.

What are the conclusions of the CHMP?

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that additional data were not needed because, based on the data submitted, Simvastatin Vale is expected to produce comparable levels of the active substance in the body as the reference medicine at both strengths. The CHMP therefore concluded that the benefits of Simvastatin Vale outweigh its risks and recommended that the marketing authorisation be granted in the concerned Member States.

The European Commission issued a decision on 27 May 2013.