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Questions and answers on Glimepirida Parke-Davis (glimepiride, tablets, 2, 3 and 4 mg)

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

On 19 July 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 Glimepirida Parke-Davis (glimepiride, tablets 2, 3 and 4 mg). The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Glimepirida Parke-Davis outweigh its risks, and that the marketing authorisation can be granted in Portugal and in the following Member States of the EU: Cyprus, France, Germany, Italy, Sweden and the United Kingdom.

What is Glimepirida Parke-Davis?

Glimepirida Parke-Davis is a medicine used to treat type 2 diabetes (a disease in which the pancreas does not make enough insulin to control the level of glucose in the blood or when the body is unable to use insulin effectively).

The active substance, glimepiride, stimulates the pancreas to produce more insulin. As a result, blood glucose is reduced and this helps to control type 2 diabetes.

Glimepirida Parke-Davis is a 'generic medicine', which means that it is similar to a 'reference medicine', already authorised in the EU, called Amaryl.

Why was Glimepirida Parke-Davis reviewed?

Parke-Davis submitted an application for Glimepirida Parke-Davis (1, 2, 3 and 4 mg tablets) to the Portuguese medicines regulatory agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Portugal) 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 Cyprus, France, Germany, Italy, Sweden and the United Kingdom). However, the Member States were not able to reach an agreement and the Portuguese medicines agency referred the matter to the CHMP for arbitration on 31 May 2012.

The grounds for the referral were concerns over the approach used to demonstrate that Glimepirida Parke-Davis 2, 3 and 4 mg are 'bioequivalent' to Amaryl at the corresponding doses. Two medicines are bioequivalent when they produce the same levels of the active substance in the body. The

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bioequivalence study submitted by the company was carried out using 1 mg of Glimepirida Parke-Davis, and the results were applied to the higher strengths. Although the Member States agreed that 1 mg Glimepirida Parke-Davis was bioequivalent to 1 mg Amaryl, concerns remained over whether a bioequivalence study should have been carried out with the highest strength, 4 mg, to show bioequivalence for Glimepirida Parke-Davis 2, 3 and 4 mg with Amaryl at the corresponding doses.

What are the conclusions of the CHMP?

Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the bioequivalence study conducted with the 1 mg tablet is adequate to show that the higher strengths of Glimepirida Parke-Davis and Amaryl are also bioequivalent. The CHMP therefore concluded that, as Glimepirida Parke-Davis 2, 3 and 4 mg strengths are bioequivalent to the reference medicine, marketing authorisation should be granted in the concerned Member States.

The European Commission issued a decision on 19 November 2012.