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Questions and answers

Withdrawal of the marketing authorisation application for Pioglitazone ratiopharm (pioglitazone)

On 3 February 2012, ratiopharm GmbH officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Pioglitazone ratiopharm, for the treatment of type 2 diabetes.

What is Pioglitazone ratiopharm?

Pioglitazone ratiopharm is a medicine that contains the active substance pioglitazone. It was to be available as tablets (15, 30 and 45 mg).

Pioglitazone ratiopharm was developed as a 'generic medicine'. This means that Pioglitazone ratiopharm is similar to a 'reference medicine' already authorised in the European Union (EU) called Actos. For more information on generic medicines, see the question-and-answer document here.

What was Pioglitazone ratiopharm expected to be used for?

Pioglitazone ratiopharm was to be used to treat type 2 diabetes in adults, particularly those who are overweight. It was to be used in addition to diet and exercise.

Pioglitazone ratiopharm was to be used on its own in patients for whom metformin (another antidiabetes medicine) is not suitable.

Pioglitazone ratiopharm was also to be used in combination with metformin in patients who are not satisfactorily controlled on metformin alone, or with a sulphonylurea (another type of antidiabetes medicine) when metformin is not suitable ('dual therapy').

Pioglitazone ratiopharm was also to be used together with both metformin and a sulphonylurea in patients who are not satisfactorily controlled despite dual therapy by mouth ('triple therapy').

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Pioglitazone ratiopharm was also to be used together with insulin in patients who are not satisfactorily controlled with insulin alone and cannot take metformin.

How is Pioglitazone ratiopharm expected to work?

Type 2 diabetes is 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 in Pioglitazone ratiopharm, pioglitazone, makes cells (fat, muscle and liver) more sensitive to insulin, which means that the body makes better use of the insulin it produces. As a consequence, the blood glucose levels are reduced and this helps to control type 2 diabetes.

What did the company present to support its application?

Because Pioglitazone ratiopharm is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Actos. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

How far into the evaluation was the application when it was withdrawn?

The evaluation had finished and the CHMP had given a positive opinion. The company withdrew before the European Commission had issued a decision on this opinion.

What was the recommendation of the CHMP at that time?

The CHMP concluded that, in accordance with EU requirements, Pioglitazone ratiopharm had been shown to have comparable quality and to be bioequivalent to Actos. Therefore, at the time of the withdrawal, the CHMP had given a positive opinion, recommending that a marketing authorisation be granted for Pioglitazone ratiopharm for the treatment of type 2 diabetes.

What were the reasons given by the company for withdrawing the application?

The withdrawal letter is available here.