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Questions and answers

Withdrawal of the marketing authorisation application for Repaglinide Sun (repaglinide)

On 23 March 2010, Sun Pharmaceutical Industries Europe B.V. officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wished to withdraw its application for a marketing authorisation for Repaglinide Sun for the treatment of type 2 diabetes.

What is Repaglinide Sun?

Repaglinide Sun is a medicine that contains the active substance repaglinide. It was to be available as tablets (0.5, 1 and 2 mg).

Repaglinide Sun was developed as a 'generic medicine'. This means that Repaglinide Sun was intended to be similar to a 'reference medicine' already authorised in the European Union called NovoNorm. For more information on generic medicines, see the question-and-answer document here.

What was Repaglinide Sun expected to be used for?

Repaglinide Sun was expected to be used in patients who have type 2 diabetes. 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.

Repaglinide Sun was to be used together with diet and exercise to lower blood glucose (sugar) levels in patients whose hyperglycaemia (high blood glucose levels) could not be controlled by diet, weight reduction and exercise. Repaglinide Sun was also to be used together with metformin (another antidiabetes medicine) in type 2 diabetes patients whose blood glucose levels were not satisfactorily controlled on metformin alone.

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How is Repaglinide Sun expected to work?

Repaglinide Sun is expected to work in the same way as the reference medicine, NovoNorm, by helping the pancreas to produce more insulin at mealtimes.

What did the company present to support its application?

Because Repaglinide Sun was developed as a generic medicine, the company presented the results of a study carried out to investigate whether it is 'bioequivalent' to the reference medicine or not. 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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn at 'day 180'. This means that the CHMP had evaluated the documentation provided by the company and formulated lists of questions. The company had not yet responded to the last round of questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

Based on the review of the data and the company's response to the CHMP list of questions, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Repaglinide Sun could not have been approved.

The CHMP was concerned about an impurity in the medicine and about the way the company had analysed the results of the bioequivalence study. Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Repaglinide Sun did not outweigh its risks.

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

The letter from the company notifying the Agency of the withdrawal of the application is available here.