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Press Office

Press release

Sun Pharmaceutical Industries Europe B.V. withdraws its marketing authorisation application for Repaglinide SUN (repaglinide)

The European Medicines Agency has been formally notified by Sun Pharmaceutical Industries B.V. of its decision to withdraw its application for a centralised marketing authorisation for the medicinal product Repaglinide SUN (repaglinide) 0.5 mg, 1 mg and 2 mg film-coated tablets.

The medicine was developed as a generic medicine to be used for the treatment of patients with type 2 diabetes whose hyperglycaemia can no longer be satisfactory controlled by diet, weight reduction and exercise. It was also intended as combination treatment with metformin of type 2 diabetes patients whose blood glucose levels are not satisfactorily controlled on metformin alone. The reference medicinal product for Repaglinide SUN is NovoNorm, which has been authorised in the European Union since 1998.

The application for the marketing authorisation for Repaglinide SUN was submitted to the Agency on 5 March 2009. At the time of the withdrawal, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that it decided to discontinue the application due to its marketing strategy.

More information about Repaglinide SUN and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the Agency's website after the CHMP meeting on 19-22 April 2010.

Notes

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.

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2. A generic medicine is a medicine which is similar to a medicine that has already been authorised (the 'reference medicine'). Generic and reference medicines are used at the same dose to treat the same disease, and they are equally safe and effective.

3. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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