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Press Office

Press release

Novartis Europharm Ltd withdraws its marketing authorisation application for Rasival (aliskiren/valsartan)

The European Medicines Agency has been formally notified by Novartis Europharm Ltd of its decision to withdraw its application for a centralised marketing authorisation for the medicine Rasival (aliskiren/valsartan), 150/160 mg and 300/320 mg film-coated tablets.

This medicine was intended to be used for the treatment of essential hypertension as a substitution therapy in adults whose blood pressure is adequately controlled with aliskiren and valsartan, given as single components concurrently, at the same dose level as in the combination.

The application for the marketing authorisation for Rasival was submitted to the Agency on 29 May 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 its decision to withdraw the application was based on their inability to address the CHMP's requests and provide additional data within the timeframe allowed in the centralised procedure.

More information about Rasival 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 next CHMP meeting on 20-23 September 2010.

Notes

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. 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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