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Press Office

**Press release**

# Krka, d.d., Novo mesto withdraws its marketing authorisation application for Desloratadine Krka (desloratadine)

The European Medicines Agency has been formally notified by Krka, d.d., Novo mesto of its decision to withdraw its application for a centralised marketing authorisation for the medicine Desloratadine Krka (desloratadine), 5 mg film coated tablets.

Desloratadine Krka was intended to be used for the relief of symptoms associated with allergic rhinitis and urticaria. Desloratadine Krka is a generic of Aerius which has been authorised in the EU since 15 January 2001.

The application for the marketing authorisation for Desloratadine Krka was initially submitted to the Agency on 03 February 2011 and the medicine received a positive opinion by the Committee for Medicinal Products for Human Use (CHMP) on 22 September 2011. At the time of the withdrawal it was awaiting marketing authorisation by the European Commission.

In its official letter, the company stated that their marketing strategy is the reason for withdrawal.

More information about Desloratadine Krka will be made available in a question-and-answer document. This document, together with the assessment report and the withdrawal letter from the company will be published on the Agency's website after the CHMP meeting on 14-17 November 2011.

## Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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