EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Only For Children Pharmaceuticals withdraws its marketing authorisation application for Loulla (mercaptopurine)

The European Medicines Agency has been formally notified by Only For Children Pharmaceuticals of its decision to withdraw its application for a centralised marketing authorisation for the medicine Loulla (mercaptopurine), 10 mg/ml, tablets and solution for oral suspension.

Loulla was intended to be used for the maintenance treatment of acute lymphoblastic leukaemia. Mercaptopurine was designated an orphan medicinal product on 22 October 2007.

The application for the marketing authorisation for Loulla was submitted to the Agency on 6 December 2011. At the time of the withdrawal it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its withdrawal letter, the company stated that they have decided to withdraw the application because Nova Laboratories orphan medicinal product Xaluprine (mercaptopurine), similar to Loulla, was granted a European marketing authorisation on 9 March 2012. Xaluprine is protected by 10 years exclusivity. Only For Children Pharmaceuticals has tried to fulfil one of the derogations criteria, as laid down in Art.8, paragraph 3 of the Commission Regulation (EC) No 847/2000, by providing a critical report claiming that Loulla was clinically superior to the authorised orphan medicinal product Xaluprine. The CHMP, however, concluded that there was insufficient evidence to support the claim of clinical superiority over Xaluprine.

More information about Loulla 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 of 14-17 January 2013.

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Notes

1. This press release, together with all related documents, is available on the Agency's website at:
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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