19 December, 2012
Only For Children Pharmaceuticals
Institut Villemin
10 avenue de Verdun
75010 PARIS
FRANCE

CHMP Chairman
Tomas Salmonson
European Medicines Agency
Loading Dock
Ontario Way
Canary Wharf
London E14 4HB
UK

Subject: Withdrawal of Loulla 10 mg/ml, tablets and solution for oral suspension.
EMEA/H/C/002501//0000

Dear Chairman,

We would like to inform you that, at this point of time, Only For Children Pharmaceuticals has taken the decision to withdraw the application for Marketing Authorisation of Loulla 10 mg/ml, tablets and solution for oral suspension, which was intended to be used for the maintenance treatment of Acute Lymphoblastic Leukaemia.

This withdrawal is based on the following reason:

Nova Laboratories orphan medicinal product, Xaluprine (previously known as Mercaptopurine Nova Laboratories), was granted European marketing authorisation on March the 09th 2012.
The CHMP concluded that Loulla (Mercaptopurine) and Xaluprine were similar as defined in Art.3 of the Commission Regulation (EC) No 847/2000. Therefore, Art. 8, Paragraph 1 of Regulation (EC) No 141/2000 applies, stating that:
"Where a marketing authorisation in respect of an orphan medicinal product is granted (…), the Community and the Member States shall not, for a period of 10 years, accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product..." unless one of the three derogation as laid down in Art.8, paragraph 3 is met.
As part of the justification of the fulfillment of the derogation criteria, Only For Children Pharmaceuticals submitted a critical report claiming that Loulla was clinically superior to the authorised orphan medicinal product Xaluprine.

Following the assessment of Only For Children Pharmaceuticals superiority report, the CHMP has concluded that there was insufficient evidence to support the claim of clinical superiority over Xaluprine (Nova Laboratories).

This withdrawal of this Loulla Application does not have any consequences on any ongoing clinical trials or compassionate use program.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA website.

[redacted]

CC: Rapporteur, Co-Rapporteur.