

To:

Head of Paediatric Medicines
European Medicines Agency
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London E14 5EU
United Kingdom
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Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): Furosemide

Invented name: N/A

Latest Decision number(s): 1) P/245/2011 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000982-PIP01-10 2) EMEA- 3) EMEA- 4)
EMEA-

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:

Treatment of fluid retention

has been discontinued

has been suspended/put on long-term hold (with possible re-start at a later time)

for the following reason(s): (tick all that apply)

(possible) lack of efficacy in adults

(possible) lack of efficacy in children

(possible) unsatisfactory safety profile in adults

(possible) unsatisfactory safety profile in children

commercial reasons (please specify:)

manufacturing / quality problems

other regulatory action (please specify:) (e.g. suspension, revocation of M.A.)

other reason (please specify:)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation / suspension:

Commercial reasons. The sponsor, Kidzpharma Inc., has discontinued all operations and has been wound-up as an organisation owing to inability to secure investment funding.

Name and signature of the PIP contact point: Dr George Overend

Date: 20 September, 2018

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