

To:
Head of Paediatric Medicines
European Medicines Agency
7 Westferry Circus
London E14 4HB
United Kingdom
paediatrics@ema.europa.eu

Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): ferumoxytol
Invented name: Rienso

Latest Decision number(s): 1) P/0060/2015 2) P/0014/2013 3) P/0086/2012 4) P/38/2010

Corresponding PIP number(s): 1) EMEA-000373-PIP02-09-M04 2) EMEA-000373-PIP02-09-M03
3) EMEA-000373-PIP02-09-M02 4) EMEA-000373-PIP02-09-M01

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

- ☒ 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: Licensing Partner, Takeda Pharmaceuticals, Inc. has notified the EMA it's intent to withdraw Rienso from the market and request withdrawal of the Marketing Authorization on 23 February 2015.)
☐ 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:

AMAG's partner, Takeda Pharmaceuticals, Inc. has notified the EMA it's intent to withdraw Rienso from the market and request withdrawal of the Marketing Authorization on 23 February 2015. Furthermore, AMAG and Takeda have terminated their licensing agreement for Rienso, and at this time, AMAG has no plans to continue marketing Rienso in the EU. A product recall was initiated by Takeda in March 2015.

Name and signature of the PIP contact point: Alka Batycky, PhD

Date: 07 April 2015

Contact for inquiries from interested parties: Robert Hydon, MBA, RAC

Telephone: +1-617-498-3304

Email: rhydon@amagpharma.com

