

To:
Head of Paediatric Medicines
European Medicines Agency
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Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): Human normal immunoglobulin
Invented name: Gammagen

Latest Decision number(s): 1) P/0079/2012 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000415-PIP01-08-M01 2) EMEA- 3) EMEA- 4) EMEA-

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

- ☒ 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:

No demonstration of significant efficacy in the pivotal phase III study

Name and signature of the PIP contact point: Nathalie PIROUX

Date: 23/09/2013

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