

To:

Head of Paediatric Medicines  
European Medicines Agency  
30 Churchill Place  
London E14 5EU  
United Kingdom  
paediatrics@ema.europa.eu

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

Actives substances(s): Human Normal Immunoglobulin

Invented name: Not Applicable

Latest Decision number(s): 1) P/120/2010 2) P/0075/2014 3) P/0143/2015 4)  
P/

Corresponding PIP number(s): 1) EMEA-000775-PIP01-09 2) EMEA-000775-PIP01-09-M01  
3) EMEA-000775-PIP01-09-M02 4) EMEA-

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

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: Kedrion has started the development of a new IgG IVIg 10% process and will therefore apply for a new Paediatric Investigation Plan procedure and will start a new PID clinical study)

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

Kedrion has started the development of a new IgG IVIg 10% process, different from the product discussed during procedure EMEA-000775-PIP01-09-M01; the aim is to develop an improved product, with respect to the one previously manufactured, having a competitive yield and an easy manufacturability. Kedrion is planning to conduct a new PID clinical study with this new product, a Paediatric Investigation Plan will be in due time.

Name and signature of the PIP contact point: Louise Pedreschi

Date: 23.01.17

Contact for inquiries from interested parties: Louise Pedreschi  
Telephone: 0039 0583 767334  
Email: [l.pedreschi@kedrion.com](mailto:l.pedreschi@kedrion.com)