

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): Preparation containing allergens of birch pollen (betula alba/pendula/verrucosa)

Invented name: AllerSlit forte Birch

Latest Decision number(s): 1) P/271/2010 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000888-PIP01-10 2) EMEA- 3) EMEA- 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:)

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

The development of AllerSlit forte Birch will be ceased due to economic reasons. Allergopharma will focus on SCIT therapy preparations.

Name and signature of the PIP contact point: Signature on file

Date: 02.Feb 2015

Contact for inquiries from interested parties: PD Dr. Dietrich Häfner

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