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): Pollen from Betula verrucosa

Invented name: AVANZ® Birch

Latest Decision number(s): 1) P/0273/2015 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000846-PIP01-10-M01 2) EMEA- 3) EMEA- 4) EMEA-

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

Treatment of allergic rhinitis / rhino-conjunctivitis

☒ 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: Streamline of product portfolio)

☐ 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:

Withdrawn due to commercial reasons and streamline of product portfolio. A notification to withdraw the marketing authorisation application has been submitted to the Paul-Erlich-Institute with the withdrawal date as of 31 March 2018.

Name and signature of the PIP contact point: Vibeke Grauenkjær

Date: 5 April 2018

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