

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): Dactylis glomerata (8%), Lolium perenne (8%), Phleum pratense (8%), Poa pratensis (8%), Anthoxanthum odoratum (8%), Secale cereale (10%), Betula pendula (16,7%), Corylus avellana (16,6%) and Alnus glutinosa (16,6%)

Invented name: Allerbio Sublingual Forte 5-Grass mix + Rye and Birch/Hazel/Alder

Latest Decision number(s): 1) P/301/2010 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000859-PIP01-10 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Withdrawn due to commercial reasons and streamline of product portfolio. The marketing authorisation application has been withdrawn at the Paul-Erlich-Institute.

Name and signature of the PIP contact point: Christina Torp Gagnér

Date: 10 Dec 2015

Contact for inquiries from interested parties: Christina Torp Gagnér

Telephone:

+45 45747578

Email:

CGTDK@alk.net