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 Dactylis glomarata (16%), Festuca pratensis (16%), Lolium perenne (16%), Phleum pratense (16%), Poa pratensis (16%), Secale cereale (20%)

Invented name: SLITone® Grass mix + Rye

Latest Decision number(s): 1) P/305/2010 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000869-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Withdrawn due to commercial reasons and streamline of product portfolio. The marketing authorisation application has been withdrawn at the Paul-Erlich-Institute.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: Vibeke Grauenkjær

Date: 10 Dec 2015

Contact for inquiries from interested parties: Vibeke Grauenkjær

Telephone: +45 4574 7719

Email: VGRDK@alk.net