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 Alnus glutinosa (33%), Betula verrucosa (33%) and Corylus avellana (33%)

Invented name: SLITonePLUS® 3-tree mix

Latest Decision number(s): 1) P/12/2011 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000863-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: 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Withdrawn due to commercial reasons and streamline of product portfolio. The marketing authorisation application has been withdrawn at the Paul-Erlich-Institute.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 Grauenkjaer

Date: 10 Dec 2015

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