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): Cebranopadol

Invented name: n.a.

Latest Decision number(s): 1) P/0145/2013

Corresponding PIP number(s): 1) EMEA-001305-PIP01-12

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

chronic pain

☐ 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: European development of cebranopadol in adults has been put on hold)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation / suspension: Due to commercial reasons Grünenthal has put the European development of cebranopadol in adults on hold. Given that the development in adults is a pre-requisite for the development in children, the paediatric development is put on hold.

Name and signature of the PIP contact point: Tom Huijbers Katrin Fleischer

Date: 5 Feb 2016

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