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): Briakinumab
Invented name: Ozespa

Latest Decision number(s): 1) P/25/2011 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000552-PIP01-09-M01 2) EMEA- 3) EMEA- 4) EMEA-

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

☒ 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: withdrawal of MAA) *(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:
On 14 January 2011, Abbott Laboratories Ltd withdrew its application for a marketing authorisation for Ozespa, for the treatment of plaque psoriasis.
The decision to withdraw the application was based on the views of the rapporteurs in their day 80 assessment reports that additional new data and analyses would be required for a favourable opinion, but those could not be generated within the timeframe allowed in the centralised procedure.
All development work with Briakinumab across all indications has been discontinued.

Name and signature of the PIP contact point: Signature on file

Date: 31 July 2015

Contact for inquiries from interested parties: AbbVie Ltd.

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