To:

Head of Paediatric Medicines
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Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): Abrilumab

Invented name: N/A

Latest Decision number(s): 1) P/0027/2016 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001671-PIP01-14 2) EMEA- 3) EMEA- 4) EMEA-

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

Treatment of Crohn's disease

Treatment of ulcerative colitis

☒ 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: Phase 2 study results suggest that abrilumab does not provide differentiated benefits to patients compared to currently available therapies.)

☐ 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:

Medimmune Ltd/AstraZeneca and its development partner Amgen have made the business decision to terminate further development of abrilumab (MEDI 7183/AMG 181) in Inflammatory Bowel Disease. This decision is not due to safety reasons; it is based on Phase 2 study results which did not demonstrate the desired clinical profile.

Name and signature of the PIP contact point:	Helene Thelin
Date:	02 May 2016

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