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Dr Harald Enzmann
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CC: Peter Kiely (CHMP Rapporteur), Jan Mueller-Berghaus (CHMP Co-Rapporteur)
Victoria Palmi Reig (EMA Procedure Manager), Mira Jehlarova (EMA Procedure Assistant)

27 May 2019

RE: Withdrawal of ABP 710 (infliximab), 100 mg, powder for concentrate for solution for infusion – Procedure No. EMEA/H/C/005020/0000

Dear Dr Enzmann,

I would like to inform you that, at this point of time, Amgen has taken the decision to withdraw the application for Marketing Authorisation of ABP 710 (infliximab), 100 mg, powder for concentrate for solution for infusion, which was intended to be used for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis (Bechterew's disease) and psoriasis in adults and for the treatment of Crohn's disease and ulcerative colitis in adults and children 6 years and older.

This withdrawal decision was taken because of a change in product strategy for ABP 710. Amgen will focus its resources on where the most value for patients can be provided.

There are no ongoing clinical trials or compassionate use programmes for this product.

We would like to thank the Rapporteur, Co-Rapporteur, EMA, PRAC and CHMP members for the time and effort dedicated and the guidance provided during the procedure.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

The applicant agrees for this letter to be published on the European Medicines Agency website.

Yours sincerely,

[redacted]