BioScience

Baxter

Tomas Salmonson
7 Westferry Circus
Ontario Way
Canary Wharf
UK – London, E14 4HB

[redacted]

Vienna, 22 October 2014

Re: EMEA/H/C/000334/II/0079/ - CEPROTIN
Withdrawal of Type II Variation CEPROTIN 500 IU and 1000IU
Extension of Indication

Dear Mr. Salmonson,

For the withdrawal of Type II variation / Annex I (Regulation 1234/2008) application linked to an extension of indication for a medicinal product already authorized

We would like to inform you that, at this point of time, Baxter has taken the decision to withdraw the application for a new indication for "treatment of purpura fulminans in patients with acquired protein C deficiency".

The withdrawal is based on the following reason:
The decision to withdraw was based on Rapporteur´s pre-Assessment report requesting additional prospectively collected clinical data to support the efficacy claim.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

Baxter agrees for this letter to be published on the EMA website.

Yours sincerely,

[redacted]