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Date: 29 March 2023

Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Feraheme 30mg/mL solution for infusion (ferumoxytol) -
EMA/H/C/0005974/0000

Dear Dr. Enzmann,

For the withdrawal of initial marketing authorisation application

I would like to inform you that, at this point of time, Covis Pharma Europe B.V. has taken the decision to withdraw the application for Marketing Authorisation of Feraheme 30mg/mL solution for infusion (ferumoxytol), which was intended to be used for intravenous treatment of iron deficiency anaemia (IDA) for adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, or with chronic kidney disease (CKD).

This withdrawal is based on commercial reasons.

The withdrawal has no impact on ongoing clinical studies.

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

I agree for this letter to be published on the European Medicines Agency website.

Yours sincerely,

For and on behalf of
Covis Pharma Europe B.V.