

ratiopharm

ratiopharm GmbH

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EMA/H/C/001035 - Ratioepo, ratiopharm GmbH

INN: Epoetin theta

Withdrawal of Marketing Authorisation Application

Dear [REDACTED]

Herewith we formally withdraw the Marketing Authorisation Application for the product "Ratioepo - epoetin theta", EU/1/09/567/001-028 (EMA/H/C/1035). Ratioepo is a second application for epoetin theta in the name of ratiopharm GmbH.

The reason for this withdrawal is that the European Commission did not accept a second Marketing Authorisation for epoetin theta in the name of ratiopharm GmbH due to the fact that no co-marketing partner was identified at the time of adoption of the opinion of the CHMP. Reference is made to the Commission decision for Ratioepo, EU/1/09/567/001-028 (EMA/H/C/1035), dated 14 September 2009.

Member of the Executive Committee
R&D Biotechnology

Head of Regulatory Affairs International