To:
Head of Paediatric Medicines
European Medicines Agency
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United Kingdom
paediatrics@ema.europa.eu

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

Actives substances(s): Colestilan
Invented name: BindRen

Latest Decision number(s): 1) P/207/2011 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000878-PIP02-11 2) EMEA- 3) EMEA- 4) EMEA-

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

☒ 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:)
☐ manufacturing / quality problems
☒ other regulatory action (please specify: Voluntary withdrawal of BindRen Marketing Authorisation [EU/1/12/804/001-016]) *(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:
Commercialisation of BindRen has been challenging since receiving the Marketing Authorisation (MA) in January 2013. Subsequent to product approval BindRen was launched in Germany, Austria and the UK, with future expansion of sales to other European countries planned. Regrettably the imposition in Germany of a reimbursement price significantly lower than comparable products has set a low benchmark price for BindRen, which has precluded the planned expansion of the product to other European countries. It is now clear that a sustained market presence for the product is not viable and therefore the Marketing Authorisation Holder has taken the decision to voluntarily request withdrawal of the MA for BindRen. All activities associated with the BindRen MA will also be discontinued which includes the on-going paediatric studies. Accordingly, the EMA/PDCO are formally notified of the Applicant's intention to close out the on-going paediatric studies that are associated with the aforementioned PIP and MA.

The European Commission and the Agency were formally notified of the MA holders intention to voluntarily withdraw the marketing authorisation for Bindren on the 09 January 2015, copies of the letters are enclosed for your reference.

Early study termination notifications for the three paediatric clinical studies associated with the MA for BindRen (MCI-196-E14, MCI-196-E16 and MCI-196-E16) will be submitted to the participatient National Agencies and Ethics Committees. All on-going patients will either be withdrawn or actively

managed out of the studies in accordance with the subjects wishes and advice of the responsible investigators.

Name and signature of the PIP contact point:	Signature on file
Date:	9 January 2015

Contact for inquiries from interested parties:	Mitsubishi Pharma Europe Ltd
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