Boehringer Ingelheim

Boehringer Ingelheim International GmbH · 55216 Ingelheim am Rhein

Product and Application Business Support
European Medicines Agency
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Boehringer Ingelheim
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10 June 2014

Reference: EMEA/H/C/003720/0000
Withdrawal of the Marketing Authorization Application for Faldaprevir Boehringer Ingelheim 120 mg soft capsules

[redacted]

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Dear Sir or Madam,

The treatment environment for hepatitis C virus (HCV) infection has significantly and rapidly evolved since the submission of the marketing application for our investigational drug product "Faldaprevir Boehringer Ingelheim 120 mg soft capsules" (INN: faldaprevir) on 25 October 2013. There are now new treatment options available for patients, and additional all-oral interferon-free treatment options are expected to be available in the near future. Thus, there is no longer a significant unmet medical need for the faldaprevir interferon-based regimen that was the subject of our marketing authorization application. Boehringer Ingelheim (BI) has therefore taken a position globally that all marketing authorization applications currently under review for faldaprevir should be withdrawn.

Accordingly, on behalf of the applicant Boehringer Ingelheim International GmbH, we herein withdraw the marketing application for "Faldaprevir Boehringer Ingelheim 120 mg soft capsules".

BI wishes to extend our thanks to the Agency for many years of collegial and robust collaboration on the faldaprevir program.

Yours faithfully,

BOEHRINGER INGELHEIM INTERNATIONAL GMBH
i.V. i.V.

[redacted]

Board

[redacted]

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Copy to:

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[redacted] (CHMP Peer-Reviewer)

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CHMP members & alternates