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19 April 2011

Dr. Abadie

European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of Beprana® (Naproxcinod) 375 mg Hard Capsules, EMEA/H/C/2159

Dear Dr. Abadie,

I would like to inform you that, at this point of time, NicOx S.A. have taken the decision to withdraw the application for Marketing Authorisation of Beprana® (naproxcinod) 375 mg hard capsules, which was intended to be used for the relief of the signs and symptoms of osteoarthritis of the knee and hip in adults.

This withdrawal is based on the following reasons: NicOx S.A. would like to withdraw their application since the CHMP considers that the data provided do not allow the Committee to conclude on a positive benefit risk balance.

This withdrawal does not have any consequences on any ongoing clinical trials or compassionate use program.

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 EMEA website.

Yours sincerely,

[redacted]

VP Regulatory Affairs & Safety, Nicox S.A.

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