SANDOZ

08-04-2015

Dr. Tomas Salmonson
CHMP Chairman
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of Duloxetine Sandoz, duloxetine (as hydrochloride) 30 mg and 60 mg, hard gastro-resistant capsules - EMEA/H/C/4009

Dear Dr. Salmonson,

I would like to inform you that, at this point of time, Sandoz has taken the decision to withdraw the application for Marketing Authorisation of Duloxetine Sandoz, duloxetine (as hydrochloride) 30 mg and 60 mg, hard gastro-resistant capsules which was intended to be used for treatment of major depressive disorder, treatment of diabetic peripheral neuropathic pain and treatment of generalised anxiety disorder.

This withdrawal is based on the following reasons:

- Identification of various GCP related issues involving a third party.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

[redacted] I agree for this letter to be published on the EMEA website.

[redacted]