NOVARTIS

Date: 14-03-2012

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

Subject: Withdrawal of Exelon® and Prometax® (ENA713) 4.6mg/24h and 9.5mg/24h transdermal patches variation **C.I.6.a Change(s) to therapeutic indication(s) -** Addition of a new therapeutic indication or modification of an approved one, respectively **EMA/H/C/0169/WS/132/G and EMA/H/C/0255/WS/132/G.**

Dear Dr Abadie

For the withdrawal of Type II variation for a medicinal product already authorised

I would like to inform you that, at this point of time, Novartis Europharm Ltd. has taken the decision to withdraw the application for a new indication for Exelon® 4.6mg/24h and 9.5mg/24h transdermal patches and the duplicates Prometax® 4.6mg/24h and 9.5mg/24h transdermal patches, to add the new indication for the ***"symptomatic treatment of mild to moderately severe dementia in patients with idiopathic Parkinson's disease"***.

This withdrawal is based on the following reason:
This decision was taken after CHMP indicated that in order to conclude a favorable approval, additional new data would be required, which could not be generated within the timeframe allowed in the Centralized Procedure.

This decision will not have consequences for patients enrolled in any ongoing Novartis sponsored Exelon® or Prometax® clinical trial.

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 European Medicines Agency website.

Yours sincerely,

[redacted]

DRA Head Europe
Novartis Europharm Ltd.