NOVARTIS

Date: 21-11-2013

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

Subject: Withdrawal of Exelon® and its duplicate Prometax® (Rivastigmine) 4.6mg/24h, 9.5mg/24h and 13.3mg/24h transdermal patches Procedures numbers respectively EMEA/H/C/0169/WS/0355/082 and EMEA/H/C/0255/WS/0355/083.

Dear Dr Salmonson

For the withdrawal of Worksharing Type II variation/Annex I (Regulation 1234/2008) applications linked to an extension of indication for medicinal products 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, 9.5mg/24h and 13.3mg/24h transdermal patches and its duplicate Prometax® 4.6mg/24h, 9.5mg/24h and 13.3mg/24h transdermal patches, namely to add the new indication for the ***''Symptomatic treatment of severe Alzheimer's dementia''***.

This withdrawal is based on the following reason:
The CHMP considers that the data provided in support of the new indication so far do not allow the committee to conclude with a recommendation for approval of this type II variation application.

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]
Novartis Europharm Ltd.