Mylan
Seeing
is believing

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

22nd December 2017

***Subject:*** Withdrawal of Rotigotine Mylan 1mg/24h, 2mg/24h, 3mg/24h, 4mg/24h, 6mg/24h, 8mg/24h transdermal patches (EMEA/H/C/004286)

Dear Tomas Salmonson,

***For the withdrawal of initial marketing authorisation application***
I would like to inform you that, at this point of time, Mylan SAS has taken the decision to withdraw the application for Marketing Authorisation of Rotigotine Mylan transdermal patches, which was intended to be used for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome (RLS) in adults.

This withdrawal is based on the following reasons:
Additional data are required to resolve some of the points raised in the assessment report. The data cannot be generated within the response deadline.

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]

Senior Registration Officer
Generics [UK] Ltd
Tel:
Fax:
Email: [redacted]