25 September 2014
EMA/CHMP/714236/2014
Committee for Medicinal Products for Human Use (CHMP)

Leganto

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: rotigotine

Procedure No. EMEA/H/C/002380/PSUV/0013

Period covered by the PSUR: 16 February 2013 – 15 February 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Leganto, the scientific conclusions of PRAC are as follows:

After the DLP of this PSUR, based on the safety data review, the rotigotine CCDS has been updated in March 2014 in relation to warnings and precautions and undesirable effects. 'Delusion' and 'Delirium' have been added to the warning on abnormal thinking and behavior and to the AE table of undesirable effects under the SOC Psychiatric disorders with a frequency of rare. Further, 'CPK elevations' which have been observed in Japanese subjects have been added to the AE table under the SOC Investigations with a frequency of common. This observation is further described in a new paragraph 'Special populations' under undesirable effects. These changes were proposed to be added to the EU Product Information as applicable and are considered correct.

Therefore, in view of available safety data, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Leganto, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance ROTIGOTINE is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.