EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 April 2011
EMA/CHMP/259223/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Leganto

rotigotine

On 14 April 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Leganto 1 mg/24 h, 2 mg/24 h, 3 mg/24 h, 4 mg/24 h, 6 mg/24 h and 8 mg/24 h transdermal patch intended for the treatment of idiopathic Restless Legs Syndrome and idiopathic Parkinson's disease. The applicant for this medicinal product is Schwarz Pharma Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Leganto is rotigotine, a dopamine agonist, (ATC code: N04BC09). It acts by activating D_3, D_2 and D_1 dopamine receptors in the brain.

The benefits of Leganto are its ability to alleviate the symptoms of moderate to severe idiopathic restless legs syndrome in adults, and to alleviate the signs and symptoms of idiopathic Parkinson's disease either as monotherapy (i.e. without levodopa) or in combination with levodopa. The most common side effects are somnolence, dizziness, headache, nausea, vomiting and application site reactions.

A pharmacovigilance plan for Leganto will be implemented as part of the marketing authorisation.

The approved indications are: "Leganto is indicated for the symptomatic treatment of moderate to severe idiopathic restless legs syndrome in adults.

Leganto is indicated for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy (i.e. without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or 'on-off' fluctuations)".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Leganto and therefore recommends the granting of the marketing authorisation.