European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 23 October 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
PRAMIPEXOLE TEVA

International Nonproprietary Name (INN): ***pramipexole***

On 23 October 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending granting a marketing authorisation for the medicinal product Pramipexole Teva 0.088 mg, 0.18 mg, 0.35 mg, 0.7 mg tablets intended for the treatment of Parkinson's disease. The applicant for this medicinal product is Teva Pharma B.V.

The active substance of Pramipexole Teva is pramipexole, which is a dopamine agonist *(*N04BC*)* that binds with high selectivity and specificity to the D_2 subfamily of dopamine receptors of which it has a preferential affinity to D_3 receptors, and has full intrinsic activity. Furthermore, pramipexole alleviates Parkinsonian motor Symptoms by stimulation of dopamine receptors in the striatum. Animal studies have shown that pramipexole inhibits the dopamine synthesis, release, and turnover.

Pramipexole Teva is a generic of Sifrol which has been authorised in the EU since 14 October 1997. Studies have demonstrated the satisfactory quality of Pramipexole Teva, and its bioequivalence with Sifrol. A question-and-answer document on generic medicines can be found here.

The approved indication is: treatment of the signs and symptoms of idiopathic Parkinson's disease, alone (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).

A pharmacovigilance plan for Pramipexole Teva, as for all medicinal products, will be implemented as part of the marketing authorisation.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and 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 that there is a favourable benefit to risk balance for Pramipexole Teva and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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