



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

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COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

PUBLIC SUMMARY OF NEGATIVE OPINION FOR ORPHAN DESIGNATION OF tramadol hydrochloride for the treatment of painful HIV-associated neuropathy

On, 5 April 2006 the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on orphan designation of tramadol hydrochloride for the treatment of painful HIV-associated neuropathy of condition. A negative decision was issued by the European Commission on 21 September 2006.

The sponsor applied for orphan designation on the basis of the chronically debilitating nature and the rarity of the condition, as well as an assumption of potential benefit despite currently available methods of treatment.

The negative opinion is based on the following elements:

- for the purpose of designation as orphan medicinal product, justification has not been provided for limiting the condition to “painful HIV-associated neuropathy”. Thus the proposed condition was not considered as a valid subset of the broader condition “peripheral neuropathy”;
- the sponsor has not provided data to establish that peripheral neuropathy (hereinafter referred to as ‘the condition’) affects not more than 5 in 10,000 persons in the Community at the time the application was made*;
- although satisfactory methods of treatment of “peripheral neuropathic pain” have been authorised in the Community, no sufficient justification has been provided that tramadol hydrochloride may be of significant benefit over current satisfactory treatments.

Requests for designation as orphan medicinal products are made for investigational products. Absence of orphan designation does not preclude the development of this product, in particular through clinical trials, and subsequently the possibility of obtaining a marketing authorisation if quality, safety and efficacy are demonstrated.

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* Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed based on data from the European Union (EU 25), Norway, Iceland and Lichtenstein. This represents a population of 459,700,000 (Eurostat 2004). This estimate is based on available information and calculations presented by the sponsor at the time of the application.

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