20 December 2011
EMA/COMP/924925/2011
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Nabilone for the treatment of amyotrophic lateral sclerosis

On 16 January 2011, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on the orphan designation application for nabilone for the treatment of amyotrophic lateral sclerosis. A negative decision was issued by the European Commission on 16 November 2011.

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

The negative opinion was based on the following reasons:

- The sponsor had not provided data on the effect of nabilone in amyotrophic lateral sclerosis.
- Without data on the effect of nabilone in amyotrophic lateral sclerosis, a potential significant benefit of nabilone over currently available methods of treatment could not be established.

Requests for designation as an orphan medicinal product are made for investigational products. Absence of orphan designation does not preclude the development of this product, including its use in clinical trials. A marketing authorisation can still be obtained if quality, safety and efficacy are demonstrated.

For more information:

Sponsor's contact details:

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For contact details of patients' organisations whose activities are targeted at rare diseases see:

- Orphanet, a database containing information on rare diseases which includes a directory of patients' organisations registered in Europe.
- European Organisation for Rare Diseases (EURORDIS), a non-governmental alliance of patient organisations and individuals active in the field of rare diseases.