19 September 2018
EMA/138943/2018

Public summary of opinion on orphan designation

Melatonin for the treatment of non-traumatic subarachnoid haemorrhage

On 15 March 2018, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on the orphan designation application for melatonin for the treatment of non-traumatic subarachnoid haemorrhage. A negative decision was issued by the European Commission on 16 April 2018

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 reason:

- the sponsor has not provided sufficient evidence to show that melatonin might be of significant benefit for patients with non-traumatic subarachnoid haemorrhage, compared with the authorised medicine nimodipine. The laboratory models used to assess significant benefit of the medicine did not adequately represent the condition.

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.

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For more information:

Sponsor's contact details:

Contact details of the current sponsor for this orphan designation can be found on EMA website, on the medicine's rare disease designations page.

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.