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Public summary of opinion on orphan designation

Melatonin for the treatment of intracerebral haemorrhage

On 6 July 2020, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on the orphan designation application for melatonin for the treatment of intracerebral haemorrhage. A negative decision C(2020) 5439 was issued by the European Commission on 31 July 2020.

The sponsor applied for orphan designation on the basis of the seriousness and the rarity of the condition.

The negative opinion was based on the following reasons(s):

- the sponsor was not able to show that intracerebral haemorrhage affected a distinct subset of patients with stroke who would benefit from the medicine;
- the sponsor had not established that the condition affects no more than 5 in 10,000 persons in the EU at the time of submission.*

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

Contact details of the current sponsor for this orphan designation can be found on the EMA website.

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.

*For the purpose of the designation, the number of patients affected by the condition is estimated and assessed on the basis of data from the European Union, Iceland, Liechtenstein, Norway and the United Kingdom. This represents a population of 519,200,000 (Eurostat 2020).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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