6 April 2018
EMA/57238/2018

Public summary of opinion on orphan designation

Melatonin for the treatment of partial deep dermal and full thickness burns

On 12 February 2018, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on the orphan designation application for melatonin for the treatment of partial deep dermal and full thickness burns. A negative decision was issued by the European Commission on 13 March 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 failed to provide sufficient justification for the assumption that the medicine would be of significant benefit to patients with partial deep dermal and full thickness burns; it was unclear whether the published clinical study presented as evidence had an adequate design to demonstrate such benefit. In addition, the product had not been compared for significant benefit with all the authorised treatments available in the EU.

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.