EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Public summary of opinion on orphan designation

Benzyl benzoate, beta-caryophyllene, cineole, cinnamaldehyde, cinnamyl acetate, linalool, trans-2-methoxycinnamaldehyde for the treatment of eumycetoma

On 18 June 2020, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on the orphan designation application for benzyl benzoate, beta-caryophyllene, cineole, cinnamaldehyde, cinnamyl acetate, linalool, trans-2-methoxycinnamaldehyde for the treatment of eumycetoma. A negative decision C(2020) 5580 was issued by the European Commission on 10 August 2020.

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(s):

- The sponsor failed to demonstrate that the medicine would provide a significant benefit to patients with eumycetoma over currently available methods of treatment. Although results from laboratory studies suggest that the medicine would provide marginal improvement in survival compared with itraconazole (standard treatment for eumycetoma), it is not clear whether these improvements would be meaningful to patients. In addition, significant benefit over other authorised treatments for eumycetoma has not been 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

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.