13 December 2016
EMA/686476/2016
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Naltrexone for the treatment of fibromyalgia

On 6 October 2016, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on the orphan designation application for naltrexone for the treatment of fibromyalgia. A negative decision was issued by the European Commission on 2.

The sponsor, Able AB, applied for orphan designation on the basis of the seriousness of the condition and insufficient return on investment.

The negative opinion was based on the following reasons:

- the sponsor failed to provide appropriate scientific references to prove that fibromyalgia is a life-threatening, seriously debilitating, or serious long-term condition;
- the sponsor failed to establish that the expected revenues from marketing the product in the European Union are unlikely to compensate for the investment necessary to develop the product. In particular, the sponsor did not provide sufficient justification for its estimates of market size and market share for the product.

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 in fibromyalgia can still be obtained if quality, safety and efficacy are demonstrated.

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.