EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2015
EMA/COMP/321004/2015
Committee for Orphan Medicinal Products

Recommendation for maintenance of orphan designation at the time of marketing authorisation

Hetlioz (tasimelteon) for the treatment of non-24-hour sleep-wake disorder

During its meeting of 12 to 13 May 2015, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/10/841 for Hetlioz (tasimelteon) as an orphan medicinal product for the for the treatment of non-24-hour sleep-wake disorder. The COMP assessed whether, at the time of marketing authorisation, the medicinal product still met the criteria for orphan designation. The Committee looked at the seriousness and prevalence of the condition, and the existence of other methods of treatment. The COMP recommended that the orphan designation of the medicine be maintained[1].

Life-threatening or long-term debilitating nature of the condition

The Committee for Medicinal Products for Human Use (CHMP) recommended the authorisation of Hetlioz for 'treatment of non-24-hour sleep-wake disorder in totally blind adults'.

During the review of the orphan designation for Hetlioz, the COMP noted that the original orphan condition, which was 'non-24-hour sleep-wake disorder in blind people with no light perception', is a subset of the condition 'non-24-hour sleep-wake disorder'. The COMP concluded that the orphan condition should be amended to the latter, in line with the current classification of the condition.

The indication recommended by the CHMP falls within the scope of the amended orphan indication.

The COMP concluded during its review that there had been no change in the seriousness of the condition since the orphan designation in 2011. Non-24-hour sleep-wake disorder is a condition that is long-term debilitating because of the excessive daytime sleepiness that affects the patient's quality of life and their ability to carry out daily activities.

[1] The maintenance of the orphan designation at time of marketing authorisation would, except in specific situations, give an orphan medicinal product 10 years of market exclusivity in the EU. This means that in the 10 years after its authorisation similar products with a comparable therapeutic indication cannot be placed on the market.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Prevalence of the condition

The sponsor provided updated information on the prevalence of non-24-hour sleep-wake disorder based on data from the WHO and published literature.

On the basis of the information provided by the sponsor and the knowledge of the COMP, the COMP concluded that the prevalence of non-24-hour sleep-wake disorder is below the ceiling for orphan designation, which is 5 people in 10,000. At the time of the review of the orphan designation, the prevalence was estimated to be less than 3.3 people in 10,000. This is equivalent to a total of around 169,000 people in the EU.

Existence of other methods of treatment

The COMP noted that, at the time of the review of the orphan designation, no treatments were authorised in the EU for the treatment of non-24-hour sleep-wake disorder.

Conclusions

Based on the data submitted and the scientific discussion within the COMP, the COMP considered that Hetlioz still meets the criteria for designation as an orphan medicinal product and that it should remain in the Community Register of Orphan Medicinal Products.

Further information on the current regulatory status of Hetlioz can be found in the European public assessment report (EPAR) on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.