24 June 2021
EMA/CHMP/306202/2021

CHMP List of questions

To be addressed by the marketing authorisation holder(s) for etifoxine-containing medicinal products

Referral under Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1509

INN/active substance: etifoxine

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1. Questions

The marketing authorisation holder (MAH) is requested to address the following questions:

Question 1

The MAH is required to provide current data on MA status worldwide including the approved indications by country.

Question 2

The MAH is required to provide the sales data for the last 5 years per year, per country.

Question 3

The MAH should provide all available efficacy data in the approved indications. A critical discussion of this data should be provided. In particular, a thorough discussion is awaited on the results of the AMETIS study, where there was no statistically significant difference in terms of efficacy between etifoxine and placebo and between lorazepam and placebo in a population of patients presenting adjustment disorders with anxiety. The MAH is requested to discuss the results of the study and how these affect the benefit/risk ratio of the product.

Question 4

The AMETIS study shows that one week after discontinuation of treatment, a statistically significant rebound of anxiety assessed by the HAM-A score was observed in the lorazepam group but not in the etifoxine group. The MAH is requested to discuss, based on relevant data, the potential for rebound effects following discontinuation of etifoxine.

Question 5

The MAH is requested to review and critically discuss all available safety data on etifoxine (pre- and post-authorisation, where rare but significant AEs have been reported) and discuss the overall safety profile of etifoxine.

Question 6

Considering responses to the above questions, and in particular the results of the AMETIS study, the MAH should provide a thorough benefit-risk balance assessment of their etifoxine-containing medicinal product. The MAH is requested to discuss the target populations where the benefits of etifoxine outweigh the risks (within the currently approved indication). Based on this discussion, the MAH should discuss the need for amendments to the product information (including possible restrictions of indication).