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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): esketamine (for centrally authorised product only)

Procedure No. EMEA/H/C/PSUSA/00010825/202203

Period covered by the PSUR: 05 September 2021 To: 04 March 2022

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for esketamine (for centrally authorised product only), the scientific conclusions of CHMP are as follows:

In view of available data on respiratory depression from spontaneous reports including in some cases a close temporal relationship, a positive re-challenge and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between esketamine (for centrally authorised product only) and respiratory depression is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing esketamine (for centrally authorised product only) should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for esketamine (for centrally authorised product only) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing esketamine (for centrally authorised product only) is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.