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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): axicabtagene ciloleucel

Procedure No. EMEA/H/C/PSUSA/00010703/202110

Period covered by the PSUR: 18 April 2021 to 17 October 2021

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for axicabtagene ciloleucel, the scientific conclusions of CHMP are as follows:

In view of available data on status epilepticus from ongoing clinical trials, the literature, spontaneous reports including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between axicabtagene ciloleucel and status epilepticus is at least a reasonable possibility. The PRAC concluded that the product information of products containing axicabtagene ciloleucel 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 axicabtagene ciloleucel the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing axicabtagene ciloleucel 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.