30 March 2023
EMA/187790/2023
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): patisiran

Procedure No. EMEA/H/C/PSUSA/00010715/202208

Period covered by the PSUR: 10 August 2021 To: 9 August 2022

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Scientific conclusions

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

In view of available data on dysphonia from clinical trial(s), and spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between patisiran and dysphonia is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing patisiran 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 patisiran the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing patisiran 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.