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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): patisiran

Procedure No. EMEA/H/C/PSUSA/00010715/202002

Period covered by the PSUR: 08/08/2019 To: 08/02/2020

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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 pruritus from spontaneous reports, the PRAC considers a causal relationship between patisiran and pruritus as a sign of infusion related reactions is at least a reasonable possibility. The PRAC 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.