25 February 2021
EMA/244222/2021
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): inotersen

Procedure No. EMEA/H/C/PSUSA/00010697/202007

Period covered by the PSUR: 04/01/2020 To: 04/07/2020

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Scientific conclusions

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

In view of available data on hypersensitivity from spontaneous reports including in some cases a close temporal relationship and in view of biological plausibility, the PRAC considers a causal relationship between inotersen and hypersensitivity is at least a reasonable possibility. The PRAC concluded that the product information of products containing inotersen 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 inotersen the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing inotersen 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.