EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2021
EMA/581034/2021
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): givosiran

Procedure No. EMEA/H/C/PSUSA/00010839/202011

Period covered by the PSUR: 18 May 2020 to 18 November 2020

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

In view of available data on pancreatitis from clinical trial(s) and spontaneous reports, the PRAC considers a causal relationship between givosiran and pancreatitis is at least a reasonable possibility. The PRAC concluded that the product information of products containing givosiran 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 givosiran the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing givosiran 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.