EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 February 2021
EMA/241723/2021
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): evolocumab

Procedure No. EMEA/H/C/PSUSA/00010405/202007

Period covered by the PSUR: 16/07/2019 To: 16/07/2020

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 evolocumab, the scientific conclusions of CHMP are as follows:

Despite lack of a plausible mechanism, in view of available data on headache from clinical trials, and spontaneous reports including in 600 cases with a close temporal relationship, a positive de-challenge and/or re-challenge or withdrawal of Repatha, the PRAC considers a causal relationship between evolocumab and headache is at least a reasonable possibility. The PRAC concluded that the product information of products containing evolocumab should be amended accordingly. Update of section 4.8 of the SmPC to add the adverse reaction headache with a frequency common. The Package leaflet is updated 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 evolocumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing evolocumab 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.