19 September 2024
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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): selexipag

Procedure No. EMEA/H/C/PSUSA/00010503/202312

Period covered by the PSUR: 20 December 2020 To: 20 December 2023

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

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Scientific conclusions

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

In view of available data on angioedema from clinical trial(s), spontaneous and solicited reports including in some cases a close temporal relationship, with positive de-challenge and/or re-challenge and absence of clear alternative aetiology, a potential plausible mechanism, the PRAC Rapporteur considers a causal relationship between selexipag and angioedema is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing selexipag should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for selexipag the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing selexipag 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.