EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2021
EMA/359079/2021
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): sulfur hexafluoride

Procedure No. EMEA/H/C/PSUSA/00002822/202009

Period covered by the PSUR: 30/09/2017 to 30/09/2020

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 sulfur hexafluoride, the scientific conclusions of CHMP are as follows:

In view of available data on PEG allergy from the literature, spontaneous reports including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers that the warning section should be amended to highlight the role of PEG in the occurrence of rare but serious hypersensitivity reactions and to strengthen the existing wording about hypersensitivity reactions.

The PRAC concluded that the product information of products containing sulfur hexafluoride should be amended accordingly.

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

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