EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): somapacitan

Procedure No. EMEA/H/C/PSUSA/00010920/202408

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Scientific conclusions

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

In view of available data on the risks of slipped capital femoral epiphysis (SCFE) in association with growth hormone treatment from clinical trials, the literature and spontaneous reporting, the PRAC considers SCFE a potential risk of somapacitan treatment, also taking into account the fact that the risk of SCFE has already been reflected in the product information for other medicinal products containing growth hormone, including a long-acting growth hormone analogue. The PRAC concluded that the product information of medicinal products containing somapacitan 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 somapacitan the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing somapacitan 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.