30 January 2020
EMA/24641/2020
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): pentosan polysulfate sodium (for centrally authorised product)

Procedure No. EMEA/H/C/PSUSA/00010614/201906

Period covered by the PSUR: 02/12/2018 to 01/06/2019

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ANNEX IV

SCIENTIFIC CONCLUSIONS AND GROUNDS FOR THE VARIATION TO THE TERMS OF THE MARKETING AUTHORISATION(S)

Scientific conclusions

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

The MAH has sought for medical expert opinions on the potential risk for developing pigmentary maculopathy and, based on the limited information available at this stage about this risk, it is considered that:

- All patients should have an ophthalmologic examination after 6 months of use of PPS, at the same time of the regular reassessment of response to treatment with PPS.

- If the examination reveals no pathologic findings, the next ophthalmologic examination should be performed regularly at 5 years of PPS treatment (or earlier, in case of visual complaints). However, in case of pathologic findings, the ophthalmological examinations should be performed every year.

Therefore, and as proposed by the MAH, it is considered that the warnings on pigmentary maculopathy should be improved regarding the periodicity of the ophthalmological examination.

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 pentosan polysulfate sodium (for centrally authorised product) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pentosan polysulfate sodium (for centrally authorised product) 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.