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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): anakinra

Procedure No. EMEA/H/C/PSUSA/00000209/202205

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Scientific conclusions

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

In view of available data on risk of MAS in patients with Still's disease from clinical trials, the literature, non-interventional studies, the PRAC considers that available evidence does not support causal association between the risk of MAS and anakinra. The PRAC concluded that the product information of products containing anakinra should be amended 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 anakinra the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing anakinra 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.