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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): dapagliflozin

Procedure No. EMEA/H/C/PSUSA/00010029/202310

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Scientific conclusions and grounds for variation to the terms of the marketing authorisations

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

In view of the available data on polycythaemia from the literature and spontaneous reports and in view of a plausible mechanism of action, the PRAC considers there is sufficient evidence to justify a causal relationship between dapagliflozin and polycythaemia. The PRAC concluded that the product information of products containing dapagliflozin 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 dapagliflozin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dapagliflozin, 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.