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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): fenfluramine

Procedure No. PSUSA/00010907/202506

Period covered by the PSUR:
1 year to 24 June 2025

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**Scientific conclusions**

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

New definite cases of valvular heart disease (VHD) and pulmonary arterial hypertension (PAH) were identified in the post-marketing setting, which are possibly related to fenfluramine used to treat DS and LGS. VHD and PAH represent important risks of fenfluramine for the treatment of DS and LGS. Taking into account the serotonergic stimulation of cardiac valve tissue as a plausible mechanism of action, the known association between VHD/PAH and higher doses of fenfluramine used as an appetite suppressant and a first definite case of valvular heart disease in a child treated with lower doses of fenfluramine (6.6 mg/day) for DS identified in the last PSUR, the PRAC considers that the identification of further definite cases of VHD as well as PAH, which are possibly related to fenfluramine, warrants an update of the product information to provide clinicians with the most up-to-date evidence on this important risk.

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 fenfluramine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing fenfluramine 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.