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 fezolinetant, the scientific conclusions of PRAC are as follows:

In view of available data on hepatic adverse events/hepatotoxicity from clinical trial(s), the literature, spontaneous reports including a close temporal relationship, a positive de-challenge reported in some cases, the PRAC considers a causal relationship between fezolinetant and drug-induced liver injury (DILI) is at least a reasonable possibility. The PRAC concluded that the product information of products containing fezolinetant 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 fezolinetant the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing fezolinetant 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.