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EMA/532577/2023
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): parecoxib

Procedure No. EMEA/H/C/PSUSA/00002314/202303

Period covered by the PSUR:
01/04/2022 To: 31/03/2023

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## Scientific conclusions

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

In view of available data on the use of parecoxib during pregnancy, and the previous PRAC advice about use of non-steroidal anti-inflammatory drugs (NSAIDs) during pregnancy, the PRAC concluded that the product information of Dynastat 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 parecoxib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing parecoxib 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.