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EMA/566491/2023
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Daxas

Active substance(s): roflumilast

Procedure No. EMEA/H/C/PSR/S/0041

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Scientific conclusions

Taking into account the PRAC Assessment Report for the non-interventional imposed PASS final study report for the medicinal product(s) mentioned above, the scientific conclusions of CHMP are as follows:

As a result of the fulfilment of the PASS, removal of the additional monitoring statement and the black triangle from the product information is warranted. Annex II of the product information is also updated to remove the PASS.

Therefore, in view of available data regarding the PASS final study report, the PRAC considered that changes to the product information and to the conditions of the marketing authorisation were warranted.

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 the results of the study for the medicinal product(s) mentioned above, the CHMP is of the opinion that the benefit-risk balance of these medicinal product(s) is unchanged, subject to the proposed changes to the product information.

The CHMP is of the opinion that the terms of the marketing authorisation(s) of the medicinal product(s) mentioned above should be varied.