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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: roflumilast

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30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for roflumilast, the scientific conclusions of CHMP are as follows:

Cumulative 35 cases containing at least one event from the Medical Dictionary for Regulatory Activities High Level Term (MedDRA HLT), Panic attacks and disorders have been retrieved for roflumilast. Overall, it is not possible to exclude a causal relationship between roflumilast and the development of panic attack due to nearly 50% reported dechallenge positive and the time to onset was plausible in most (80%) of the cases. In COPD controlled clinical trials 4 out of 5766 subjects who received roflumilast experienced a TEAE of panic attack. Therefore, panic attack should be included in the product information with a frequency rare.

Therefore, in view of available data regarding roflumilast, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for roflumilast the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing roflumilast is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.