28 January 2021
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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): levodopa

Procedure No. EMEA/H/C/PSUSA/00107800/202006

Period covered by the PSUR: 19 December 2019 to 20 June 2020

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Scientific conclusions

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

Based on the cumulative review of medication errors and commercial product quality complaints, the PRAC considers that the mitigation strategies in place in the US regarding the addition of a new cleaning step in order to provide more detailed directions, accompanied by visual aids, on how to clean the inhaler mouthpiece as well as increase cleaning frequency should also be included in the EU product information.

The PRAC concluded that the product information (Instruction for use and SmPC) of products containing levodopa should be amended accordingly.

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