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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): dulaglutide

Procedure No.: EMEA/H/C/PSUSA/00010311/202009

Period covered by the PSUR: 17/09/2019 To: 17/09/2020

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Scientific conclusions

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

In view of available data on pancreatitis and acute pancreatitis from spontaneous reports, the PRAC considers that the wording currently included in section 4.8 of the SmPC is not adequate. Such wording refers only to pre-authorisation studies, and does not reflect the current knowledge, where acute pancreatitis and pancreatitis have been reported also in the post-marketing setting. The PRAC concluded that the product information of products containing dulaglutide 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 dulaglutide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dulaglutide 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.