EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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/00010311/201609

Period covered by the PSUR: 19 March 2016 to 18 September 2016

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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:

Based on the review of a cumulative review provided by the Marketing Authorisation Holder and further analysis of EudraVigilance reports, the PRAC concluded that a causal relationship between dulaglutide and the adverse reactions hypersensitivity, anaphylactic reaction and angioedema cannot be excluded. Therefore, section 4.8 of the Summary of Product Characteristics will be updated to reflect these adverse reactions, with frequencies of uncommon, rare and rare, respectively. The Package Leaflet is updated in accordance.

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

Grounds for the variation to the terms of the marketing authorisation

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.