

Annex IV

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

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 the overall MAH's review of hypersensitivity it is considered that the information available in section 4.8 of the SmPC adequately reflects the evidence. The PL was, however, lacking in the description of the systemic hypersensitivity events, and it is therefore recommended to be updated with information on hypersensitivity, for consistency with the SmPC.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the Package Leaflet of medicinal products containing dulaglutide 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 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.