

## **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 liraglutide, the scientific conclusions of CHMP are as follows:

In view of available data on headache from clinical trial, the literature, spontaneous reports including in 12 cases a close temporal relationship, a positive de-challenge and in at least one case a re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between liraglutide in weight management and headache is at least a reasonable possibility. The PRAC concluded that the product information of products containing liraglutide for weight management should be amended accordingly.

Update of section 4.8 of the SmPC to add the adverse reaction 'headache' with a frequency very common.

The Package leaflet is to be updated 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 liraglutide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing liraglutide 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.