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

Active substance(s): insulin glargine / lixisenatide

Procedure No. EMEA/H/C/PSUSA/00010577/202111

Period covered by the PSUR: 21/11/2020 To: 21/11/2021
Annex IV

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**Scientific conclusions**

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

In view of available data on delayed gastric emptying from spontaneous reports including a case with close temporal relationship and a positive de-challenge and in view of a plausible mechanism of action for all GLP 1 RA products, the PRAC considers a causal relationship between lixisenatide and delayed gastric emptying is at least a reasonable possibility. The PRAC concluded that the product information of products containing insulin glargine/ lixisenatide 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 insulin glargine / lixisenatide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing insulin glargine / lixisenatide 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.