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): insulin glargine / lixisenatide

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

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

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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.