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/00010577/201905

Period covered by the PSUR: 21/11/2018 To: 21/05/2019

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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:

The MAH identified 29 case reports of 'cutaneous amyloidosis' at the injection site for insulin glargine, one of the components of this FRC, in their pharmacovigilance database. In 15 of the 29 cases 'cutaneous amyloidosis' was confirmed by histopathology analysis. The time to onset ranged from 4 years to 19 years in these cases. In none of the cases were potential confounders reported that could explain the events. In two cases, insulin glargine was the only insulin used. In the remaining cases, insulin glargine was used concomitantly with other insulins. These well-documented pharmacovigilance cases in which the event is confirmed with histopathology provide sufficient evidence to establish an association between insulin glargine and 'cutaneous amyloidosis'. Therefore, the Product Information should be amended in order to include the adverse drug reaction (ADR) 'cutaneous amyloidosis' and to amend method of administration instructions accordingly. The SmPC should also be amended to include the ADR 'lipodystrophy' in line with the Package Leaflet.

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.