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

Procedure No. EMEA/H/C/PSUSA/00001751/201904

Period covered by the PSUR: from 20 April 2018 to 20 April 2019

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Scientific conclusions

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

The cumulative review of cutaneous amyloidosis included 29 cases of which 15 were well documented cases in which the event was confirmed with histopathology. These cases did not contain confounders and have a compatible time to onset. Together with the available evidence from literature and text books, this signal contains sufficient evidence to establish an association between insulin glargine and cutaneous amyloidosis. As cutaneous amyloidosis may lead to insulin resistance due to poor absorption from the infiltrated site, health care professionals and patients should be informed of this event in the PI. Absorption of insulin could be improved by rotating the injection site. The MAH is therefore requested to include the event cutaneous amyloidosis in the SmPC and PIL.

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 the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing insulin glargine 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.