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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): sitagliptin

Procedure No. EMEA/H/C/PSUSA/00002711/201708

Period covered by the PSUR: 4 August 2014 – 3 August 2017

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Scientific conclusions

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

Thrombocytopenia is cumulatively described in 307 reports of patients using sitagliptin-containing products. Forty-five of the cases describe positive de-challenges, including 4 reports also describing positive re-challenges. Thirty-nine of the 45 reports with positive de-challenge lack information or were confounded. The remaining 6 reports, especially the 4 aforementioned reports with positive re-challenges support a true relationship between sitagliptin use and the events. This is further strengthened by the absence of alternative aetiologies. As a result, section 4.8 of the Summary of Products Characteristics should be updated to add thrombocytopenia to the list of adverse reactions with a frequency rare.

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