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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name:SITAGLIPTIN

Procedure No. EMEA/H/C/PSUSA/00002711/201408

Period covered by the PSUR: 4 August 2011 to 3 August 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for SITAGLIPTIN, the scientific conclusions of CHMP are as follows:

The evidence on the association between bullous pemphigoid and the use of DPP-4 inhibitors including sitagliptin is growing. The four cases reported in literature, of which one showed a clear positive dechallenge, suggest a causal relationship between sitagliptin and bullous pemphigoid. Confounding factors do not seem to explain the occurrence of these cases. Based on these literature cases, the possible mechanism, and further spontaneous reports, the PRAC was of the view that “bullous pemphigoid” should be added to the product information as an adverse drug reaction.

In addition, based on the literature and reported cases of polyarthritis and arthropathy, the product information should be updated to include arthropathy as an adverse drug reaction.

Therefore, in view of available data regarding sitagliptin, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for SITAGLIPTIN the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing SITAGLIPTIN is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisations should be varied.