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Committee for Medicinal Products for Human Use (CHMP)

Onglyza

Saxagliptin

Procedure number: EMEA/H/C/001039/PSU/022

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

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

In the cumulative cases of patients with abdominal pain, there were 12 cases reporting a positive de- and rechallenge and in five of the cases a second positive de-challenge of abdominal pain was reported. The time to onset of the events was relatively short (hours to days). This was suggestive of a causal relationship. Of note, abdominal pain is listed in section 4.8 of the SmPC of another DPP-4 inhibitor, sitagliptin. Overall, the cases discussed by the MAH pointed towards a causal relation between saxagliptin use and abdominal pain. Therefore, 'abdominal pain' should be included in section 4.8 of the SmPC. However, at this time no frequency can be assigned based on the provided data in the PSUR and the MAH response.

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 Onglyza the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance saxagliptin is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms to the Marketing Authorisation should be varied.