25 April 2013
EMA/CHMP/780867/2013
Committee for Medicinal Products for Human Use

Bydureon

International non-proprietary name: exenatide

Procedure No. EMEA/H/C/002020/PSU/0014

Period covered by the PSUR: 01 April 2012 to 30 September 2012

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 exenatide, the scientific conclusions of PRAC are as follows:

Thirtytwo cases of pancreatitis have been reported cumulatively with once weekly-treated patients. 25/32 cases were reported during the period of review for this PSUR, of which positive de-challenge was reported in 13 of the cases. Therefore as data is now available for patients treated with once-weekly exenatide (Bydureon), section 4.8 of the SmPC of Bydureon should be updated to add "acute pancreatitis" under the SOC Gastrointestinal disorders with a frequency "not known" (as post-marketing experience for Bydureon, table 1, while removing "acute pancreatitis" as reflecting experience from Byetta only, table 2). The Package leaflet should be updated accordingly.

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

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