24 October 2014
EMA/CHMP/630136/2013
Committee for Medicinal Products for Human Use (CHMP)

Bydureon

International non-proprietary name: exenatide

Procedure No.: EMEA/H/C/002020/PSUV/014

Period covered by the PSUR: 01 October 2012 to 31 March 2013

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:

The MAH has within this PSUR procedure provided supplementary information regarding post-marketing cases of acute renal failure for Bydureon. Based on the post-marketing experience where cases of altered renal function, including acute renal failure, worsened chronic renal failure, renal impairment, increased serum creatinine during the treatment with Bydureon have been reported with a close temporal relationship and positive dechallenge, it is considered that there is sufficient information to conclude that a causal relationship between Bydureon and the above mentioned renal adverse reactions is at least a reasonable possibility. Therefore, in view of available data regarding renal function with the use of Bydureon, 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 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.