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Committee for Medicinal Products for Human Use (CHMP)

Bydureon

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

International non-proprietary name: EXENATIDE

Procedure No. EMEA/H/C/002020/PSUV/0024

Period covered by the PSUR: 1 October 2013 – 30 March 2014

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

Rapid weight loss at a rate of >1.5 kg per week is a known risk factor in patients treated with exenatide. Weight loss of this rate may have harmful consequences, such as cholelitiasis. Therefore, in view of available data regarding occurrence of cholelithiasis linked to the rapid weight loss during exenatide treatment, the PRAC considered that changes to the product information were warranted. In addition, due to increase experience with the use of exenatide administered once weekly and evidence the spontaneous reports of several adverse reactions, additional changes to product information of exenatide administered once weekly were warranted.

Therefore, in view of available data regarding rapid weight loss and postmarketing safety reports, 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.

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