22 May 2014
EMA/394090/2014
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/2020/PSUV/0018

Period covered by the PSUR: 01 April 2013 to 30 September 2013

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7455
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Scientific conclusions

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

Following the submission, at the request of the PRAC, with the previous PSUR of a cumulative review on injection site abscess and cellulitis with exenatide once weekly and the additional clarifications (cumulative number of events and narratives of the reported cases) provided by the MAH with the present PSUR, the PRAC considers that a causal relationship between exenatide once weekly and injection site abscess and cellulitis is possible. In at least 23 of the provided post-marketing cases there is considered to be a close temporal relationship to injection site abscess and cellulitis during treatment with exenatide once weekly. Although the time to onset from start of treatment may vary from days to months amongst the cases, there were cases where the events occurred after the first injection(s), or with close temporal relationship between injection on that particular site and the subsequent events. Although most of the cases were classified as non-serious, 15 serious cases have been reported. In three patients the adverse event occurred after switching from twice daily to once weekly exenatide. Two patients were switched to exenatide twice daily after experiencing the adverse event and tolerated it well, suggesting a risk related to once weekly and not twice daily exenatide. A potential mechanism has not yet been identified. The reported events of injection abscesses and cellulitis may reflect handling errors with the rather complicated Bydureon kit and should therefore continue to be monitored in future PSURs.

Therefore, in view of available data regarding injection site abscess and cellulitis, the PRAC considered that changes to the product information for exenatide once weekly (Bydureon) 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.