EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

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

International non-proprietary name:exenatide

Procedure No. EMEA/H/C/PSUSA/00009147/201503

Period covered by the PSUR: 01 April 2014 – 31 March 2015

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Scientific conclusions

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

Scientific conclusions and grounds for variation to the terms of the marketing authorisations

Data presented in this PSUR show that the incidence for exenatide containing products has changed for the following adverse events: anaphylactic reaction, dehydration, somnolence, constipation, flatulence, alopecia, pruritus, and/ or urticaria, altered renal function including acute renal failure, worsened chronic renal failure, renal impairment, increased serum creatinine, injection site reactions, injection site pruritus, injection site rash, weight decreased, vomiting, eructation, macular or popular rash, angioedema, international normalized ratio (INR) increased, and acute pancreatitis. Based on the review of the reported cases, the PRAC considers that the frequency information for these adverse reactions should be updated in the product information.

Therefore, in view of the available data regarding the above mentioned adverse events, the PRAC considered that changes to the product information of medicinal products containing exenatide were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for exenatide the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing exenatide is favourable subject to the proposed changes to the product information

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