EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 November 2020
EMA/120245/2021
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): exenatide

Procedure No.: EMEA/H/C/PSUSA/00009147/202003

Period covered by the PSUR: From: 01/04/2019 To: 31/03/2020

Medicinal product no longer authorised

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Scientific conclusions

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

In view of available data on delayed gastric emptying from clinical trials and in view of a plausible mechanism of action, the PRAC considers a causal relationship between exenatide and delayed gastric emptying is at least a reasonable possibility. The PRAC concluded, that the product information of products containing exenatide should be amended accordingly.

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

Grounds for the variation to the terms of the marketing authorisation(s)

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

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.

Medicinal product no longer authorised