EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): belatacept

Procedure No. EMEA/H/C/PSUSA/00000311/201606

Period covered by the PSUR: 15 June 2015 - 14 June 2016

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

Infusion related events are any signs or symptoms experienced by patients during the infusion of pharmacologic agents or any event occurring on the first day of drug administration. Symptoms are timely related to the drug administration and may range from symptomatic discomfort to serious or fatal events caused by anaphylaxis. One case of anaphylactic reaction (including symptoms of generalized rash, dyspnea, dizziness, arterial hypotension and atrial fibrillation with tachycardia) has been reported post-marketing for belatacept. The present product information for belatacept contained information that there have been no reports of anaphylaxis and hence the product information has been amended to reflect that anaphylaxis has been reported during post-marketing surveillance.

The risk management plan (RMP) has been updated accordingly to include information on the event of anaphylaxis. Infusion-related events, including anaphylactic reactions, are included as a potential risk in the RMP.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC Rapporteur considered that changes to the product information of medicinal products containing belatacept were warranted.

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 belatacept the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing belatacept is unchanged subject to the proposed changes to the product information

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