EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 January 2019
EMA/219028/2019
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): pertuzumab

Procedure No. EMEA/H/C/PSUSA/00010125/201806

Period covered by the PSUR: 8th June 2017 to 7th June 2018

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Scientific conclusions

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

Data available for Infusion Related Reactions (IRR) and anaphylaxis/hypersensitivity with fatal outcome for patients treated with Perjeta in clinical trials, data from published literature, and relevant data from the Roche global safety database showed that there were no cases of confirmed IRRs or anaphylaxis/hypersensitivity with a fatal outcome in pivotal clinical trials in patients treated with pertuzumab. From the global safety database of the MAH a total of 15 case reports were retrieved inculding MedDRA PTs potentially indicative of an IRR or hypersensitivity/anaphylaxis which were associated with fatal outcome. Medical review of these 15 reports showed that in 8/15 cases, the reported events were not indicative of IRR/hypersensitivity/anaphylaxis. In the remaining 7 cases the events reported were indeed suggestive of IRR/ hypersensitivity/ anaphylaxis and in 3/7 of them, a causal relationship between the administration of pertuzumab and the fatal event could not be excluded.

In conclusion, administration of Pertuzumab may cause Infusion Related Reactions (IRR) and hypersensitivity/anaphylaxis reactions that can be associated with fatal outcome and the Product Information should be updated to reflect such outcome.

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 pertuzumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pertuzumab 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.