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:PERTUZUMAB

Procedure No. EMEA/H/C/PSUSA/00010125/201412

Period covered by the PSUR: 8 June 2014 to 7 December 2014

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

Pre-clinical and Clinical Trials data document that pertuzumab is associated with diarrhoea. Grade 3/4 diarrhoea is an Important Identified Risk in the Risk Management Plan (toxicity and Clinical Trials data), and a recently published study found the frequency of diarrhoea to be 28.1 % in the pertuzumab vs. 14.2% in the control-arm. Additionaly, grade 3/4 diarrhoea is described in the Summary of Product Characteristics as one of the most common serious adverse drug reactions.

In the provided data of events of diarrhoea received from Clinical Trials and Post-Marketing experience, from the 22 patients with reporting grade>3 diarrhoea, only 3 patients were reported to have received treatment for diarrhoea, which is an indicator that further advice to prescribers may be required.

Adverse consequences of diarrhoea – notably dehydration and electrolyte imbalance – can be prevented by early institution of anti-diarrhoeal medication, and fluid and electrolyte substitution. In light of the requirement for further advice, it is recommended that a warning regarding ‘diarrhoea’ should be specifically included in section 4.4 of the Summary of Product Characteristics. The Package Leaflet is to be updated accordingly.

Therefore, in view of available data regarding pertuzumab, the PRAC considered that changes to the product information 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 PERTUZUMAB the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing PERTUZUMAB is favourable subject to the proposed changes to the product information

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