29 May 2019
EMA/429226/2019
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): trastuzumab

Procedure No. EMEA/H/C/PSUSA/00003010/201809

Period covered by the PSUR: 08 Nov 2017 to 24 Sep 2018

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Scientific conclusions

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

Although the number of cases identified by a search of the safety database and meeting the Cairo-Bishop criteria for diagnosis was low, it is endorsed that a contributing factor of trastuzumab to tumour lysis syndrome (TLS) could not be excluded. Although there are some limitations when using Cairo-Bishop criteria for diagnosis leading to underestimation of the number of cases, the update of the Product Information to include TLS with a frequency unknown is endorsed, because trastuzumab is a potent mediator of antibody-dependent cell-mediated cytotoxicity (ADCC). Therefore, from the mechanism of action there is evidence that trastuzumab can cause tumour lysis syndrome. One case of tumour lysis syndrome with trastuzumab administration as monotherapy lends further support.

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