22 February 2018
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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: temozolomide

Procedure No. EMEA/H/C/PSUSA/00002886/201707

Period covered by the PSUR: 13 July 2014 to 12 July 2017

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Scientific conclusions

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

Sepsis is the second most frequent infection. During the reporting interval 34 cases of sepsis including associated terms (e.g. neutropenic sepsis, urosepsis) were reported in the post-marketing setting. Due to its severity and considering that less severe and less frequent infections such as upper respiratory infection, sinusitis or wound infection are labelled, the PRAC considered that sepsis should be included in the product information and not merged under the event 'infections'. Based on the available evidence, the PRAC concluded that 'sepsis' should be included with an uncommon frequency in section 4.8 of the SmPC and in section 4 of the Package Leaflet.

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

Grounds for the variation to the terms of the marketing authorisation

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

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