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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): venetoclax

Procedure No. EMEA/H/C/PSUSA/00010556/201912

Period covered by the PSUR:03/06/2019 to 03/12/2019

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Scientific conclusions

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

The serious infections (such as sepsis, pneumonia, septic shock etc.) are considered to be the most common cause of death (after those associated with the underlying malignancy or disease progression) in relation to venetoclax treatment. In this reporting interval, a total of 765 reports of serious infections were identified. Since the overall number of events of serious infections is high, the healthcare professionals should be explicitly reminded of these cases. Section 4.4 of the SmPC for Venclyxto should therefore include a standalone undersection entitled "infections", including the warning statement regarding the risk of infections and their monitoring. The Package leaflet should be updated accordingly.

In addition, the actual format of text for recommendation for dose reduction in case of concomitant use with CYP3A inhibitors is considered difficult to read and respective data would be more easily readable when displayed in tabular format. The relevant information in section 4.2 of the SmPC for Venclyxto should be amended accordingly.

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