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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): paliperidone

Procedure No. EMEA/H/C/002105/PSUV/0016

Period covered by the PSUR: 1 July 2013 – 30 June 2014

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Scientific conclusions

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

Following a case of medication error with Xeplion, the PRAC was of the view that in order to prevent medication errors during the monthly maintenance dosing schedule, the text in section 4.2 of the Summary of Products Characteristics for paliperidone palmitate prolonged-release suspension for injection (Xeplion) should be updated in order to clarify that the third injection should be administered one month after the second injection and then monthly thereafter.

Therefore, in view of available data regarding paliperidone palmitate prolonged-release suspension for injection, 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 Xeplion, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance paliperidone is favourable subject to the proposed changes to the product information.

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