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Committee for Medicinal Products for Human Use (CHMP)

Cinryze

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: c1 inhibitor, human

Procedure No. EMEA/H/C/001207/PSUV/0023

Period covered by the PSUR: 16 June 2013 – 15 December 2013

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Scientific conclusions

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

Following the modification of the summary of safety concerns and the definition of identified risks of the RMP, where hypersensitivity was classified as an identified risk for patients taking medicinal products containing C1 inhibitor (human), the PRAC considered that hypersensitivity reactions should also be considered an identified risk in the Product Information. Therefore, the PRAC considered that section 4.8 of the SmPC and relevant section of the package leaflet should be adjusted accordingly.

Therefore, in view of available data the PRAC Rapporteur 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 Cinryze, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance c1 inhibitor, human is favourable subject to the proposed changes to the product information.

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