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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): florbetaben (18f)

Procedure No. EMEA/H/C/PSUSA/00010094/201508

Period covered by the PSUR: 21 February 2015 – 20 August 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for florbetaben (18f), the scientific conclusions of CHMP are as follows:

During this PSUR procedure the ADRs "injection site erythema" and "application site erythema" were merged and their frequencies were modified from 'uncommon' to 'common' in section 4.8 of the summary of product characteristics. This change was also reflected in the package leaflet.

In addition the overall safety profile of Neuraceq was updated as it is now based on data from 1090 administrations of Neuraceq, an increase from 978 previously used. This modification was accepted by the PRAC.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that the changes to the product information of Neuraceq (18F-florbetaben) were warranted.

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 18F-florbetaben the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing 18F-florbetaben 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.