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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

Active substance: florbetaben (18f)

Procedure No. EMEA/H/C/PSUSA/00010094/201602

Period covered by the PSUR: 21 August 2015 – 20 February 2016

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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:

Due to the very short half-life of 18F florbetaben (circa 110 minutes) the bone uptake of this compound is likely to be of limited clinical significance and overall associated to a level of risk compatible to the one derived from the 'normal' bio-distribution of the drug. However, the spurious signal resulting from non-specific 'bone uptake' in the face could lead to incorrect image interpretation. Therefore, due to the studies reported, the spontaneous report and the strong likelihood of a class effect, section 4.4 and 5.2 of the Summary of Product Characteristics should be updated with this safety concern.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing 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

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