

**SCIENTIFIC CONCLUSIONS AND GROUNDS RECOMMENDING THE VARIATION  
TO THE TERMS OF THE MARKETING AUTHORISATION**

## **Scientific conclusions**

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

Based on the review of cases in the saxagliptin PSUSA covering the reporting period 31 July 2013 to 30 July 2014 (EMEA/H/C/PSUSA/00002685/201407), the PRAC requested the MAH to add “constipation” to section 4.8 of the saxagliptin SmPC with a frequency of “not known”. The PRAC considered that the product information of the saxagliptin/metformin fixed dose combination should be updated accordingly.

Therefore, in view of available data regarding constipation, 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 METFORMIN, SAXAGLIPTIN the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing METFORMIN, SAXAGLIPTIN 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.