



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 September 2014  
EMA/CHMP/772726/2014  
Committee for Medicinal Products for Human Use (CHMP)

## Humira

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

International non-proprietary name: adalimumab

Procedure No.: EMEA/H/C/000481/PSUV/0131

Period covered by the PSUR: 01 January 2011 – 31 December 2013





EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

### **Scientific conclusions**

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

During the review of the PSUR data, cases of systemic vasculitis were evaluated. Although causality with adalimumab cannot be reliably determined due to the limited available information, in a few of these cases an association with adalimumab is at least possible. In addition, development of vasculitis can be considered a class effect for other TNF-blockers. Therefore, in view of available data regarding vasculitis, 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 Humira, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance adalimumab is favourable subject to the proposed changes to the product information.

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

