



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): adalimumab (except for biosimilars)

Procedure No. EMEA/H/C/PSUSA/00000057/201612

Period covered by the PSUR: 01 January 2014 to 31 December 2016



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for adalimumab (except for biosimilars), the scientific conclusions of the CHMP are as follows:

Immune reactions are an important identified risk associated with exposure to adalimumab and addressed in the RMP. In the review by the MAH of "Immune reactions" during this reporting period 33,746 relevant reports were identified and 3803 (11%) of these were serious. Among the serious reports 67 (1.8%) had a fatal outcome. It is acknowledged that there are cases within the 67 reports which have been excluded from analysis because of confounding factors or too limited information and that certain terms in the SMQ Hypersensitivity may not permit differentiation between hypersensitivity/allergic reactions and other causes for the given event. Nevertheless, although several of the medical conditions cited in the company summary do not provide evidence of a causal association with a hypersensitivity reaction, the total amount of data shall be interpreted as inadequate to rule out any association with adalimumab, especially considering the number of cases retrieved by the Hypersensitivity SMQ narrow search strategy with cause of death unknown. In addition, fatal cases of hypersensitivity reactions were already reported in the previous PSUR. Therefore, it seems relevant to strengthen the information to patients concerning these reactions.

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 adalimumab (except for biosimilars) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing adalimumab (except for biosimilars) 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.