



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Review of factor VIII medicines and risk of developing inhibitors in patients starting treatment for haemophilia A

EMA evaluating data from recent study comparing blood-derived and recombinant factor VIII products

The European Medicines Agency (EMA) has started a review of medicines containing factor VIII to evaluate the risk of developing inhibitor proteins in patients starting treatment for haemophilia A. This follows the recent publication of a study, in which the authors suggest that inhibitors develop more frequently in patients receiving factor VIII medicines made by DNA recombinant technology than in those receiving factor VIII medicines derived from blood.¹

Inhibitors are a treatment challenge for both blood-derived and recombinant factor VIII medicines. They are produced by the body as a reaction to factor VIII medicines in some patients, particularly in those starting treatment for the first time, and can block the effect of these medicines, causing loss of bleeding control.

EMA will now evaluate data from the recent study together with all other relevant data on blood-derived and recombinant factor VIII medicines. The Agency will consider the implications of these data for previously untreated patients with haemophilia A and whether there is a need for risk minimisation measures or other changes to the marketing authorisations of these products.

More about the medicines

The review covers all medicines containing factor VIII authorised in the European Union. Factor VIII is a clotting protein and these medicines are used to temporarily increase levels of this protein in patients with haemophilia A, helping to prevent and control bleeding.

Human blood-derived factor VIII medicines are extracted from blood plasma. Recombinant factor VIII products, on the other hand, are produced by biotechnology methods. These products include efmoctocog alfa, moroctocog alpha, octocog alpha, simoctocog alfa, susoctocog alpha and turoctocog alfa.

¹ Peyvandi F, Mannucci PM, Garagiola I, et al. A Randomized Trial of Factor VIII and Neutralizing Antibodies in Hemophilia A. *The New England journal of medicine* 2016; 374(21): 2054-64.



More about the procedure

The review of factor VIII medicines has been initiated at the request of the Paul-Ehrlich-Institute, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations.

The PRAC recommendations will then be sent to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.

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