



QSM/MC/IEA.103

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## Information Exchange System

### Alert No. 103

## **Nonacog alfa (Benefix) : Intensive post-marketing surveillance and new clinical trials for additional data**

The Committee for Proprietary Medicinal Products (CPMP) at the European Medicines Evaluation Agency (EMA) is of the opinion that there are serious deficiencies in the pivotal clinical studies on the safety issues for Nonacog alfa (Benefix), a human recombinant factor IX product used in treating hemophilia B patients.

The Committee considers that the benefit/risk balance for the treatment and prophylaxis of bleeding in previously treated patients is adequate but that the data on the frequency of some adverse reactions especially those linked to inhibitor formation and to allergic reactions are insufficient. The committee has therefore made recommendations to collect new efficacy and safety data from two additional clinical trials on the product in previously treated patients and to generate sufficient data on the use of Nonacog alfa in children under 6 years of age including previously treated and previously untreated patients.

Immediate measures will involve

1. Creating an intensive post-marketing surveillance for nonacog alfa that will register all new patients treated with nonacog alfa in Europe with careful monitoring for adverse reactions
2. Allowing patients already receiving nonacog alfa to carry on with the treatment with careful monitoring for any suspected adverse reactions that they may experience during the course of the treatment
3. Requiring all suspected adverse drug reactions to be reported to the Marketing Authorization Holder or the National Health Authorities.
4. Considering alternative haemostatic measures in the case of severe allergic reactions.
5. Switching patients to another factor IX product if doses higher than 100 IU/kg are needed for routine prophylaxis or treatment, even in the absence of inhibitor formation.

#### **Reference:**

EMA Public Statement on Benefix (nonacog alfa), EMA/CPMP/2777/01 dated 20 September 2001.

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