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Public statement

Nonafact

Withdrawal of the marketing authorisation in the European Union

On 13 May 2019, the European Commission withdrew the marketing authorisation for Nonafact (human coagulation factor IX) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Sanquin Plasma Products B.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Nonafact was granted marketing authorisation in the EU on 3 July 2001 for treatment of haemophilia B. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2006.

The European Public Assessment Report (EPAR) for Nonafact will be updated to indicate that the marketing authorisation is no longer valid.

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