28 January 2016
EMA/CHMP/15062/2016
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Coagadex

## Human coagulation factor X

On 28 January 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Coagadex, intended for the treatment and prophylaxis of bleeding episodes and for perioperative management in patients with hereditary factor X deficiency. Coagadex was designated as an orphan medicinal product on 17 September 2007. The applicant for this medicinal product is Bio Products Laboratory Limited.

Coagadex will be available as 250 IU and 500 IU powder and solvent for solution for injection. The active substance of Coagadex is factor X, an anti-haemorrhagic (ATC code: B02BD13). It works as replacement therapy and temporarily increases plasma levels of factor X, helping to prevent and control bleeding.

The benefits with Coagadex are its ability to stop bleeding when given on demand and prevent bleeding when used as routine prophylaxis or for surgical procedures. The most common side effects are back pain, redness or pain at the site of the infusion and tiredness.

The full indication is: "Coagadex is indicated for treatment and prophylaxis of bleeding episodes and for perioperative management in patients with hereditary factor X deficiency". It is proposed that Coagadex be prescribed by physicians experienced in the treatment of rare bleeding disorders

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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