17 March 2011
EMA/CHMP/87152/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Eliquis

apixaban

On 17 March 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Eliquis 2.5mg film coated tablet intended for the prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery. The applicant for this medicinal product is Bristol-Myers Squibb/Pfizer EEIG. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Eliquis is apixaban, a reversible direct and selective inhibitor of factor Xa, which inhibits free and clot-bound factor Xa and prothrombinase activity, leading to indirect inhibition of platelet aggregation induced by thrombin.

The benefits with Eliquis are its ability to exert anticoagulant properties and demonstrate antithrombotic activity in the prevention of venous thromboembolism. The most common side effects are anaemia, haemorrhage, contusion and nausea.

A pharmacovigilance plan for Eliquis will be implemented as part of the marketing authorisation.

The approved indication is: "the prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery".

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 will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Eliquis and therefore recommends the granting of the marketing authorisation.

[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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