European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 24 July 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
XARELTO

International Nonproprietary Name (INN): ***rivaroxaban***

On 24 July 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Xarelto, *10* mg,Film-coated tablet intended for the prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery. The applicant for this medicinal product is Bayer HealthCare AG.

The active substance of Xarelto is Rivaroxaban, an antithrombotic medicinal product (ATC Code: B01AX06. Rivaroxaban is a highly selective direct factor Xa inhibitor with oral bioavailability. Inhibition of Factor Xa interrupts the intrinsic and extrinsic pathway of the blood coagulation cascade, inhibiting both thrombin formation and development of thrombi. Rivaroxaban does not inhibit thrombin (activated Factor II) and no effects on platelets have been demonstrated.

The benefits with Xarelto are the reduced occurrence of venous thromboembolic events in adult patients undergoing elective surgery of the hip or knee. The most common side effects are bleedings and vascular disorders. Other common adverse effects included gastrointestinal disorders, such as nausea; investigations, such as increased levels of transaminases and gamma-glutamyl transpeptidase; and procedural complications, such as postoperative anaemia and haemorrhage.

A pharmacovigilance plan for Xarelto, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: “Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery”.
Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) 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 that there is a favourable benefit to risk balance for Xarelto and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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