22 September 2011
EMA/CHMP/753436/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Xarelto
rivaroxaban

On 22 September 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted two positive opinions for the medicinal product Xarelto one recommending an extension to the terms of the marketing authorisation and the other recommending a variation to the terms of the marketing authorisation.

The marketing authorisation holder for this medicinal product is Bayer Pharma AG. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication for two new strengths as follows:

Treatment of deep vein thrombosis (DVT), and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.

Furthermore, in parallel the CHMP adopted another new indication for the same strengths as follows:

Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack.

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

For information, the full indications for Xarelto will be as follows[2]:

- Xarelto 10 mg tablet

Prevention of venous thromboembolism (VTE) in adult patients undergoing hip and knee replacement surgery

- **Xarelto 15 mg and 20 mg tablets**

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended indication.

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Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack.

Treatment of deep vein thrombosis (DVT), and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.