



Summary Interim Report - EUPAS3911

Title: Xarelto (Rivaroxaban) Risk-Minimisation Plan Evaluation: Patient and Physician Knowledge of Key Safety Messages (Wave 2)

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Keywords: Xarelto (rivaroxaban); post-authorisation safety study; evaluation of risk-minimisation measures; physician survey

Rationale and background: At the request of the European Medicines Agency (EMA), a prescriber guide and patient alert card were developed and distributed to increase awareness and understanding about risks associated with rivaroxaban. The current study was designed to evaluate physician and patient awareness and understanding of the key messages in these educational materials at 18 months (wave 1), 3 years (wave 2), and 7 years (wave 3) post–drug launch. The wave 1 assessment was conducted among both patients and physicians. Based on the results of wave 1 and in agreement with the EMA, the wave 2 and wave 3 assessments include physicians only. This report summarises results from the wave 2 assessment to evaluate physicians’ knowledge of the key messages in the prescriber guide.

Research question and objectives: The primary objectives are to measure whether physicians and patients received and used the prescriber guide and patient alert card, respectively, and to evaluate their awareness and understanding of the key safety messages.

Study design: The study is an observational, cross-sectional study among physicians and patients with recent rivaroxaban experience. Eligible physicians and patients were invited to complete a brief questionnaire regarding their knowledge of key safety in the rivaroxaban educational materials.

Setting: France, Germany, Spain and the UK

Subjects and study size, including dropouts: Physicians were eligible to participate if they had prescribed rivaroxaban in the past 6 months for one of the indications of interest. A total of 19,310 physicians were invited to participate in wave 2; 1,950 responded. Of those who responded, 476 physicians opted not to participate, 3 did not provide informed consent, 106 did not meet eligibility criteria, 131 were excluded because the quota was already met for their physician specialty, and 8



started the questionnaire but did not answer enough of the questions to meet the definition for a completed survey. The remaining 1,226 physicians, between 304 to 310 per country, completed the questionnaire for an evaluable response rate of 6%.

Variables and data sources: Data were obtained through questionnaire responses.

Results: In general, physicians' knowledge of the key safety information in the Xarelto educational materials was high. Physicians' knowledge was particularly high questions related to the risk of bleeding (94%), populations that are at increased risk of serious side effects (69%-94%), and contraindications (73%-92%). Physician knowledge was also high for questions related to invasive procedures (80%) and medically important bleeding (59%-81%). Fewer physicians (62%) were aware that rivaroxaban (15 mg or 20 mg) should be taken with food for stroke prevention in atrial fibrillation (SPAF) and deep vein thrombosis (DVT) treatment and secondary prevention. Knowledge was lower for situations that require international normalised ratio monitoring (58%-76%), procedures for converting from vitamin K antagonist (VKA) to rivaroxaban (52%-66%) and from rivaroxaban to VKA (36%-62%), and for converting from parenteral anticoagulants to rivaroxaban (51%-54%). Physicians' knowledge of dosing recommendations varied by question. The proportion of correct responses was 75% for the standard recommended dose of rivaroxaban for SPAF, 58% for the recommended dose of rivaroxaban for SPAF in patients with renal impairment, and 62% for the recommended dose of rivaroxaban for DVT treatment and secondary prevention. More than half of physicians reported that they received the prescriber guide for rivaroxaban (57%), and of those physicians, 80% felt the guide was very helpful or extremely helpful. Most physicians (85%) reported that they would discuss information on the patient alert card with patients when first prescribing rivaroxaban.

Discussion: Physicians' knowledge was highest for the most important risks in the educational materials and lower for more complex aspects of safe use for which we would assume that physicians would consult the prescriber guide and/or label rather than relying on memory. Physicians' knowledge was consistent between waves 1 and 2.

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