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EMA starts review of study on bleeding risk with direct oral anticoagulants

EMA is reviewing the results of a study with the direct oral anticoagulants Eliquis (apixaban), Pradaxa (dabigatran etexilate) and Xarelto (rivaroxaban). This observational study, commissioned by EMA, assessed the risk of major bleedings with these medicines when used to prevent blood clotting in patients with non-valvular atrial fibrillation (irregular rapid contractions of the heart), in comparison with other oral anticoagulants.

Results from this study show differences in the risk of major bleedings between these medicines. They also raise concerns about the level of adherence in clinical practice to restrictions, special warnings and precautions in the medicines' product information.

The review aims to assess whether the results of this study have implications on the use of the medicines in clinical practice and whether any changes to the conditions of use and current measures to minimise the risk of bleeding would be needed.

The study followed a workshop held by EMA in 2015, which highlighted the need for further research to optimise use of anticoagulants in clinical practice. Details on the study can be found in the EU register of post-authorisation studies (with the study register number 16014). An abstract of the results will be available in the register in the next few days.

More about the medicines

The direct oral anticoagulants Eliquis (apixaban), Pradaxa (dabigatran etexilate) and Xarelto (rivaroxaban) are taken by mouth to prevent blood clotting in a number of situations, including for the prevention of venous thromboembolism (the formation of blood clots in the veins) in patients who have had an operation to replace a hip or knee, and prevention of stroke (caused by blood clots in the brain) and the formation of clots in other organs in patients with non-valvular atrial fibrillation. They are also used to treat deep vein thrombosis (a blood clot in a deep vein, usually in the leg) and pulmonary embolism (a clot in a blood vessel supplying the lungs), and to prevent these conditions from reoccurring.

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These medicines work by directly blocking a single blood clotting factor in the body; this is why they are called 'direct anticoagulants' as opposed to other anticoagulants such as warfarin that indirectly target various clotting factors.

More information about these medicines can be found on the EMA website: www.ema.europa.eu/en/medicines.

More about the procedure

The review of direct oral anticoagulants has been initiated at the request of the EMA Executive Director, under Article 5(3) of Regulation 726/2004.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will issue a scientific opinion.