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EMA concludes defective device in ROCKET study does not impact Xarelto's safety

Study is the main trial supporting use of Xarelto in atrial fibrillation

The European Medicines Agency (EMA) has concluded that a defect with the INR device used in the ROCKET study does not change its conclusions on the overall safety or benefit-risk balance of Xarelto (rivaroxaban). The ROCKET study was the main clinical trial underpinning the use of this anti-clotting medicine in patients with non-valvular atrial fibrillation (irregular heartbeat).

This means that Xarelto can continue to be used as before, in line with the current prescribing information.

In the study, which compared Xarelto with warfarin, the INR device was used to measure blood clotting in patients taking warfarin. Because of the defect, there were concerns that the INR device could have provided lower INR values in some patients in the warfarin group. The lower values could in turn have led investigators to give too high a dose in the warfarin group, increasing their risk of bleeding and so giving a false impression of the comparative safety of Xarelto.

After further analyses of the ROCKET study data taking into account the defect in the INR device, EMA's Committee for Medicinal Products for Human Use (CHMP) concluded that any incorrect measurements obtained with the defective device would have had only a marginal effect on the study results, and the safety of Xarelto remains unchanged. In addition, data from other large studies confirmed the comparative safety of the medicine and showed similar rates of bleeding in their warfarin groups.

The CHMP therefore considered that the benefit-risk balance of Xarelto in patients with non-valvular atrial fibrillation remains unchanged.

EMA started investigating this issue as soon as it was informed of the defect in the INR device by the marketing authorisation holder of Xarelto, Bayer Pharma AG, in September 2015.

The CHMP assessment report with detailed information on the analyses performed will be published shortly on EMA's website.

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