13.06.2024

Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Dabigatran etexilate Teva (INN: Dabigatran etexilate) 75mg, 110mg & 150mg, capsules hard - **EMEA/H/C/006023**

Dear Harald Enzmann

I would like to inform you that, at this point of time, Teva GmbH has taken the decision to withdraw the application for Marketing Authorisation of Dabigatran etexilate Teva 75mg, 110mg & 150mg capsules hard, which was intended to be used for following indication:

Primary prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.

Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischemic attack (TIA); age ≥ 75 years; heart failure (NYHA Class ≥ II); diabetes mellitus; hypertension.

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

Treatment of VTE and prevention of recurrent VTE in paediatric patients from the time the child is able to swallow soft food to less than 18 years of age.

This withdrawal is based on the commercial reason.

I agree for this letter to be published on the EMA website.
Yours sincerely,

[redacted]