

Annex

Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the member states

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The Member States shall ensure that the following conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

- The MAH shall provide an educational pack, targeting all physicians who are expected to prescribe/use Xarelto prior to the launch of the new indication for the treatment of deep vein thrombosis (DVT) and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.
- The MAH shall provide an educational pack, targeting all physicians who are expected to prescribe/use Xarelto prior to the launch of the new indication for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors.
- The educational pack is aimed at increasing awareness about the potential risk of bleeding during treatment with Xarelto and providing guidance on how to manage that risk.
- The content and format of the educational material, together with a communication plan, should be agreed with the MAH prior to distribution of the educational pack and launch of the new indication.
- The physician educational pack should contain:
 - The Summary of Product Characteristics
 - Prescriber Guide
 - Patient Alert Cards
- The Prescriber Guide should contain the following key safety messages:
 - Details of populations potentially at higher risk of bleeding
 - Recommendations for dose reduction in at risk populations
 - Guidance regarding switching from or to rivaroxaban treatment
 - The need for intake of the 15 mg and 20 mg tablets with food
 - Management of overdose situations
 - The use of coagulation tests and their interpretation
 - That all patients should be provided with a Patient alert card and be counselled about:
 - Signs or symptoms of bleeding and when to seek attention from a health care provider.
 - Importance of treatment compliance
 - The need for intake of the 15 mg and 20 mg tablets with food
 - Necessity to carry the Patient alert card with them at all times
 - The need to inform Health Care Professionals that they are taking Xarelto if they need to have any surgery or invasive procedure.
- The Patient alert card should contain the following key safety messages:
 - Signs or symptoms of bleeding and when to seek attention from a health care provider.
 - Importance of treatment compliance
 - The need for intake of the 15 mg and 20 mg tablets with food
 - Necessity to carry the Patient alert card with them at all times
 - The need to inform Health Care Professionals that they are taking Xarelto if they need to have any surgery or invasive procedure.