

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 for each therapeutic indication, targeting all physicians who are expected to prescribe/use Pradaxa. This educational pack is aimed at increasing awareness about the potential risk of bleeding during treatment with Pradaxa and providing guidance on how to manage that risk.
- The content and format of the educational material, together with a communication plan, is agreed with the MAH prior to distribution of the educational pack.
- The educational pack must be available for distribution for both therapeutic indications prior to the launch of the new indication (prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation with one or more risk factors) in the Member State.

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
- Recommendation not to use Pradaxa in patients with prosthetic heart valves
- Recommendation for kidney function measurement
- Recommendations for dose reduction in at risk populations
- 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:
 - o Signs or symptoms of bleeding and when to seek attention from a health care provider.
 - o Importance of treatment compliance
 - o Necessity to carry the Patient alert card with them at all times
 - o The need to inform Health Care Professionals that they are taking Pradaxa if they need to have any surgery or invasive procedure.
- An instruction how to take Pradaxa

The Patient alert card should contain the following key safety messages:

- o Signs or symptoms of bleeding and when to seek attention from a health care provider.
- o Importance of treatment compliance

- Necessity to carry the Patient alert card with them at all times
- The need to inform Health Care Professionals that they are taking Pradaxa if they need to have any surgery or invasive procedure.
- An instruction how to take Pradaxa