Annex IV

Conditions to the marketing authorisations

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National competent authorities of Member State(s) or reference Member State(s) if applicable, shall ensure that the following conditions are fulfilled by the MAH(s):

Conditions	Date
The MAH(s) should submit the core elements (including outline of DUS, PASS and educational materials) of a risk management plan in EU format.	Within 3 months after EC decision
The MAH(s) should submit the next PSUR by:	29 August 2014
The MAH(s) should provide within the risk management plan submission, a protocol for the drug utilisation study to characterise prescribing practices for the medicinal products during typical clinical use in representative groups of prescribers and to assess main reasons for prescription. Final study report by:	31 July 2015
The MAH(s) should provide a protocol of a PASS within the risk management plan submission, to evaluate the effectiveness of the risk minimisation activities. Final study report by:	31 July 2015
The MAH(s) should provide within the risk management plan Educational material for prescribers and patients. This will be included in the risk management plan, highlighting the risks and warnings of thromboembolism (by e.g. a checklist, to be implemented at national level).	Outline of the education materials within 3 months after EC decision