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 the EC decision
The MAH(s) should submit the next yearly PSUR by:	10 April 2014 (DLP:22 January 2012)
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 product during typical clinical use in representative groups of prescribers and to assess main reasons for prescription. Final study report by:	Within 18 months after the EC decision
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:	Within 18 months after the EC decision
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, warnings and monitoring of hepatotoxicity	Outline of the education materials within 3 months after the EC decision