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 Marketing Authorisation Holders of Novantrone and associated names shall submit for assessment to the Reference Member State a Risk Management Plan containing key elements as described in the CHMP assessment report.	Within 2 months of the Commission Decision for this procedure
The Marketing Authorisation Holder(s) shall ensure that in each Member State where Novantrone and associated names are marketed, all healthcare professional (HCP) and patients/carers who are expected to prescribe and dispense or use Novantrone in treatment of multiple sclerosis have access to/are provided with the following educational package: HCP brochure including the following key-elements: • Novantrone could cause cardiotoxicity o signs and symptoms o need for echocardiogram or multiple-gated acquisition (MUGA) evaluation of the left-ventricular ejection fraction (LVEF) prior to administration of each dose and yearly for up to 5 years after the end of therapy. • Novantrone could cause haematotoxicity, including secondary acute myeloid leukaemia and myelodysplastic syndrome o signs and symptoms o the need for monitoring at the start and prior to each treatment administration HCP checklist including the following key-elements: • evaluation of the left-ventricular ejection fraction (LVEF) • life-time maximum dose • full blood count including platelets Patient information document including the following key-elements: • signs and symptoms of cardiotoxicity and haematotoxicity • Information on the need of regular monitoring, and when it should be carried out, for cardiotoxicity and haematotoxicity Patient alert card including the following key-elements: • key signs and symptoms regarding cardiotoxicity and haematotoxicity	Within 2 months of the Commission Decision for this procedure