

ANNEX IV
CONDITION OF THE MARKETING AUTHORISATIONS

CONDITIONS OF THE MARKETING AUTHORISATIONS

National Competent Authorities, coordinated by the Reference Member State where applicable, shall ensure that the following conditions are fulfilled by the Marketing Authorisation Holders:

Risk Management Plan

Following the European Commission Decision the Risk Management Plan should be submitted with any new application for extending the indication regarding the treatment of mania in bipolar disorder, as relevant.