

Annex III

Conditions of the marketing authorisations

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

An updated version of the Risk Management Plan will be submitted to National Competent Authorities within 3 months of the Commission Decision for this procedure, to reflect the updated information on the paediatric population as agreed by CHMP.