Annex III

Conditions of the marketing authorisation

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

A case-control study shall be performed to further investigate the possibility of an association between pholcodine use and NMBA-related anaphylactic reactions. A draft protocol should be submitted to CHMP for assessment and approval within 3 months of the Commission Decision. The final study report should be submitted to the National Competent Authorities by December 2016.