

Annex III

Conditions for the lifting of the marketing authorisations suspension

Prior to the lifting of the suspension of the marketing authorisations, the national competent authorities, coordinated by the reference Member State, shall ensure that the following conditions are fulfilled by the marketing authorisation holder:

The marketing authorisation holder demonstrates bioequivalence in the fed state, in compliance with the guidance on the investigation of bioequivalence in place at the time of lifting the suspension.