

Annex III

Conditions for lifting the 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:

New clinical and bioanalytical studies are performed and submitted to the relevant national competent authorities.

The marketing authorisation holder should demonstrate therapeutic equivalence based on a clinical and bioanalytical study performed in compliance with GCP requirements.