

Annex III

Conditions for lifting the suspension of the Marketing Authorisations

Conditions for lifting the suspension of the Marketing Authorisations

The National Competent Authorities of Member States, coordinated by the Reference Member State, shall ensure that the following conditions are fulfilled by the MAH:

The MAH should provide adequate and satisfactory data confirming the bioequivalence of their product with the reference product within one year of the European Commission decision.