Annex III

Condition for lifting the suspension of the Marketing Authorisations

Conditions for lifting the suspension of the Marketing Authorisations

The National Competent Authorities of Member States or Reference Member States if applicable, shall ensure that the following condition is fulfilled by the MAH(s):

Suspension of the marketing authorisations should be lifted when bioequivalence to an EU Reference Medicinal Product has been established based on a bioequivalence study conducted vis-à-vis the EU Reference Medicinal Product.