Annex III

Conditions for lifting the suspension of the marketing authorisations

Conditions for lifting the suspension of the marketing authorisations

For the suspension of the marketing authorisations referred to in Annex IB to be lifted, the competent authorities of the EU Member States shall ensure that the below condition has been completed by the marketing authorisation holder(s):

- Bioequivalence vis-à-vis an EU reference medicinal product has been demonstrated, based on relevant data, in accordance with the requirements of Article 10 of Directive 2001/83/EC (e.g. a bioequivalence study conducted vis-à-vis the EU reference medicinal product as defined in Article 10(2)(a)), or, for well-established use products, bioequivalence vis-à-vis the medicinal product referred in the scientific literature has been demonstrated.