

#### **Annex IV**

#### **Conditions for lifting the suspension of the marketing authorisation**

## **Conditions for lifting the suspension of the marketing authorisation**

National Competent Authorities of Member State(s) or Reference Member State(s) if applicable, shall ensure that the following conditions are fulfilled by the MAH(s):

The MAHs should identify a specific patient population for which the benefits of the product outweigh the risk.