

### **Annex III**

#### **Conditions for lifting the suspension of the Marketing Authorisation(s)**

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*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 marketing authorisation holders should provide convincing and robust data to identify a patient population in which the clinical benefits of ketoconazole-containing products for oral use clearly outweigh the risks.