

### **ANNEX III**

### **CONDITIONS OF THE MARKETING AUTHORISATIONS**

For the suspension to be lifted the Marketing Authorisation Holders would need to provide the National Competent Authorities with the following:

- Data demonstrating that the products can be used safely taking into account information on intoxications from poison centres in Europe.
- Data demonstrating convincing efficacy and safety derived from appropriately designed clinical trials (including an active comparator) and data justifying the proposed dose.
- Detailed risk minimisation measures and ways to ensure that the impact of such measures could be adequately evaluated once in place.