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## **BULGARIA** (December 2017)

### **OVERVIEW OF NATIONAL REQUIREMENTS**

#### **Summary:**

The GMO aspects of clinical trials with medicinal products for human use containing or consisting of GMOs are regulated under contained use and deliberate release frameworks.

Clinical trials of human medicinal products are treated as experimental deliberate releases into the environment. In addition, the premises of the hospitals and other facilities where the clinical trials will take place should comply with the safety requirements for contained use of the specific class but no special notification is needed. In some cases, when the whole clinical trial takes place in a hospital, it might be considered entirely under the framework for contained use.

Authorization of GMO aspects is required prior to the submission of the clinical trial application: the opinion of MoEW related GMO aspects of the application should be issued before further steps are taken in front of BDA.

### **APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS**

The Environmental Risk Assessment and related technical information are usually submitted in the format of Annex II and Annex IIIA of Directive 2001/18/EC.

The other relevant national forms (currently only in Bulgarian) are available at <http://www.moew.government.bg/bg/priroda/obrazci-na-zayavleniya-i-uvedomleniya/gmo/>

#### **Language requirements:**

Application should be submitted in the national language but technical documents in English are acceptable: usually the cover letter should be in Bulgarian as well as some of the technical information related to the safety of personal that is going to carry out the trials.

### **PUBLIC CONSULTATION**

There is no public consultation on GMO aspects prior to granting authorisation.

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### **NATIONAL AUTHORITIES INVOLVED**

#### **Authorization of clinical trials:**

- **Bulgarian Drug Agency (BDA)**

Contact details: 8 Damyan Gruev St., 1303 Sofia  
e-mail: [bda@bda.bg](mailto:bda@bda.bg)

#### **Authorisation of GMO aspects:**

- **Ministry of Environment and Water (MoEW)**

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