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## SLOVAKIA (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 the deliberate release framework- Part B of Directive 2001/18.

Authorization of GMO aspects is required prior to the submission of the clinical trial application.

#### Additional information can be found at:

[http://www.sukl.sk/sk/klinicke-skusanie-liekov/pokyny?page\\_id=605](http://www.sukl.sk/sk/klinicke-skusanie-liekov/pokyny?page_id=605) - SK version

[http://www.sukl.sk/en/clinical-trials/instructions?page\\_id=2821](http://www.sukl.sk/en/clinical-trials/instructions?page_id=2821) - EN version

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

The details of the application are set in the Decree No. 399/2005.

<https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2005/399/20130415> - SK version

<http://bch.cbd.int/database/record.shtml?documentid=47486> – EN version

#### Language requirements:

Application should be submitted in the national language but technical documents in English are acceptable.

### PUBLIC CONSULTATION

Yes. The Ministry informs the public about applications for approval as well as on issued permits through the Internet (<http://www.minzp.sk/postupy-ziadosti/geneticky-modifikovane-organizmy/pripomienky-k-ziadostiam-ohlasienam/>), and by any other appropriate means as well if it is necessary to effectively inform the public, with a call for public comments within a deadline of 30 days.

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### NATIONAL AUTHORITIES INVOLVED

#### Authorisation of clinical trials:

- **The State Institute for Drug Control**

Contact details: Department of Clinical Trials,  
Kvetná 11, 825 08 Bratislava  
Phone: +421 2 5070 1208; 1209  
Fax: +421 2 5070 1237  
Email: [trial-sukl@sukl.sk](mailto:trial-sukl@sukl.sk)

#### Authorisation of GMO aspects:

- **Ministry of Environment of the Slovak Republic**

Contact details: Department of Environmental Hazards and Biosafety  
Námestie Ľ. Štúra 1, 812 35 Bratislava  
Phone: +421 2 5956 2539; 2717  
Fax : +421 2 5956 2508  
Email: [odbor-1.9@enviro.gov.sk](mailto:odbor-1.9@enviro.gov.sk)  
[pripomienky\\_GMO@enviro.gov.sk](mailto:pripomienky_GMO@enviro.gov.sk)