National procedures that must be followed for the conduct of clinical trials with medicinal products that contain or consist of GMOs

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:

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

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-ziadostigenerickymodifikovanychorganizmovpripomienkyk-ziadostiam-ohlaseniam/), 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

**Authorisation of GMO aspects:**

- **Ministry of Environment of the Slovak Republic**
  
  **Contact details:** Department of Environmental Hazards and Biosafety
  Námestie L’Štúra 1, 812 35 Bratislava
  Phone: +421 2 5956 2539; 2717
  Fax: +421 2 5956 2508
  Email: odbor-1.9@enviro.gov.sk
  pripomienky_GMO@enviro.gov.sk