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

CZECH REPUBLIC (December 2017)

OVERVIEW OF NATIONAL REQUIREMENTS

Summary:
The GMO aspects of clinical trials with medicinal products for human use containing or consisting of GMOs can be regulated under either the contained use or the deliberate release frameworks (Directive 2001/18 – Part B). While the manufacturing and application of the medicinal product to the patient is in principle regulated under the contained use rules, the deliberate release framework applies if there is a possibility of shedding of the GMM into the environment after the application.

The applications to seek authorization under the clinical trials framework and under the GMO framework can be submitted in parallel (*i.e.* the sponsor should apply for GMO authorization but does not need to wait for the GMO authorization before submitting the clinical trial application).

Additional information can be found at:
https://www.mzp.cz/Biosafety/pdf/Information_for_notifiers_about_clinical_trials.pdf
http://www.sukl.eu/medicines/clinical-trial-on-pharmaceuticals

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Application forms can be found at:
https://www.mzp.cz/cz/formulare_metodicke_pokyny_gmo

Language requirements:
Application should be submitted in the national language (Czech) but technical documents in English are acceptable.

PUBLIC CONSULTATION

The Ministry of the Environment makes a summary of the notification for deliberate release, which is made published on its website. The Ministry also ensures its publication by the relevant municipality and regional authorities, according to the intended release location.

After the publication, there is a period of 30 days for public comments.

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NATIONAL AUTHORITIES INVOLVED

Authorization of clinical trials:

- **State Institute for Drug Control**
  Contact details: Srobarova 49, 130 00, Prague 3, Czech Republic

  Dr Alice Nemcova, Head of Clinical Trials and Unregistered Medicinal Products Section, Marketing Authorisation Branch:
  tel: +420 272 185 817,
  e-mail: alice.nemcova@sukl.cz

Authorisation of GMO aspects:

- **Ministry of the Environment**

  Contact details: Vrsovicka 65, 100 00 Prague 10, Czech Republic,

  Ms Zuzana Doubkova, Head of GMO Unit, Department of Environmental Risks and Ecological Damage:
  tel: +420 26712 2922,
  e-mail: zuzana.doubkova@mzp.cz