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

HUNGARY (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.

The applications to seek authorization under clinical trials and under GMO frameworks 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.ogyei.gov.hu/gmo_engedelyezes/

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

There is no specific application form for the submission, the required documentation is provided on the Institute's website: https://www.ogyei.gov.hu/gmo_engedelyezes/

Language requirements:
Application should be submitted in the national language.

PUBLIC CONSULTATION

A 30 day public consultation is carried out via the OGYÉI's (NIPN) website:
https://www.ogyei.gov.hu/felhivas_tarsadalmi_konzultaciora/

NATIONAL AUTHORITIES INVOLVED

Authorization of clinical trials:

- **National Institute of Pharmacy and Nutrition (OGYÉI)**
  Contact details: Ms. Ágnes Tamásné Németh, email: tamasne.agnes@ogyei.gov.hu

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Authorisation of GMO aspects:

- **National Institute of Pharmacy and Nutrition**: it is the competent authority responsible for the granting of GMO authorizations

  Contact details: H-1051 Budapest, Zrínyi u. 3.
  Ms. Dóra Kovács, email: kovacs.dora@ogyei.gov.hu

- **Ministry of Agriculture**: it provides an opinion
  Contact details: H-1055 Budapest Kossuth Lajos tér 11.

- **GMO committee** (Géntechnológiai Eljárásokat Véleményező Bizottság) : it provides an opinion.
  Contact details: H-1024 Budapest Keleti Károly u. 24.