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

SLOVENIA (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.mop.gov.si/si/zakonodaja_in_dokumenti/veljavni_predpisi/okolje/zakon_o_ravnanju_z_gensko_spremenjenimi_organizmi/

https://www.jazmp.si/en/human-medicines/clinical-trials-and-compassionate-use-of-medicinal-products/clinical-trials-of-medicinal-products/notificationauthorisation-of-clinical-trials/

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Application forms can be found at:
http://www.mop.gov.si/si/delovna_podrocja/biotehnologija/postopek_prijave_namernega_sproscanja_gso_v_okolje/

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

PUBLIC CONSULTATION

The Slovene GMO act provides for public consultation in the process of a GMO deliberate release authorization. The public is allowed to access the technical documentation and risk assessment. The timelines for public consultation are fixed in the range from 15 to 30 days.

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NATIONAL AUTHORITIES INVOLVED
Authorisation of clinical trials: • **JAZMP –Agency for Medicinal Products and Medical devices** Contact details: Email: CT@jazmp.si, info@jazmp.si
Authorisation of GMO aspects: • **MESP Ministry of the Environment and Spatial Planning** Contact details: Dunajska 48, 100 Ljubljana Email: gp.mop@gov.si martin.batic@gov.si