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

POLAND (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 contained use framework.

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

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Application forms can be found at:
http://gmo.ekoportal.pl/wzory.html

Language requirements:
Application forms must be submitted in national language (Polish).

PUBLIC CONSULTATION

In compliance with Law of 3 October 2008 about information disclosure and protection, public participation in environmental protection and on environmental impact assessment,[1] applications for contained used of GMO's are subject to public consultation.

The application are available for public consultation via the website of the GMOs register (http://gmo.mos.gov.pl/Public/Registers). The period for consultations is 30 days.

[1] Ustawa z dnia 3 października 2008 r. o udostępnianiu informacji i jego ochronie, udziale społeczeństwa w ochronie środowiska oraz o ocenach oddziaływania na środowisko (t.j. Dz. U. z 2017 r. poz. 1405.

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NATIONAL AUTHORITIES INVOLVED
Authorization of clinical trials: • **The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products** Contact details: Al. Jerozolimskie 181C, 02-222 Warszawa
Authorisation of GMO aspects: • **Ministry of the Environment** Contact details: Ministry of the Environment, GMO Unit, Department Nature Conservation, Wawelska 52/54, 00-922 Warszawa, tel. 223692723, fax: 223692730 Ms. Joanna Rybak: joanna.rybak@mos.gov.pl Mr. Marcin Grabowski: marcin.grabowski@mos.gov.pl