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

CROATIA (December 2020)

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 Act on medicines and medical devices (Official Gazette, 76/2013, 90/2014 and 100/18), Ordinance on clinical trials of medicinal products and good clinical practice (OG 25/2015 and 124/2015) and Act of genetically modified organisms (Official Gazette, 126/2019).

Under Act of genetically modified organisms, the authorisation for a clinical trial is issued without prejudice to the *Chapter V. Placing on the market products which containing, consisting of GMOs or combination of GMOs* and Chapter II. Contained use of genetically modified microorganisms.

Applications have to be submitted to Croatian Ministry of Health, competent authority for clinical trials and to Ministry of Science and Education, competent authority for the contained use.

The GMO and the clinical trial applications can be submitted in parallel.

Additional information on the conduct of clinical trials can be found at:
https://zdravlje.gov.hr/o-ministarstvu/djelokrug-1297/lijekovi-i-medicinski-proizvodi/1349

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Common application forms for genetically modified cells, AAVs and other viral vectors can be used for submissions in Croatia (available at: https://ec.europa.eu/health/human-use/advanced-therapies_en).

Submission procedure for a closed system for contained use:
https://mzo.gov.hr/istaknute-teme/znanost/zatvoreni-sustavi-i-ogranicena-uporaba-gmo-a/123

Form to be used for a closed system for a contained use in a class 1 containment level:
Obrazac za prijavu zatvorenoga sustava za ograničenu uporabu GMO-a

Form to be used for containment levels 2, 3 and 4:
Obrazac za procjenu rizika

Form to be used for changing contact details:
Obrazac izmjena kontakt podataka - PZ

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Language requirements:
Application should be submitted in the national language, but common application forms for genetically modified cells, AAVs and other viral vectors in English are acceptable.

PUBLIC CONSULTATION

When applicable, public consultation lasts 30 days.

Deliberate release (Part B of Directive 2001/18):
In the case a competent authority determines that deliberate release legislation should apply, the following documents and information are subject to public consultation:

- a summary of the dossier supplying information necessary to carry out the environmental risk assessment of the deliberate release of a GMO;
- the environmental risk assessment;
- any new information available on risks for human health and the environment.

NATIONAL AUTHORITIES INVOLVED

Authorization of clinical trials:

- **Ministry of Health, Directorate for Primary Health Care, Health Tourism, Medicines and Medicinal Products, Public Health and Public Health Care:**.

  Contact details: Ksaver 200 a 10 000 Zagreb
  Email: gmo@miz.hr

Authorisation of GMO aspects:

- **Ministry of Science and education:**

  Contact details: Donje Svetice 38 10 000 Zagreb
  Email**:** GMO@mzo.hr