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

GREECE (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.

A single submission procedure applies to seek authorization under the clinical trials framework and under the GMO framework (submission to EOF).

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Information on GMO aspects should be submitted together with the clinical trial application form but there is not a specific form regarding GMO aspects.

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

PUBLIC CONSULTATION

There is no prior consultation on GMO aspects prior to granting authorisation.

NATIONAL AUTHORITIES INVOLVED

Authorization of clinical trials:

- **National Organization for Medicines (EOF):** responsible for evaluation of the clinical trial protocol and the initial evaluation of ERA.

  Contact details: Mesogeion 284, 155 62, Athens.

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Email: trials@eof.gr
Authorisation of GMO aspects: • **Ministry of Environment & Energy:** responsible for completion of the ERA in case that the initial evaluation performed by EOF indicates outstanding issues. Contact details: 17 Amaliados str., 115 23 Athens. Email**:** g.alvanopoulos@prv.ypeka.gr