
CYPRUS (December 2017)

OVERVIEW OF NATIONAL REQUIREMENTS

Summary:

Clinical trials with medicinal products for human use containing or consisting of GMOs are regulated under both the contained use and deliberate release frameworks. GMO products are regulated by the Genetically Modified Organisms (Release in the Environment) Law of 2003. The Competent Authority for authorising the release of GMOs is the Ministry of Agriculture, Natural Resources and Environment who is advised by a scientific committee. Applications should be submitted to the Director of Environmental Services of the said Ministry. In addition, GMOs are regulated by the Genetically Modified Organisms (during Contained Use) Law. The Competent Authority is the Ministry of Labour and Social Security.

The applications to seek authorization under clinical trials and under GMO frameworks are not linked (*i.e.* the applicant can decide the timing of the submission of the GMO application).

Language requirements:

Applications can be submitted in English.

PUBLIC CONSULTATION

There is no public consultation on GMO aspects prior to granting authorization.

NATIONAL AUTHORITIES INVOLVED

- **Drugs Council** (competent authority responsible for medicinal products).
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1475 Lefkosia, Cyprus
Email: emavrokordatou@phs.moh.gov.cy
- **Cyprus' National Bioethics Committee** (ethical assessment).
- **Ministry of Agriculture, Natural Resources and Environment.**
- **Ministry of Labour and Social Security.**

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

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