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## LATVIA (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.

The applications to seek authorization under clinical trials and under GMO frameworks can be submitted in parallel (*i.e.* the sponsor should apply for GMO authorization but does not need to wait for the GMO authorization before submitting the clinical trial application).

**Additional information can be found at:**

<https://likumi.lv/doc.php?id=192625>

English translation of the national law regulating deliberate release of genetically modified organisms (Cabinet Regulation No 457):



457-2008\_release  
into environment.pdf

General information on clinical trials can be found at:

<https://www.zva.gov.lv/?id=381&sa=381&top=333>

### APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Applicants should fill in annex 1 of the Cabinet Regulation No 457.

**Language requirements:**

Applications can be submitted in English.

### PUBLIC CONSULTATION

There is a web-based consultation (*see* Section 5 of the Cabinet Regulation No. 457).

Additional details can be found at:

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[http://www.loketgentherapie.nl/en/Gene\\_Therapy\\_Office/Assessment\\_procedures/lenM\\_permit\\_procedure](http://www.loketgentherapie.nl/en/Gene_Therapy_Office/Assessment_procedures/lenM_permit_procedure)

### NATIONAL AUTHORITIES INVOLVED

#### Authorization of clinical trials:

- **State Agency of Medicines of the Republic of Latvia**

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Fax: +371-67078428  
e-mail: [info@zva.gov.lv](mailto:info@zva.gov.lv)

#### Authorisation of GMO aspects:

- **Institute of Food Safety, Animal Health and Environment “BIOR”**

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E-mail: [bior@bior.lv](mailto:bior@bior.lv)