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):

General information on clinical trials can be found at: https://www.zva.gov.lv/?id=381&sa=381&top=333

APPLICATION FORMS TO SEEK AUTHORIZATION 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:
National procedures that must be followed for the conduct of clinical trials with medicinal products that contain or consist of GMOs

**LATVIA (December 2017)**

http://www.loketgentherapie.nl/en/Gene_Therapy_Office/Assessment_procedures/IenM_permit_procedure

### NATIONAL AUTHORITIES INVOLVED

#### Authorization of clinical trials:

- **State Agency of Medicines of the Republic of Latvia**
  
  **Contact details:** Jersikas street 15, Riga, LV-1003  
  Phones: +371-67078424, +371-67078410  
  Fax: +371-67078428  
  e-mail: info@zva.gov.lv

#### Authorisation of GMO aspects:

- **Institute of Food Safety, Animal Health and Environment “BIOR”**
  
  **Contact details:** Lejupes iela 3, Riga, LV-1076,  
  Phones: +37167620513; +371 28369560  
  E-mail: bior@bior.lv