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

ESTONIA (December 2017)

OVERVIEW OF NATIONAL REQUIREMENTS

Summary:
A single submission procedure applies to seek authorization under the clinical trials framework and under the GMO framework (submission to the State Agency of Medicines ("SAM").

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:
Applications can be submitted in English.

PUBLIC CONSULTATION

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

NATIONAL AUTHORITIES INVOLVED

- **State Agency of Medicines** (SAM)

  Contact details: http://www.ravimiamet.ee/en

- **Gene Technology Commission**: an advisory body established within the area of government of the Ministry of the Environment