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

LITHUANIA (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 Medicines Control Agency.
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.
PUBLIC CONSULTATION
There is no public consultation on GMO aspects prior to granting authorization.
NATIONAL AUTHORITIES INVOLVED
• **Ministry of Health:** Competent authority responsible for medicinal products for human use containing or manufactured from GMOs. Contact details: Vilniaus Street No 33, LT-01506 e-mail: ministerija@sam.lt • **State Medicines Control Agency:** Contact details: Žirmūnų Street No 139A, LT-09120 Vilnius e-mail: vvkt@vvkt.lt specific queries on clinical trials: arunasvaitkevicius@vvkt.lt • **Bioethics commitee**: Contact details: Vilniaus Street No 16, LT-01402 Vilnius e-mail: lbek@bioetika.sam.lt