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 contained use framework as far as production, storage, application and inactivation of GMOs used for somatic gene therapy is concerned. In addition, the administration of the product to the clinical trial subject requires an approval under special regulations for gene therapy only.¹

The applications to seek authorization under the clinical trials framework and under the GMO framework 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 on the conduct of clinical trials (in German and English) can be found at:

Additional information on the application somatic gene therapy can be found at (in German):
https://www.bmgf.gv.at/home/Gesundheit/Gentechnik/Fachinformation_Humanmedizin/Somatische_Gentherapie_am_Menschen_zu_medizinischen_Zwecken_-_Informationen_fuer_den_Antragsteller

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

**Contained use** (production, storage, application and inactivation of GMOs used for somatic gene therapy):
https://www.bmgf.gv.at/cms/home/attachments/0/7/0/CH1054/CMS1086176168146/(1)erstalige_s1_s2.docx

¹ According to the Austrian Gene Technology Act (Gentechnikgesetz, GTG), somatic gene therapy aims at a targeted insertion and expression of nucleic acids in somatic cells for the treatment of a hereditary disease or disorder. Investigational medicinal products that contain or consist of GMO but do not fall under the definition of somatic gene therapy do not require a separate authorization for the administration to the clinical trial subjects (e.g. GMO-vaccines).
National procedures that must be followed for the conduct of clinical trials with medicinal products that contain or consist of GMOs

AUSTRIA (December 2017)

Administration of Somatic Gene Therapy:

Language requirements:
Applications for authorization of GMO aspects should be submitted in German but technical documents in English are acceptable

PUBLIC CONSULTATION

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

NATIONAL AUTHORITIES INVOLVED

Authorisation of clinical trials:

- **BASG** - Bundesamt für Sicherheit im Gesundheitswesen (Federal Office for Safety in Health Care);
  
  Contact details:  
  Traisengasse 5, 1200 Vienna;  
  Email: clinicaltrials@ages.at  
  www.basg.gv.at

Authorisation of GMO aspects:

- **BMGF** – Bundesministerium für Gesundheit und Frauen (Federal Ministry of Health and Women): Department II/B/16c - Legislation for Gene Technology & Medical Applications thereof.

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