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## AUSTRIA (December 2020)

### 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.<sup>1</sup>

The applications to seek authorization under 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:

<https://www.basg.gv.at/en/healthcare-professionals/clinical-trials/clinical-trials-with-medicinal-products>

#### Additional information on the application somatic gene therapy can be found at (in German):

[https://www.verbrauchergesundheit.gv.at/gentechnik/humanm/GenHumBehoerdenifo.html#heading\\_Somatische\\_Gentherapie\\_am\\_Menschen\\_zu\\_medizinischen\\_Zwecken\\_Information\\_en\\_fuer\\_den\\_Antragsteller](https://www.verbrauchergesundheit.gv.at/gentechnik/humanm/GenHumBehoerdenifo.html#heading_Somatische_Gentherapie_am_Menschen_zu_medizinischen_Zwecken_Information_en_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.verbrauchergesundheit.gv.at/gentechnik/form/%281%29erstmalige\\_s1\\_s2\\_Nov2020.docx?7qrggv](https://www.verbrauchergesundheit.gv.at/gentechnik/form/%281%29erstmalige_s1_s2_Nov2020.docx?7qrggv)

**Administration of Somatic Gene Therapy:**

[https://www.verbrauchergesundheit.gv.at/gentechnik/humanm/antragsunterlagen\\_somatische](https://www.verbrauchergesundheit.gv.at/gentechnik/humanm/antragsunterlagen_somatische)

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<sup>1</sup> 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 a somatic gene therapy do not require a separate authorization for the administration to the clinical trial subjects (*e.g.* GMO-vaccines)

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[gentherapie\\_04.pdf?7i5611](#)

### 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) - **AGES** - Agentur für Gesundheit und Ernährungssicherheit (Austrian Agency for Health and Food Safety);

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Email: [clinicaltrials@basg.gv.at](mailto:clinicaltrials@basg.gv.at)  
<https://www.basg.gv.at/>

#### Authorisation of GMO aspects:

- **BMSGPK** – Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz (Federal Ministry of Social Affairs, Health, Nursing and Consumer Protection); Department VI/A/4a - Genetic Engineering Law and Medical Applications of Genetic Engineering

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