OVERVIEW OF NATIONAL REQUIREMENTS

Summary:
The GMO aspects of clinical trials with medicinal products for human use containing or consisting of GMOs can fall under either the contained use or the deliberate release frameworks, depending on the product. A decision is taken on a case-by-case basis. For example, ex-vivo stable modification of patients' cells is considered under contained use and, due to the absence of risk of spreading after transfusion of the GM-cells back to the patients, patients may leave the clinic after treatment.

On the other hand, persisting, circulating GMO medicinal products may require an approval under deliberate release. This will partly depend on the condition to be treated. Thus, long-time hospitalization (as for cancers) may be assessed under contained use, since the GMO will be eliminated by/from the body within the time the patient is in hospital. In contrast, when the treatment only involves a short visit (as for receiving a GMO vaccine), the deliberate release framework applies, due to the risk of spreading the GMO when leaving the site after vaccination.

The applications to seek authorization under clinical trials and under GMO frameworks are not linked (i.e. the applicant can decide the timing of the submission of the GMO application).

Additional information can be found at:
https://helsedirektoratet.no/bioteknologi/genterapi
https://helsedirektoratet.no/lover/genteknologiloven

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Contained use:
Application form for approval of the contained site area:
https://helsedirektoratet.no/Documents/Genteknologi/GMM_godkjenning_laboratorier.doc

Notification form:
https://helsedirektoratet.no/Documents/Genteknologi/GMM_melding_eller_soknad.docx

Deliberate release (Directive 2001/18 – Part B):
There is no standardized form. The Applicant must submit an application for deliberate release of GMO according to the Gene Technology Act and to part B of Directive 2001/18/EC
National procedures that must be followed for the conduct of clinical trials with medicinal products that contain or consist of GMOs

**NORWAY** (December 2017)

On the deliberate release of GMO into the environment. The application must include an impact assessment of the GMO to be used in a clinical trial. The content of the impact assessment is given in Regulations relating to impact assessment pursuant to the Gene Technology Act ([https://www.regjeringen.no/en/dokumenter/impact-assessment/id440455/](https://www.regjeringen.no/en/dokumenter/impact-assessment/id440455/)). A summary (SNIF) according to part B of directive 2001/18/EC on the deliberate release into the environment of GMO, which is added to a publically available EU register, must also be provided.

**Language requirements:**
Applications can be submitted in English.

### PUBLIC CONSULTATION

The Norwegian Environment Agency may conduct a public consultation on GMO aspects pursuant to the Gene Technology Act. However, public consultations are not conducted as a standard with regards to applications for experimental releases such as clinical trials, but rather evaluated on a case by case basis. If a public consultation is deemed necessary, the consultation takes place via the official public consultation's website of the Norwegian Environment Agency ([http://www.miljodirektoratet.no/no/Horinger/GMO/](http://www.miljodirektoratet.no/no/Horinger/GMO/)). The period of the consultation is restricted to 30 days.

### NATIONAL AUTHORITIES INVOLVED

**Authorisation of clinical trials:**

- **The Norwegian Medicines Agency**
  
  **Contact details:** Postboks 6167 Etterstad, 0602 Oslo. (Please note that submissions via e-mail or eudralink are preferred).
  
  Email: post@noma.no
  
  Queries on submissions can be sent to: klut@noma.no.
Authorisation of GMO aspects:

- **The Norwegian Directorate for Health** (for contained use)
  
  Contact details: Dept. of Biotechnology and Health Legislation, P.O. Box 7000 St. Olavs plass, N-0130 Oslo.

- **The Norwegian Environment Agency** (for deliberate release)
  
  Contact details: P.O.Box 5672 Torgarden, NO-7485 Trondheim.
  Email: post@miljodir.no