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

THE NETHERLANDS (December 2017)

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 deliberate release framework- Part B of Directive 2001/18.

The applications to seek authorization under clinical trials and under GMO frameworks are not linked. The applications to seek authorization under clinical trials and under GMO frameworks can be submitted in parallel (*i.e.* the sponsor may apply for GMO authorization but does not need to wait for the GMO authorization before submitting the clinical trial application).

Additional information can be found at:
http://www.loketgentherapie.nl/en
http://www.ccmo.nl/en

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Application forms can be found at:
http://www.loketgentherapie.nl/en/Application_form/Application_forms

Language requirements:
Applications can be submitted in Dutch or English.

PUBLIC CONSULTATION

A draft decision together with the public part of the research file is made available for comments for a period of six weeks. Third parties can raise objections to the proposed permit. The final decision takes effect as soon as the perusal deadline of another six weeks, in which appeal to Council of State is possible, has passed. If any objections to the permit are lodged, the Council of State informs the investigator and the Ministry of IenW. In case an injunctive relief is granted by the Council of State, all activities have to be stopped.

Additional details can be found at:
http://www.loketgentherapie.nl/en/Gene_Therapy_Office/Assessment_procedures/IenM_per

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mit_procedure

NATIONAL AUTHORITIES INVOLVED

Authorisation of clinical trials:

- **Medicines Evaluation Board:** MEB has been tasked (by the Ministry of Health, Welfare and Sport) with the evaluation and statement of no-objection on clinical trials.

  Contact details: PO Box 8275, 3503 RG Utrecht, Email: info-bi@cbg-meb.nl

- **Central committee on research involving human subjects** (CCMO): CCMO is a medical research ethics committee that performs an integrated review of scientitic, medical and ethical aspects of clinical trials.

  Contact details: PO Box 16302, 2500 BH The Hague.
  Tel: + 3170340 6700
  Email: ccmo@ccmo.nl
  www.ccmo.nl

Authorisation of GMO aspects:

- **Ministry of Infrastructure, Environment and Water Management (IenW):** IenW makes decisions on permit applications.

  Contact details:
  PO Box 1, Intern Postvak 1, 3720 BA Bilthoven
  Tel: +31302747569
  Email: bggo@rivm.nl
  www.ggo-vergunningverlening.nl

- **Gene therapy office**
  The Gene Therapy Office serves as a central point of contact between investigators and the GMO and clinical trial assessment bodies. It was set up as a service to professionals in the field of gene therapy. The Office has no role in the assessment process.
  Contact details: PO Box 1, Intern Postvak 1, 3720 BA Bilthoven
  Tel: +31302747569.
  Email: contact@loketgentherapie.nl
  www.loketgentherapie.nl/en