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

DENMARK (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 contained use framework.

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 can be found at:
https://arbejdstilsynet.dk/da/selvbetjening/blanketter/anmeldelse-af-genteknologi

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Application forms can be found at:
http://engelsk.arbejdstilsynet.dk/en/forms/gen-anmeldelse

Language requirements:
Technical documents in English are acceptable. However, documents intended for the clinical trial subjects and the laymen summary should be submitted in Danish.

PUBLIC CONSULTATION

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

NATIONAL AUTHORITIES INVOLVED

Authorization of clinical trials:

- **Danish Medicines Agency**

  Contact details: Axel Heides Gade 1, DK-2300 Copenhagen

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

DENMARK (December 2017)

Clinical trials unit; email: kf@dkma.dk

- **National Committee on Health Research Ethics** (NEC): Clinical trials with advanced therapy medicinal products should be notified to NEC, which assesses aspects related to the safety of participants.

Authorisation of GMO aspects:

- **Environmental Protection Agency** (EPA), Ministry of Environment and Food of Denmark, is responsible for safety regarding the external environment.

  Contact details: Haraldsgade 53, DK-2100 Copenhagen
  Mr. Finn Bech Welner; email: fwb@mst.dk

- **Working Environment Authority** (WEA), Ministry of Employment, is responsible for the safety regarding contained use.

  Contact details: Ms. Susanne Høyer; email: suh@at.dk