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

SWEDEN (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.

A single submission procedure applies to seek authorization under the clinical trials framework and under the GMO framework (submission to Medical Products Agency).

Additional information can be found at:
https://lakemedelsverket.se/malgrupp/Foretag/Lakemedel/Kliniska-provningar/Ansokan-steg-for-steg/

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

There is no formal application form for GMO. Applicants should submit a SNIF and an ERA according to Directive 2001/18.

Language requirements:
Applications can be submitted in English.

PUBLIC CONSULTATION

The ERA and SNIF is referred to members of the Swedish GMO network. The referral time is 30 days. In total, the maximum approval time for a clinical trial including a GMO is 90 days.

A short summary about the trial (non-confidential information) is also published on the MPA webpage.

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NATIONAL AUTHORITIES INVOLVED
• **Medical Products Agency (Lakemedelsverket)** Contact details: Uppsala Science Park, Dag Hammarskjölds väg 42, 75237 Uppsala Email: dariush.mokhtari@mpa.se