### 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/](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.
National procedures that must be followed for the conduct of clinical trials with medicinal products that contain or consist of GMOs

**SWEDEN** (December 2017)

### National Authorities Involved

<table>
<thead>
<tr>
<th><strong>Medical Products Agency (Lakemedelsverket)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contact details:</strong></td>
</tr>
<tr>
<td>Uppsala Science Park, Dag Hammarskjölds väg 42, 75237 Uppsala</td>
</tr>
<tr>
<td>Email: <a href="mailto:dariush.mokhtari@mpa.se">dariush.mokhtari@mpa.se</a></td>
</tr>
</tbody>
</table>