OVERVIEW OF NATIONAL REQUIREMENTS

Summary:

The GMO aspects of clinical trials with medicinal products for human use containing or consisting of GMOs can be regulated under the contained use and/or the deliberate release frameworks. A decision is taken case-by-case.

Applicants should submit the dossier to the Ministry of Research (Ministère de l'Enseignement supérieur, de la Recherche et de l'Innovation) for the classification and the conditions of contained use of the GMO. The Ministry of Research gives an opinion on the type of contained use regarding manufacturing and administration and it also states whether this research presents a risk of deliberate release of GMO into the environment.

When a risk of deliberate release is identified, the applicant should submit a second dossier to the Ministry of Environment (Ministère de la Transition écologique et solidaire) for the deliberate use assessment.

The applications to seek authorization under the clinical trials framework and under the GMO framework are not linked; both applications can be submitted in parallel.

Additional information on the conduct of clinical trials can be found at:

http://www.enseignementsup-recherche.gouv.fr/cid66768/o.g.m.-en-milieu-confine-procedure-administrative.html


http://ansm.sante.fr/Activites/Medicaments-et-produits-biologiques/Essais-cliniques-portant-sur-les-medicaments-et-produits-biologiques/(offset)/0

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Application forms can be found at:
https://duo.adc.education.fr/duo/connexion.jsp
National procedures that must be followed for the conduct of clinical trials with medicinal products that contain or consist of GMOs

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Language requirements:
Applications for authorization of GMO aspects should be submitted in French but technical documents in English are acceptable.

Public Consultation

There is a public consultation on GMO aspects prior to granting authorization for a period of between 15 to 30 days.

National Authorities Involved

Authorisation of clinical trials:
• Agence Nationale de Sécurité du Médicament et des produits de Santé (ANSM)

  Contact details: 143/147 bld Anatole France  93285 Saint Denis CEDEX
  Email: aec@ansm.sante.fr (correspondence should indicate “gene therapy” in the title).
  http://www.ansm.sante.fr

Authorisation of GMO aspects:
• Ministère de l’enseignement supérieur, de la recherche et de l’innovation (MESRI): Competent authority under the contained use framework.

  Contact details: Email: ogm.confine@recherche.gouv.fr
  http://www.enseignementsup-recherche.gouv.fr/

• Ministère de la Transition écologique et solidaire (MTES): Competent authority under the deliberate release framework.

  Contact details: Email: biotech@developpement-durable.gouv.fr
  https://www.ecologique-solidaire.gouv.fr/

• Haut Conseil des biotechnologies (HCB): The HCB is an independent body whose role is to inform public decision-making. It delivers opinions on all biotechnology-related issues.
National procedures that must be followed for the conduct of clinical trials with medicinal products that contain or consist of GMOs

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Contact details: 246, boulevard Saint Germain, 75007 Paris.
http://www.hautconseildesbiotechnologies.fr