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

PORTUGAL (December 2017)

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 either the contained use or the deliberate release frameworks (Directive 2001/18- Part B). A decision is taken case-by-case taking into account the specificity of the clinical trial with medicinal products for human use containing or consisting of GMO.

The applications to seek authorization under the clinical trials framework and under the GMO framework are not linked (*i.e.* the applicant can decide the timing of the submission of the GMO application).
Although the applications to seek authorization under clinical trials and under GMO frameworks can be submitted in parallel, the authorization of the clinical trial can only be approved after GMO authorization under GMO framework.

Additional information can be found at:
http://www.infarmed.pt/documents/15786/1539458/Perguntas+Frequentes+sobre+Ensaios+Cl%C3%ADnicos+com+medicamentos+contendo+organismos+Geneticamente+Modificados/51f6cb18-066f-4b0b-9899-87017c811ef5

https://www.apambiente.pt/index.php?ref=16&subref=85&sub2ref=429&sub3ref=599

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Deliberate release (Directive 2001/18 – Part B)
Applicants should provide the following information:

- Technical dossier providing the information specified in Annex IIIA, Decree-Law no. 72/2003 on the release into the environment of GMOs with the exception of higher plants;
- Environmental risk assessment (ERA) in accordance with Annex II of Decree-Law no. 72/2003 (part II of Directive 2001/18(EC)
- Summary Notification Information Format in accordance with Council Decision 2002/813/EC of 3 October - Part 1 of the Annex.

Application form available at:
https://www.apambiente.pt/index.php?ref=16&subref=85&sub2ref=429&sub3ref=599

Contained use

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Applicants should provide the following information:

- Technical dossier providing the information specified in Annex V, Decree-Law no. 55/2015 on the contained use of GMM / GMOs
- Assessment of risks to human health and the environment in accordance with Annex III of Decree-Law no. 55/2015 (Directive 2009/41/EC).

Application form available at:
https://www.apambiente.pt/index.php?ref=16&subref=85&sub2ref=430&sub3ref=615

Language requirements:
Documents should be submitted in the national language for the purposes of publication in the public consultation (Notification and ERA) although the technical dossier can be submitted in English.

PUBLIC CONSULTATION

Deliberate release:
Pursuant to Decree-Law no. 72/2003, APA shall make available to the public information on all deliberate releases of GMOs in the environment for any other purposes than placing on the market. Therefore APA promotes a 30 days public consultation.

Contained use:
Pursuant to Decree-Law no. 55/2015, if considered appropriate, APA may promote a public consultation for a period of no less than 20 days.

NATIONAL AUTHORITIES INVOLVED

Authorization of clinical trials:

- **INFARMED, I.P. – National Authority of Medicines and Health Products, I.P.**
  Contact details: Parque de Saúde de Lisboa, Avenida do Brasil, 53, 1749-004 Lisboa
  Email: ensaios.clinicos@infarmed.pt

- **CEIC – National Ethics Committee for Clinical Research**
  Contact details: Parque da Saúde de Lisboa, Av. do Brasil, 53 - Pav. 17-A, 1749-004 Lisboa

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Authorisation of GMO aspects:

- **APA – Portuguese Environment Agency**
  Contact details: Rua da Murgueira, 9/9A - Zambujal Ap. 7585, 2610-124 Amadora
  Email: lilia.martins@apambiente.pt; luis.gramacho@apambiente.pt