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## ITALY (December 2017)

### OVERVIEW OF NATIONAL REQUIREMENTS

The applications to seek the authorization under clinical trial and GMO frameworks have to be submitted to Italian Medicines Agency (AIFA) and Ministry of Health (Competent Authority for the contained use).

In addition, if the assessment of a genetically modified microorganism (GMM) contained use shows that the medicinal product contains a GMO that can replicate, transmit and disseminate into the environment, an authorization under Part B of Directive 2001/18 should also be obtained from the Ministry for Environment, Land and Sea Protection (Competent Authority for the deliberate release).

Each of the above-referred applications can be submitted in parallel (*i.e.* the applicant can decide the timing of the submission). However, the authorizations issued by Italian Medicines Agency, Ministry of Health and, where applicable, Ministry of Environment have to be issued prior to the beginning of the clinical trial.

**Additional information can be found at:**

<http://www.agenziafarmaco.gov.it/content/sperimentazione-e-ricerca>

Premises authorization procedure:

[http://www.salute.gov.it/portale/ministro/p4\\_8\\_0.jsp?lingua=italiano&label=servizionline&idMat=BIOT&idAmb=NIA&idSrv=A1&flag=P](http://www.salute.gov.it/portale/ministro/p4_8_0.jsp?lingua=italiano&label=servizionline&idMat=BIOT&idAmb=NIA&idSrv=A1&flag=P)

Activities authorization procedure:

[http://www.salute.gov.it/portale/ministro/p4\\_8\\_0.jsp?lingua=italiano&label=servizionline&idMat=BIOT&idAmb=NIE&idSrv=ACL2&flag=P](http://www.salute.gov.it/portale/ministro/p4_8_0.jsp?lingua=italiano&label=servizionline&idMat=BIOT&idAmb=NIE&idSrv=ACL2&flag=P)

Submission procedure of notifications for the deliberate release of GMOs for experimental purposes:

<http://bch.minambiente.it/index.php/en/ita-biosafety-clearing-house/legislation/17-web-page/280-procedure-for-the-deliberate-release-of-gmos-for-experimental-purposes>

### APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

**Form to be used for a class 1 containment level:**

“[Modulo di impianto e impiego terapia genica con MOGM appartenenti alla classe di rischio 1](#)”. The form includes the requested information for both premise and activity.

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### Forms to be used for a containment level higher than class 1:

Premise: “[Modulo di notifica di impianto destinato ad impieghi di MOGM di classe 2 o 3 o 4](#)”

and Activity: “[Modulo per impieghi per terapia genica di classe 2 o 3 o 4](#)”

**Submission procedure of notifications for the deliberate release** of GMOs for experimental purposes: <http://bch.minambiente.it/index.php/en/ita-biosafety-clearing-house/legislation/17-web-page/280-procedure-for-the-deliberate-release-of-gmos-for-experimental-purposes>

### Summary notification information format (snif):

<http://bch.minambiente.it/images/pdf/en/Decision%202002-813-EC%20sintesi.pdf>

### Language requirements:

Application should be submitted in the national language but technical documents in English are acceptable.

## PUBLIC CONSULTATION

### Contained use:

Public consultation is mandatory when a notification for a class 4 premise is submitted to the Ministry of Health (MoH). In parallel to the submission of the notification to the MoH, the notifier, should:

- submit a copy of the notification to the municipality where the class 4 premise is planned;
- on the same day, he/she should also publish on the two most widely disseminated newspapers in the territory concerned a notice of the filing of the documentation, indicating the place where it is possible to consult it.

Comments may be submitted in writing to the Ministry of Health and the local Authorities within 30 days of the publication of the notice referred to the previous paragraph.

The public is also informed before a contained use commences if the MoH considers (on the basis of the Biotechnology Health Technical Committee assessment) that failure of the containment measures can lead to serious danger, whether immediate or delayed, to humans outside the premise and/or to the environment. In such cases, the MoH informs as soon as possible the Prefect, the Major and the Presidents of the concerned Region and Province that they should draw up the emergency plans promptly and, in any case, within 60 days. Information on such emergency plans, including the relevant safety measures to be applied, has to be made publicly available.

### Deliberate release (Part B of Directive 2001/18):

The following documents and information are subjected to public consultation:

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- the synthesis of the dossier supplying information necessary to carry out the environmental risk assessment of the deliberate release of a GMO;
- the environmental risk assessment; and
- any new information available on risks for human health and the environment.

In order to facilitate the participation in the public consultation, a consultation list has been prepared which includes central and local institutional authorities, trade associations and non-governmental organizations for environmental and consumer protection. Upon request, any natural or legal person, institution, organization or association can be included in the consultation list. The members of the consultation list are informed at the start of every public consultation.

Registered subjects have the opportunity to express opinions or to submit information on the notification during the public consultation period of 30 days.

Any relevant opinion or information received is taken into account by the NCA prior to granting an authorization.

Additional information can be found at: <http://bch.minambiente.it/index.php/it/bch-italiana/consultazione-pubblica>

### NATIONAL AUTHORITIES INVOLVED

#### Authorization of clinical trials:

- **Italian Medicines Agency (AIFA)**  
Contact details: AIFA, Clinical Trials Office, Via del Tritone, 181, 00187, Rome  
Email: [sperimentazione.clinica@aifa.gov.it](mailto:sperimentazione.clinica@aifa.gov.it)

#### Authorisation of GMO aspects:

- **Ministry of Health, Directorate General for Preventive Health; Office 4 – DGPREV** (Competent Authority for Directive 2009/41/EC).  
Contact details: Viale Giorgio Ribotta, 5, 00144, Rome  
Dr. Pasqualino Rossi: Tel: +39 06 59943636,  
email: [p.rossi@sanita.it](mailto:p.rossi@sanita.it)
- **Ministry for Environment, Land and Sea Protection, Directorate General for Environmental Assessments and Permits; Unit IV - Assessment and reduction of**

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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**risks arising from chemicals and genetically modified organisms** (Competent Authority for Directive 2001/18/EC)

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