



## Clarification of the authorization process for the cultivation of cannabis for research, medical or scientific purposes

*Information notes from the Division of Inspection and Control of Medicines of the Spanish Agency of Medicines and Medical Devices (AEMPS) published in the AEMPS' website*

### Cultivation of cannabis in Spain

In Spain, the cultivation of Cannabis for research, medical and/or scientific purposes is totally forbidden unless an authorization from the AEMPS is obtained.

The process to obtain such authorization, as well as the documentation and information to be provided during such process, is regulated with little accuracy in very old regulations (a Law passed in 1967 regulating narcotics; and an Order approved in 1963 including rules for cultivation of plants used in the production of narcotics).

All such regulations are pre-constitutional and were approved in an economic and social context that has nothing to do with the current one. This situation has generated legal uncertainty to the companies interested in obtaining this type of authorizations.

The AEMPS was asked in February 2018 (under the Law 19/2013, on transparency, access to public information and good governance) about the process to obtain an authorization for the cultivation of Cannabis. The AEMPS answered with just a brief guidance list of the documentation that "is usually requested". The AEMPS also clarified that it did not have a "public document with an exhaustive list of all the information needed" and that each specific case could have its own "particularities". Recently, there are signs of improvement towards legal certainty in this field.

In December 2018, the AEMPS published two informative notes detailing the contents that any authorization for the cultivation of cannabis shall include. Also in December, after being requested by the Council on Transparency and Good Government, the AEMPS published a list of the existing authorizations for the cultivation of Cannabis in Spain: only four for the cultivation of Cannabis for research purposes and three for the cultivation of such plant for medical and scientific purposes.

### Authorization application for cultivation

The AEMPS has stated the following regarding the data and information to be provided by the applicant of an authorization for the cultivation of cannabis in Spain:

For the cultivation of cannabis for medical, scientific or research purposes, the applicant shall provide the AEMPS with documentation regarding the purpose of the cultivation, the origin of the seeds, the THC and CBD content of the plants to be produced, the land plots and facilities to be used, and the security measures to be adopted.

Additionally, and only for the cultivation of cannabis for medical and scientific purposes, it is expressly foreseen that the authorization application must include information about the authorized manufacturer to whom the harvest will be delivered.