

# Hemp cultivation

for the sole purpose of  
producing finished medicinal  
cannabis products

L. 4523/2018 (GG 41/07-03-2018)- Granting licenses for the establishment and operation of facilities processing and producing finished medicinal hemp products (Cannabis Sativa L (THC) > 0.2%).

Joint Ministerial Decision No. oik. 51483/700/ .15 (GG 1692/15-05-2018)- Terms and conditions for the cultivation and processing of medicinal cannabis.

and relevant amendments:

Ministerial Decision No. oik. 118694/1485/ 15 (GG 5129/15-11-2018)

Ministerial Decision No. oik. 103057/1342/ 15 (GG 4426/05-10-2018)

Explanatory Circular 18010/12-2-2019

Ministerial Decision No. 3( )52588 (GG 2840/16-07-2018 - Terms and conditions for the production and circulation of nal products from pharmaceutical cannabis

## Innovative regulation

- » By way of exception, natural and legal entities are granted the option of cannabis cultivation for the sole purpose of producing finished medicinal cannabis products to supply the state monopoly and make them available to patients or export them for medical purposes
- » Access to cannabis of a specific strain (Cannabis Sativa L with more than 0.2% tetrahydrocannabinol (THC) content) and exclusively for medical purposes.
- » Cannabis still remains in the set of addictive substances, therefore the licence for installation and/or operation is granted under strict terms and conditions
- » The approval of production, possession, transportation, storage, supply of raw materials and substances, as well as the establishment and operation of a facility for the processing and production of finished medicinal products can be obtained by a joint decision of the Ministers of Development & Investments, of Health, and of Rural Development and Food
- » The licence is non-transferable
- » Storage, security and delivery specifications

## The Benefits from the legislation for the medicinal cannabis:

- » Access of the country's patients to finished cannabis medicinal products given the therapeutic properties of cannabis in specific cases
- » Natural persons and legal entities are allowed to cultivate cannabis varieties for the processing of raw materials and of these substances in general for the sole purpose of producing finished products of medicinal cannabis in Greece, investing in securing the appropriate space and establishing cultivation and processing facilities
- » Creation of new jobs that will contribute to the growth of the economy in a cutting-edge sector that makes the most of the comparative, productive advantages of the country
- » Economic benefits for the State from the exports of finished medicinal cannabis products, and the taxation of economic activities in the sector

## Bene ciaries

Natural persons or legal entities, residing either in Greece or abroad , provided that:

- » they or the persons involved in the administration or management thereof (in the case of legal entities) or the employees/workers in cultivation areas and in processing, treatment and storage facilities, or the transport drivers employed have not been convicted of or indicted by nal ruling for a felony, or any penalty for speci c crimes (e.g. the , embezzlement, fraud, extortion, forgery, etc.) and are not placed under judicial support (curatorship) (privative or auxiliary, complete or partial)
- » legal entities with registered headquarters abroad, which have authorized a tax and procedural representative in Greece. Persons that come from non-EU countries must reside permanently in Greece or have their head o ces in Greece
- » the activity must extend over a single, enclosed area, stretching over a minimum surface area of 4 stremma (approx. 1 acre) , and the cultivated area must be closed

## Facilities approval procedure

- » Submission of the M.D Annex I questionnaire (No. 51483/700/ .15) to the Directorate of Licensing of Businesses and Business Parks, General Secretariat for Industry
- » Submission of supporting documents in digital and printed form
- » The Directorate of Licensing of the General Secretariat for Industry shall forward a digital copy accompanied by a copy of the submitted questionnaire to each of the relevant departments of the Ministry of Rural Development and Food, the Ministry of Health /National Organization for Medicines (E.O.F.) and the Hellenic Police
- » The facilities approval is granted following a decision by the Ministers of Development & Investments, Health, and Rural Development and Food, within 30 days after receiving a complete dossier and is valid for five (5) years
- » An on-site inspection is conducted by the Licensing Directorate within fifteen (15) days after the facilities approval has been granted

## Required Documentation for the facilities approval

1. Land use certificate by the relevant land registry agency accompanied by the submitted topographic diagram used for its issuance -
2. Decision for the Approval of Environmental Terms (AEPO) or Standard Environmental Commitments (PPD), where deemed necessary -
3. Copy of identity card or valid passport of the applicant natural persons or the natural persons involved in the administration or management of the applicant legal entity. For legal entities, the aforementioned document is submitted: for all the members of the Board of Directors (SA), or for all the partners (GP, LTD,P.C.) or for all the members of the consortium (joint venture) -
4. Non judicial support certificate for applicant natural persons or the natural persons involved in the administration or management of the applicant legal entities
5. A copy of the criminal record for general use of the applicant natural persons, or the natural persons involved in the administration or management of the applicant legal entities
6. An attestation in lieu by the applicants certifying that they have not been indicted by a national ruling for the offenses in par. 5 of Article 2A of Law 4139/2013 for the applicant natural persons or the natural persons involved in the administration or management of the applicant legal entities. -
7. An attestation in lieu by the applicant natural persons or the persons involved in the administration of the applicant legal entities as to their status as «beneficiaries», according to the requirements of the law -
8. Certificate of non-bankruptcy, non-filing a bankruptcy petition, non-filing a request for conciliation - consolidation, non-filing a request for dissolution and non-dissolution of the legal entity -
9. Tax and social security clearance certificates of the applicant natural person or legal entity
10. Permanent residence certificate for liable persons (persons from non-EU countries)
11. Nomination of an authorized tax and procedural representative, if the applicant has headquarters abroad
12. An attestation in lieu of the applicant natural person or the legal representative of the applicant legal entity that there is no school at a distance of less than 1000 m from the boundaries of the site of the unit to be licensed
13. A fee of ten thousand (10,000) euros, deposited into the Revenue Number Code 1450189001 (Other Administrative Fees) in favour of the General Secretariat for Industry (Ministry of Development & Investments)
14. In the case of applicants coming from countries other than Greece, documentation 5 and 6 is deemed necessary, nevertheless, failing that, an equivalent document issued by a competent judicial or administrative authority of the applicant's Member State or country of origin, officially translated into Greek, need to be submitted. Where the country in question does not issue such documents or certificates, the document or certificate may be replaced by a declaration on oath or, in Member States where there is no provision for declarations on oath, by a solemn declaration made by the person concerned before a competent judicial or administrative authority, a notary or a competent professional or trade body, in the country of origin or provenance. -

# Procedure for issuing an authorization to operate

- » Upon submission of the questionnaire, the applicant submits the supporting documents to the Directorate of Licensing of the General Secretariat for Industry, in both printed and electronic form. An authorization to operate is granted within 30 days after filing a complete dossier and is valid for ten (10) years
- » The Directorate of Licensing of the General Secretariat for Industry shall forward a digital copy to each of the relevant departments of the Ministry of Rural Development and Food, the Ministry of Health/National Organization for Medicines (E.O.F.) and the Hellenic Police. The authorization to operate is granted by decision of the Ministers of Development & Investments, Health, and Rural Development and Food within 30 days after filing a complete dossier and is valid for ten (10) years
- » Within two (2) months after issuing the authorization to operate, the Directorate of Licensing of the General Secretariat for Industry carries out an on-site inspection to assess whether the requirements for granting the authorization to operate are being abided by or not.

## Documents to be submitted for issuing an authorization to operate

1. A certified title of ownership, or a lease contract, or a free-of-charge concession certified by the competent tax authority
2. Plan view of the premises
3. Certificate of the relevant Security Sub-Division or Security Department that the terms and conditions of safe and secure storage are met
4. Greenhouse permit, where required, and a topographic diagram showing the location and size of the cultivated area
5. An affirmation in lieu by the body as to the compliance with the legal requirements for those associated with the production facility in any employment capacity whatsoever
6. An affirmation in lieu by a statutory engineer with regards to the static structural adequacy, the industrial-manufacturing use of the building, the installation of the mechanical equipment in a main use area (not an auxiliary or communal one), the number of the existing building permit, as well as the non-requirement to issue a new one
7. An affirmation in lieu by the body stating how many and what kind of specialised personnel it intends to use by law
8. An affirmation in lieu by specialized engineers, as appropriate, that the facilities are in accordance with the facilities approval granted and that the projected works were carried out in accordance with the approved designs
9. An affirmation in lieu by the owner and the statutory technician, respectively, regarding the assignment - assumption of supervision, operation and maintenance of the facilities
10. A copy of the building permit, where required
11. An affirmation in lieu that the planned fire protection and prevention measures have been taken
12. Certificate of acceptance and certificate of inspection in force for the boilers of the production facility, where required
13. LPG tanks inspection certificate in force, where applicable
14. An affirmation in lieu by a statutory engineer that the site's traffic connection was carried out in accordance with the approved designs
15. A water use permit, if required
16. A port facilities construction permit, and a seashore and beach use permit, if required
17. A power generator licence, in the event it exists and/or is used
18. A fee of ten thousand (10,000) euros, deposited into the Revenue Number Code 1450189001 (Other Administrative Fees) in favour of the General Secretariat for Industry (Ministry of Development & Investments)

# Export of finished medicinal cannabis products

The export of finished medicinal products of hemp of the Cannabis Sativa L strain with more than 0.2% tetrahydrocannabinol (THC) content, exclusively for medical purposes is carried out through the Piraeus Customs Office and the Thessaloniki Free Zone by producing an authorisation by the competent authorities of the country in which they are to be shipped, certified by the Greek consular authorities; the authorization must clearly state that the products in question are allowed to enter the country, they are to be used for medical purposes, as well as the name and address of the recipient, the amount of the products, and the period within which import must take place.

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