

## INFORMATION NOTE

Subject: Medical Cannabis – Key points in Greek Legal Framework

### I. Authorization amplitude

A single authorization shall be granted hereby for the production, possession, transport, and procurement of raw materials and substances of cannabis varieties of the Cannabis sativa L species with a tetrahydrocannabinol (THC) content exceeding 0.2%, as well as the installation and operation of a manufacturing unit for the processing and manufacture of medical final cannabis products, with the exclusive purpose of either supplying them to the State monopoly for distribution for medical purposes or exporting them.

The authorization provided shall suffice for the import of sowing-seeds and propagating material of cannabis varieties of the species Cannabis sativa L. with a tetrahydrocannabinol (THC) content exceeding 0.2%, for medical purposes, as well as for the export of medical cannabis products of the cannabis varieties of the species Cannabis sativa L. with a tetrahydrocannabinol (THC) content exceeding 0.2%.

The land on which all the activities referred above take place, for which the authorization is granted, shall constitute a single parcel with a surface area of at least 4,000 square meters, with specific security prerequisites required by the relevant legal framework.

### II. Entity Choice– Terms and Conditions

Authorization shall be granted to natural persons or to legal persons in whose management or administration no natural persons participate who are subject to the following incompatibilities:

(a) Have been convicted for a felony and to any sentence for theft, embezzlement, fraud, extortion, forgery, legal malpractice, bribery, corruption, coercion, unlawful conflict of interest, breach of duty, as well as any sexual or sexual exploitation offence.

(b) have been indicted by means of a final ruling for a felony or for a misdemeanor

(c) are under custodial wardship, or under subsidiary wardship, or under both conditions.

It therefore arises that an authorization is possible to be granted to either a natural person or to any form/type of legal person (company) under the above-mentioned provisions

The available company form/types in Greece are the following:

- i. public limited company
- ii. limited liability company
- iii. private company
- iv. general partnership
- v. limited partnership

Among the above list, the best option will be selected according to the investment primary needs and the required actions will take place for the installation of the company in front of the competent authorities

### **III. Authorization required Documents, Procedures and Duration**

#### **A. Supporting documents for the issue of the installation approval**

1. Land use certificate by the competent Building Agency, accompanied by the topographical chart that was submitted for the issue thereof. Where this topographical chart does not indicate the surface area of the area where all activities are to be performed, or the facilities or infrastructure neighboring the particular area and which could possibly affect the location of the activities, a separate topographical chart shall be submitted, to an appropriate scale, indicating the foregoing.
2. Environmental Impact Assessment (EIA) and Decision on the Approval of Environmental Conditions (DAEC).
3. Technical report by the entity documenting that the capacity of the manufacturing unit for the processing of cannabis is sufficient for the utilization/management of the quantity of cannabis produced and cultivated in the facility. The technical report shall contain a top view of the area occupied by the manufacturing unit, with an indicative location of the machinery.
4. A copy of the police identity card or valid passport of the applicant natural persons or the natural persons participating in the management or administration of the applicant legal entities.
5. A certificate that all applicant natural persons or the natural persons participating in the management or administration of the applicant legal entities , are not under guardianship.

6. A copy of a general use criminal record of the applicant natural persons or the natural persons participating in the management or administration of the applicant legal entities, as defined.
7. A Solemn Statement stating that no final indictment has been issued in respect of the crimes of para. 5 of Article 2A of Law 4139/2013 for all applicant natural persons or the natural persons participating in the management or administration of the applicant legal entities.
8. A Solemn Statement regarding compliance with the requirements of para. 5 of Article 2A of Law 4139/2013 of the applicant natural persons or the natural persons participating in the management or administration of the applicant legal entities.
9. A certificate that the legal entity has not been declared bankrupt, that no application has been filed for declaring the legal entity bankrupt, that no application for conciliation-consolidation has been filed, that no application for dissolution has been filed and a certificate that the legal entity has not been dissolved.
10. Tax and social insurance clearance certificates for the applicant natural person or the legal entity, which have been issued at the earliest one month before the application submission date.
11. A permanent residence certificate for the persons set forth in the last section of para. 2a of Article 2A of Law 4139/2013.
12. A tax and procedural representative statement, where the applicant has its registered office abroad.
13. Opinions by the entities referred to the questionnaire, if required.
14. A Solemn Statement of the applicant natural person or the legal representative of the applicant legal entity that no school operates within a distance of less than 1,000 meters from the boundaries of the land plot of the unit to be licensed.
15. A ten thousand (10,000) euro fee, deposited in KAE 3741 in favor of the General Secretariat for Industry (Ministry of Economy & Development).

Without prejudice to urban planning legislation, any architectural diagrams (topographical chart, coverage chart, top view, sections) or certifications thereof shall not be required for the grant of the installation approval. Where the urban legislation requires a certification of the architectural charts, the Directorate for Licensing of Undertakings & Industrial Parks of the General Secretariat of Industry, which grants the installation approval pursuant to the provision, shall certify them, provided that the installation approval can be granted.

## B. Procedure for the issue of the installation approval

For the grant of the installation approval, the entity of the unit being licensed (henceforth the entity) must submit to the Directorate for Licensing of Undertakings & Industrial Parks of the General Secretariat for Industry (hereinafter Licensing Directorate of the GSI) the questionnaire required by the relevant laws filed in.

The Licensing Directorate of the GSI shall grant to the entity, within three (3) working days, a response which shall list the required supporting documents for the installation and operation approval, respectively. The entity shall submit the designated supporting documents in five copies, of which one (1) in printed form and the remaining four (4) in digital form. The Licensing Directorate of the GSI shall transmit to the competent Agencies of the Ministry of Rural Development and Food, of the Ministry of Health/National Organization for Medicines, and the Hellenic Police, one of the digital copies, respectively, accompanied by the submitted questionnaire.

The installation approval shall be granted by means of a decision of the Minister for Economy and Development, the Minister for Health, and the Minister for Rural Development & Food within 30 days from the submission of a complete dossier and shall be valid for five (5) years.

Within fifteen (15) days from the grant of the installation approval, the Licensing Directorate of the GSI shall perform an on-site inspection, aiming at verifying the correctness of the questionnaire, the suitability of the area, if pre-existing, as well as the conditions prevailing in the area where the unit will be installed. Where the inspection discovers deviations from the contents of the questionnaire or unsuitability of the area or incompatibility of the conditions prevailing in the area, within ten (10) days the entity shall be notified in writing and/or electronically in respect of such discoveries, of the deadline for correcting the discovered deviations, if possible, as well as in respect of the sanctions should such deviations are not corrected. If the correction of the deviations is impossible, the installation approval shall be revoked.

## C. Supporting documents for the issue of the operation approval

1. A certified property deed or a lease agreement or an assignment of use free of charge, certified by the competent Tax Office, covering the entire area of the unit being licensed. The duration of the lease agreement or the assignment of use free of charge must correspond to the duration for which the interested party applies for the operation approval.

2. A top view of the area, with an indicative location of the machinery inside said area, including an indication of its power, signed by a competent engineer under the law.
3. A certificate by the respective Security Sub-division or Security Department regarding compliance with the terms and conditions for the safe guarding of the cultivation areas, the facilities of the manufacturing unit, the storage areas of raw materials, substances and final products of pharmaceutical cannabis.
4. A greenhouse type approval, where required.
5. A Solemn Statement of the entity regarding compliance with the requirements of para. 5 of Article 2A of Law 4139/2013 in respect of any person that has a relationship of any kind of employment status with the unit.
6. A Solemn Declaration by the competent engineer under the law, in respect of the structural sufficiency, the installation of the mechanical equipment in the primary (not auxiliary or jointly-used) area, the number of the existing building permit and the fact that no additional permit is required.
7. A solemn statement by the entity indicating the number and the specialty of technicians it will occupy under the law.
8. A solemn statement by engineers of a respective specialty, as the case may be, certifying that the installation was performed in accordance with the installation approval granted and that the foreseen works were implemented in accordance with the approved designs.
9. A solemn statement for the assignment - undertaking of the supervision, operation and maintenance of the installation by its owner and the competent engineer under the law, respectively, where the total power exceeds 59 kW.
10. A copy of the building permit, if the activity is to be performed in a newly constructed building.
11. A Solemn statement as per Law 1599/1986 by the competent engineer under the law certifying that the fire protection measures and means, as foreseen in Joint Ministerial Decision Φ15/οικ.1589/104/2006 (Government Gazette, Series II, No. 90), as in force at each time, in respect of the installation of the manufacturing unit for the production of pharmaceutical cannabis, have been implemented and are in good order.
12. An acceptance certificate and a valid control certificate for the steam boilers of the installation, in accordance with Articles 5 and 9 of Ministerial Decision No. 10735/651/2012 (Government Gazette, Series II, No. 2656), where the unit is equipped with steam boilers.

13. A valid control certificate of liquid propane gas tanks, in accordance with Ministerial Decision No. Δ3/14858/1993 (Government Gazette, Series II, No. 477), Article 3.3.13, where the unit is equipped with a liquid propane gas installation.
14. A solemn statement by a competent engineer under the law that the traffic connection of the installation has been performed in accordance with the approved designs.
15. Water usage license, where required.
16. License for the construction of port works and use of shoreline and beach, where required.
17. Power generator license, where one exists and/or is used.
18. A ten thousand euro (€ 10,000) fee, deposited in KAE 3741 in favor of the General Secretariat for Industry (Ministry of Economy & Development).

#### D. Procedure for the issue of the operation approval

For the grant of the operation approval, the entity must submit to the Licensing Directorate of the GSI the supporting documents set forth in the reply document determining the supporting documents that were sent upon submission of the questionnaire at the installation stage. The supporting documents shall be submitted in five copies, of which one (1) in printed form and the remaining four (4) in digital form. The Licensing Directorate of the GSI shall transmit to the competent Agencies of the Ministry of Rural Development and Food, of the Ministry of Health/National Organization for Medicines, and the Hellenic Police, one of the digital copies, respectively.

The operation approval shall be granted by means of a decision of the Minister for Economy and Development, the Minister for Health, and the Minister for Rural Development & Food within 30 days from the submission of a complete dossier and shall be valid for ten (10) years.

Within two (2) months from the operation approval, the Licensing Directorate of the GSI shall perform an on-site inspection in order to verify compliance with the terms for the grant of the operation approval. Throughout the duration of the operation of the unit, the Licensing Directorate of the GSI shall perform on-site inspections on at least an annual basis to verify compliance with the terms for the grant of the installation and operation approvals. Where breaches are discovered, the inspection findings shall be promptly notified to the competent Agencies of the Hellenic Police, as such are defined in Article 4, and to the competent agencies of the Ministry of Rural Development and Food, as such are defined in Article 6.

#### E. Update of supporting documents

The entity shall be obliged to re-submit to the Licensing Directorate of the GSI updated versions of the installation approval supporting documents set forth under A 4-11, as well as of the operation approval supporting documents set forth under C 3 and C 5, by 31 December of each year, as from the year following the year of the approval. This obligation shall apply, in respect of installation approval supporting documents (A 4-11), throughout the validity term of the installation approval and, in respect of the operation approval supporting documents (C3 and C5), throughout the validity term of the operation approval.

#### F. Renewal of operation approval

For the renewal of the operation approval, the entity shall submit the questionnaire required by the law. The Licensing Directorate of the GSI shall review the dossier of the supporting documents and shall determine the supporting documents which it deems that the entity must submit again.

#### G. Special Marketing Authorization required information and documents

1. Name or trade name and home address or registered office of the applicant legal entity;
2. name of the final pharmaceutical cannabis product;
3. qualitative and quantitative composition of the final pharmaceutical cannabis product;
4. methods and specifications of raw materials quality control and verification of control methods;
5. final pharmaceutical cannabis product development designed;
6. manufacturing process (e.g. raw material processing, any addition of additional additives, manufacture, use of auxiliary solvents, purification, formation, packaging), necessary intermediate quality controls during manufacture, crucial stages of manufacturing process, verification of the manufacturing process, in compliance with the principles and guidelines in force concerning the good manufacturing rules for medicinal products intended for human use and which at the moment
7. methods and specifications of final product quality control, verification of control methods, results of test lots analysis;
8. composition, type, characteristics of direct container;

9. final product stability studies (which document the life cycle, the storage conditions and any required lifetime after the opening of a container with multiple doses);
10. therapeutic indications, contra-indications and adverse reactions;
11. dosage, pharmaceutical form, method and route of administration and expected life time of the final pharmaceutical cannabis product;
12. justification for any precaution and safety measure that must be taken for the storage of the medicinal product, the administration thereof to patients and the disposal of remnants, along with an indication of any danger caused by the medicinal product to the environment;
13. summary of the applicant's adverse reaction monitoring system, which must contain the following information:
  - a. proof that the applicant has at its disposal a specialized person who shall be responsible to monitor adverse reactions;
  - b. the contact details of the specialized person, a declaration signed by the applicant that it has the required means for the performance of the duties and competences;
  - c. reference to the place where the main file of the adverse reaction monitoring system for final pharmaceutical cannabis products is kept;
14. the risk management plan that describes the risk management system to be introduced by the applicant for the specific final pharmaceutical cannabis product, accompanied by a relevant summary;
15. a summary of the product characteristics in accordance with the provisions of laws, a model of the outer packaging, information regarding the primary packaging of the medicinal product that contains the details provided for in relevant law, as well as the patient information leaflet in accordance with the provisions of the relevant requirements by the law.

#### H. Procedure and renewal of Special Marketing Authorization

The special marketing authorization shall be granted by National Organization of Medicines (NOM) pursuant to the provisions of law and shall be valid for three (3) years, subject to a relevant application by the interested financial entity. The special marketing authorization may be renewed every three years, following a reevaluation.



#### **IV. Seeds**

The quantity of imported seeds shall not exceed three (3) kilograms of seeds per thousand square meters of cultivated area, and shall be imported for covering the needs of seeding of the approved cultivation area.

#### **V. Safety and guarding specifications**

1. All cultivation and processing activities shall be performed within a fenced area, where the storage areas shall also be located. The cultivation area shall be closed.

2. In respect of the protection of the perimeter, the following shall be at least implemented:

a) The area shall be fenced with a permanent mesh grid and/or wall, with a height of at least 3 m. Inside the fence, a free - empty zone of at least 3 m shall be constructed.

b) Lighting, from the sunset until the sunrise, with adequate sufficiency that renders any movement for the approach of the fence visible, both from the inside and the outside thereof.

c) Safety alarm system, operating continuously, with external motion detectors which shall report every attempt to breach the fence.

d) The fence shall be equipped with an integrated, 24/7 operational, supervision system, with the use of cameras, that will cover the perimeter and the free - empty zone, with no blind spots. The cameras must be able to record under any visibility conditions. The system must be equipped with a back-up battery to ensure uninterrupted operation. Recordings shall be kept for at least 90 days.

e) Guarding duties shall be performed by uniformed personnel and trained private guards in accordance with the provisions of Law 2518/1997, on a 24-hour basis, who shall continuously monitor the fencing, the empty zone and the safety systems. At least one moving guard per shift along the internal free-empty zone. For surface areas exceeding 10,000 m<sup>2</sup>, the moving guards shall be at least two. Upon change of shifts, the guards shall verify, on the log specially kept to this end, the proper operation of the cameras and of the electronic center.

f) A central outpost shall be located at the main entrance, to guard the entry-exit and to check the persons entering-leaving the facility. It shall be manned by at least two guards. At the same time, the gates shall be equipped with an integrated monitoring system, operating 24/7, with the use of cameras, which shall record under any visibility conditions equipped with a back-up battery to ensure uninterrupted operation.

3. In order to protect the cultivation, the manufacturing unit and the storage areas, the following shall be mandatory:

a) Sufficient lighting, from sunset to sunrise, in order to ensure that any entry or exit, to or from the cultivation area, the manufacturing unit and the storage areas is visible.

b) Operation of a safety alarm system, with exterior motion detectors that will sound the alarm when anyone tries to violate the doors of these spaces.

c) The integrated monitoring system that operates 24/7, with the use of cameras, shall cover the entries and the interior of said spaces, without any blind spots. The cameras shall record under any visibility conditions. The system shall be equipped with a back-up battery to ensure uninterrupted operation. Recordings shall be kept for at least 90 days.

4. Only specially authorized persons may enter the spaces of the aforementioned area, who shall be logged electronically. The electronic logs of entry-exit shall be kept for ten years and shall be made available to all and any inspections by the Hellenic Police, both routine and non-routine.

5. In addition to the aforementioned security measures, the undertaking must ensure the adoption of any additional measure that is deemed necessary, in order to prevent any risk of destruction, damage, theft or loss, excluding the possibility that the above elements end up in the hands of any third person, in any manner. Moreover, the operation of the security measures must be continuous, constant, and uninterrupted; any damage or fault must be promptly restored. Damages, faults, destructions, losses and any need for maintenance shall be promptly taken care of on the same day.