



The New Legislative Regime on Pharmaceutical Cannabis

Under law 4139/2013, the production, possession, transportation, storage, and supply of raw materials and substances, as well as the establishment and operation of facilities for the processing and production of finished pharmaceutical cannabis products, were in principal subject to the necessary licences and permits being obtained.

The adoption of new law 4801/2021 on May 24th 2021 amended law 4139/2013 by introducing simplified procedures and removing to a large extent the ambiguities of the previous regime. Greek pharmaceutical cannabis exports are expected to be henceforth more efficient and less time consuming.

The key changes / amendments introduced by new L. 4801/2021 may be summarized as follows:

- i. The **State's monopoly** on the sale of final products **is repealed**. As a result, final products may be sold in the Greek market for medical purposes through direct sales to pharmacies, wholesalers, clinics and public hospitals.
- ii. **The Narcotics Committee's positive opinion is no longer a prerequisite** for the production and distribution of pharmaceutical cannabis products, which significantly expedites the time for issuing all relevant permits and approvals.
- iii. The National Organization for Medicines (EOF) **is the only competent regulatory body to issue the required production and/or distribution licences** for the manufacturing of final pharmaceutical cannabis products regardless of whether the products are intended for the Greek market or for exportation.
- iv. Pharmaceutical cannabis **products can be exported irrespective of their intended final form in the importing country**; in this regard, they may be used as finished or semi-finished products or raw material for medical and pharmaceutical purposes and irrespective of their therapeutic indications.
- v. Finished products of medical cannabis containing THC over 0.2% may be exported from the competent **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 imported, certified by the Greek consular authorities. Said authorization shall expressly state that (i) the pertinent products are allowed to enter the importing country, (ii) they are to be used for medical/pharmaceutical purposes, (iii) the name and address of the recipient, (iv) the quantity of the products, and (v) the period within which importation must be effected.
- vi. **EOF's license is not required for products intended solely for export**; therefore, the exportation process is expected to significantly speed up.
- vii. In case of **production license exclusively for exportation, EOF is required to issue such** within an exclusive period of ninety (90) days following the submission of the complete file.



- viii. Cannabis sativa L cannabis **propagating material with a THC content exceeding 0.2% is allowed for exportation.**
- ix. **Power generation stations** (solar, wind or co-generation of natural gas and other renewable energy sources) **may operate** within the medical cannabis site to meet the electricity needs of the facility.
- x. Cannabis products in the form of **dried flower** may be exported **in packaging up to thirty (30) grams** for medical and pharmaceutical purposes regardless of whether in the exporting country they are intended to be used as finished or semi-finished product or raw material for medical and medicinal purposes.
- xi. **Exportation of dried flower is allowed** provided that the medical cannabis plant **maintains production capacity for at least two (2) forms of pharmaceutical products;** one relating to products in the form of dried flower and the other to products that do not constitute dry flower or do not include dried flower.

In order for a Greek company to be able to engage in the aforesaid activities, the following requirements must be met in terms of licensing:

1. Establishment Permit (or Installation Licence)

The establishment permit is granted following a Ministerial Decision within thirty (30) days after filing a complete dossier with all necessary documentation to the Directorate of Licensing of Businesses and Business Parks, General Secretariat for Industry (“GSI”). Within fifteen (15) days from the approval of the installation, the GSI conducts an *in situ* inspection, to ascertain the actual conditions of the facilities where the company’s activities are carried out. Once granted, the establishment permit is valid for five (5) years.

2. Operation Permit

According to article 2A of L. 4139/2013 as amended by the new L. 4801/2021, **upon obtaining the required installation licence** (1st stage), in order of an operational licence (2nd stage) to be issued, the applicant must file to the GSI the **documents requested to the GSI document received in response to the submission of the dossier during the installation stage.** The **operation permit is granted within thirty (30) days of the submission of a full dossier** and is **valid for ten (10) years**, with the possibility of renewal.

3. EOF approval for the production and circulation of final products in Greece or abroad (Production Licence)

Production and circulation of pharmaceutical cannabis final products intended to cover the national needs are subject to the approval of the President of EOF before being prescribed to patients, in accordance with the requirements of Ministerial Decision 32221/2013 on pharmaceutical products for human use, without the need to obtain the Narcotics Committee’s approval.

4. Production licence exclusively for exportation

The issuance of a production licence exclusively for exports requires the submission of a permit or another equivalent document from the authorities of the importing country as well as the full description of the product, while EOF must issue the said licence within ninety (90) days from the application’s submission. Issuance of this licence by EOF requires neither the latter’s prior approval for the production and circulation of final products nor the approval of the Narcotics Committee.



5. Production licence for final products in the form of dried flowers exclusively for exportation

Final products in the form of dried flowers in packaging up to thirty (30) grams may be exported, pursuant to the production licence solely for exportation as abovementioned and on

condition that the additional documentation of art. 21B of L. 4139/2013 is submitted. This production licence is issued exclusively in cases where the pharmaceutical cannabis plant has concurrently applied for a production and circulation licence of final products in Greece, in a form other than dried flowers.

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