GOVERNMENT GAZETTE
OF THE HELLENIC REPUBLIC

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LAW NO 4523

Provisions on the production of medical final cannabis products and other provisions

THE PRESIDENT
OF THE HELLENIC REPUBLIC
We hereby promulgate the following law adopted by the Parliament:

Article 1

The following new Article 2A is added after Article 2 of Law 4139/2013 (Government Gazette No 74, Series I) as follows:

'Article 2A

1. By way of exception, 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.
2. The authorization shall not be transferrable, and the assignment and concession of any activity, at any of the stages referred to in para. 1, to any third party shall be prohibited, and [the authorization] shall be granted by means of a joint decision of the Ministers for the Economy and Development, for Health, and for Rural Development and Food, for all the activities referred to in para. 1, in accordance with the provisions of Law 3982/2011 (Government Gazette, Series I, No 143), in particular Article 43(1)(i) of Law 4442/2016 (Government Gazette, Series I, No 230) and Decision No οικ.483/35/Φ. 15/2012 (Government Gazette, Series II, No 158) of the Minister for Development, Competitiveness and Maritime Affairs, unless otherwise provided for in this Article, subject to the following terms and conditions:
   (a) Authorization shall be granted to natural persons who are not subject to the incompatibilities referred to in para. 5 or to legal persons in whose management or administration no natural persons participate who are subject to the incompatibilities referred to in para. 5, following submission of an application and payment of a fee, along with the supporting documents referred to in the following indents. If the legal person has its registered office abroad, it shall appoint a tax representative and agent in Greece. In any event, persons coming from non-EU countries must be permanent residents of Greece or have a registered office in Greece.
   (b) The land on which all the activities referred to in para. 1 take place, for which the authorization is granted, shall constitute a single parcel with a surface area of at least 4,000 square meters, proven by means of a ratified title of ownership or a lease or free concession agreement, which must be ratified by the competent Tax Office (DOY).
   (c) The single parcel where the activity is carried out shall be fenced and the cultivated area shall be closed.
   (d) The application shall be accompanied by a copy of a police identity card or valid passport, a certificate that the persons concerned have not been made wards of court, a copy of a criminal record issued for all purposes and a solemn declaration certifying that no final indictment for the offences referred to in para. 5(a), (b) and (c) has been handed down in respect of the applying natural persons or the natural persons participating in the management or administration of the applying legal persons.
   (e) The application shall also be accompanied by a certificate that the legal person has not been declared bankrupt, that no application has been filed for declaring the legal person bankrupt, that no application for conciliation-consolidation has been filed, that no application for dissolution has been filed and that the legal person has not been dissolved.
   (f) The application shall be accompanied by tax and social insurance clearance certificates for the applying natural or legal person, which must have been issued one month before the date of submission of the application at the earliest.
   (g) The application shall be accompanied by a certificate from police security subdivision or security department that the terms and conditions for the security of the cultivation areas, the manufacturing unit facilities, the storage areas for raw materials, substances and final medical cannabis products of the cannabis varieties of the species *Cannabis sativa* L. with a tetrahydrocannabinol (THC) content exceeding 0.2%, and the transport procedure have been followed as such are laid down in the decision referred to in para. 4.
   3. The aforementioned supporting documents shall be updated and submitted annually, and compliance with the aforementioned terms and conditions for the granting of authorization shall be reviewed annually. In the event of breaching the terms and conditions for the granting of authorization, the competent Ministers referred to in para. 2 shall revoke the authorization, after giving a maximum thirty (30) day compliance deadline. The authorization shall be revoked without setting a compliance deadline in cases of violation of the terms regarding the security of the site set forth in subparagraph (g) and in the decision referred to in the following paragraph.
4. Any further terms and conditions concerning, in particular, the granting of the authorization, the submission of additional supporting documents, the amount of the fee, the security and safety specifications of the cultivation and storage areas, the manufacturing units, the transport procedures, the security and storage deadline, which may not exceed five (5) years, the method used to authorize the import of the sowing-seeds, the procedure used to verify compliance with the terms and conditions for the granting of the authorization, the procedure for ordinary and extraordinary inspections intended to monitor continuous compliance with the terms and conditions for the granting of the authorization at any stage of the cultivation and manufacturing procedure, as well as all other matters shall be determined by decision of the Ministers for the Interior, for the Economy and Development, for Justice, Transparency and Human Rights, for Health, and for Rural Development and Food.
5. The authorization referred to in para. 2 shall not be granted to natural persons, or to legal persons which are managed or administered by natural persons, who:
   (a) Have been convicted for a felony and to any sentence for theft, embezzlement (common and in service), 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 referred to in subparagraph (a);

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

The incompatibilities referred to in subparagraph (a) shall be lifted only upon issuance, under Article 47(1) of the Hellenic Constitution, of a decree that lifts the consequences of the sentence.

The incompatibilities referred to in subparagraphs (a), (b), and (c) shall also apply to employees and workers in cultivation areas and manufacturing, processing, and storage facilities, as well as to the drivers of the transport vehicles used.The incompatibilities shall apply, in particular, to the chairman and CEO in the case of public limited companies, the manager in the case of limited liability and private companies, or to the person of all general partners in the case of general and limited partnerships.The existence of incompatibilities shall be checked at the time of hiring or appointment of the aforementioned persons, as well as at any time thereafter.

6. The recommendation of the Drugs Commission shall not be required for the issue the aforementioned decisions.

7.The authorization provided for in para. 2 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 import, distribution, and export of raw materials and substances, as well as the distribution and export of sowing-seeds and propagating material of the cannabis varieties of the species *Cannabis sativa* L. with a tetrahydrocannabinol (THC) content exceeding 0.2% shall be prohibited.

8. Medical cannabis products of the cannabis varieties of the species *Cannabis sativa* L. with a tetrahydrocannabinol (THC) content exceeding 0.2% intended for medical purposes shall be exported through the Piraeus Customs Office and the Thessaloniki Free Zone, subject to the production of a permit issued by the authorities of the importing country and certified by the Greek consular authorities, which must certify that the import of such products is permitted in the said country, that their intended use is for medical purposes, the name and address of the recipient, their quantities and the deadline within which the import must be completed.

9. The National Organization for Medicines shall authorize the manufacture and distribution of the final medical cannabis final from cannabis varieties of the species *Cannabis sativa* L. with a tetrahydrocannabinol (THC) content exceeding 0.2% for medical purposes, in accordance with the terms and conditions laid down in Law 1316/1983 (Government Gazette, Series I, No 3) and Joint Ministerial Decision No Δ.ΥΓΘα/ Γ.Π. 32221/2013 (Government Gazette, Series II, No 1049), particularly in Article 3(1)(d) of Law 1316/1983 (Government Gazette, Series I, No 3), Articles 57 to 76 and 133 to 159 of Joint Ministerial Decision No Δ.ΥΓ3α/Γ.Π. 32221/2013 (Government Gazette, Series II, No 1049), applied *mutatis mutandis,* as they shall be more specifically determined by decision by the Minister for Health, following a recommendation from the National Organization for Medicines.

10. Articles 11, 17, 18 and 19 hereof shall not apply where the authorization referred to in Article 2A(1) and (2)hereof has been granted'.

Article 2

Article 20(2) of Law 4139/2013 (Government Gazette, Series I, No 74) is replaced by the following:

'2. Without prejudice to the provisions of Articles 2A and 29, the crime of drug trafficking means any act whereby the narcotic substances or precursor substances that are listed in the tables of Article 1(2) are trafficked, and, in particular, the import, export, transit, sale, purchase, offer for sale, distribution, disposal, sending, delivery, storage, deposit, possession, transport, adulteration, sale of adulterated narcotic substances belonging to the monopoly, the cultivation or harvesting of any plant of the genus *Cannabis*, any plant of the genus *Papaver*, any plant of the genus *Erythroxylum*, as well as any plant from which narcotic substances can be produced, the production and infusion of narcotic substances, the administration of substances for the substitution of addiction in breach of the relevant provisions, the management of any store where drugs are systematically trafficked with the knowledge of the perpetrator, the financing, organization or management of narcotic substances trafficking activities, the modification or forgery or use of a forged doctor's prescription for the administration of drugs for the purpose of trafficking them, as well as the mediation in any of these activities.'

Article 3
Amending Articles 27 and 34 of Law 4472/2017 (Government Gazette, Series I, No 74)

1. Article 27(3) of Law 4472/2017 is replaced by the following:
'3. Procurement arrangements implemented by the bodies referred to in Article 23, which are included in co-financed operational programs of the National Strategic Reference Framework (NSRF) and are financed with national and Community funds, those co-financed by the European Structural and Investment Plans (ESIPs), the European Economic Area (EEA) or other specific co-financed programs (EIB, CEB, etc.), as well as those included in the Public Investment Program or those financed from appropriations registered under codes Φ 210, 5115 and 5117 and fund-raising shall not be subject to the provisions of this Article and of Article 26. Such procurement needs not be included in the procurement and service plans and programs of healthcare bodies.
The feasibility of the above procurement and of the conduct of the relevant tenders shall be approved by decision of the Minister for Health. The same decision shall specify, in particular, the beneficiary, object and budget of the procurement. Moreover, the project feasibility approval decisions that were issued for the NSRF programming period 2007-2013, which were not implemented or were implemented only partially, shall remain in force with a view to speeding up the procedures for including the financing proposals in the NSRF 2014-2020. In any event, such procurement must comply with the Registry of Uniform Technical Specifications. As regards procurement whose technical specifications have not been included in the above registry, the awarding authorities shall continue to draw these up independently, in accordance with the applicable provisions'.
2. (b) The first indent of Article 34(2) of Law 4472/2017 is replaced by the following:
'The 2015 procurement program shall remain in force and shall be amended and implemented in accordance with the procedures provided for to date'.

3. The provisions of this Article shall take effect retroactively as of the date of publication of Law 4472/2017.

Article 4
Non-interventional studies

1. Non-interventional studies, which are regarded as clinical studies without the clinical trials defined in Article 2(2) of Regulation (EU) No 536/2014 of the European Parliament, shall be permitted in Greece subject to the following conditions:

(a) the patients participating in the study are provenly already undergoing treatment with the investigational medicinal product;

(b) the investigational medicinal product is administered to the participating patients in accordance with the therapeutic

protocol for the disease concerned, the terms and conditions laid down in its marketing authorisation and the approved indications;
(c) the study is carried out in a number of countries or in Greece only in accordance with Union law at least in three centers (healthcare institutions or primary health care units). Private physicians with a similar specialty, who have a practice in the same health region, may participate in the centers carrying out the non-interventional study as collaborating physicians;
(d) no diagnosis or monitoring procedures are used on participating patients other than those included in the standard clinical practice provided for by the guidelines;
(e) the chief investigator must be a physician in the national health system, a member of teaching and research staff or a physician in charge of a department in a private healthcare institution in which a Scientific Board or a Scientific Committee is established and in operation;
(f) the investigational medicinal product is paid for by the social security organizations;
(g) where there is a registry in place for the disease concerned, the chief investigator notifies the competent scientific team that handles the registry and enters the study data;
(h) the study aims to assess the safety or effectiveness of the investigational medicinal product in day-to-day clinical practice or its consequences on the quality of life of the patients taking it.

2. A Committee for Non-Interventional Studies (CNIS) shall be set up at the National Organization for Medicines, which shall be staffed by decision of the Minister for Health following a proposal from the President of the National Organization for Medicines. The Committee shall give opinions on whether the conditions referred to in para. 1 are met. It shall comprise seven members as follows: four (4) physicians, two (2) scientists from the Directorate for Pharmaceutical Studies and Research of the National Organization for Medicines and one (1) hospital pharmacist. The Committee members shall not be paid for their services. An employee of the National Organization for Medicines shall serve as secretary. The above decision shall also regulate all other matters relating to the functioning of the Committee.
3. Following a positive opinion from the committee referred to in para. 2, to carry out a non-interventional study in Greece: (a) where the study is carried out in a healthcare institution, approval must be obtained from the scientific board and authorization from the director of the institution, or (b) where the study is carried out in a non-hospital environment, approval must be obtained from the scientific board and authorization from the director of the competent health region.
4. After the above authorization is granted and before the non-interventional study is started, a quadrilateral contract shall be entered into by and between the sponsor, the chief investigator, the legal representative of the healthcare institution or of the competent health region and the administrator of the ELKE/ELKEA.
5. A registry shall be kept at the National Organization for Medicines, to enter all non-interventional studies that are authorized as per the above, along with the results upon completion thereof.
6. A decision of the Minister for Health to be published in the Hellenic Government Gazette shall regulate the more specific matters and all other details relating to the approval procedure and the carrying out of non-interventional studies in Greece.

Article 5
Amending Article 11 of Law 4052/2012

Article (11)(d) of Law 4052/2012 (Government Gazette, Series I, No 41) is replaced by the following:
'(d) The National Healthcare Service Provider (EOPYY) may offset the above sums against equal sums that it owes to medicinal product marketing authorization holders on account of the procurement of proprietary medicinal products for the needs of its pharmacies. The offsetting shall be made between rebates owed by medicinal product marketing authorization holders and EOPYY's cleared debts to these holders, as generated in the same, previous, or following year'.

Article 6
Repayment in installments of debts owed by medicinal product marketing authorization holders to EOPYY

The debts owed by medicinal product marketing authorization holders to EOPYY from rebate amounts under Article 35(3) of Law 3918/2011 (Government Gazette, Series I, No 31) and clawback amounts under Article 11 of Law 4052/2012 (Government Gazette, Series I, No 41) for the years 2012 to 2017, as these resulted following completion of the offsetting provided for by the above provisions, may be repaid in instalments. A decision of the Minister for Health shall specify the number of installments, the procedure used for payment thereof, as well as all necessary details for applying the above provision. In the event of delayed payment of even just one of the above installments, as well as delayed payment of any current debt owed by medicinal product marketing authorization holders to EOPYY, the above arrangement shall be terminated automatically.

Article 7
Amending Articles 3 and 4 of Law 3892/2010

1. The following paragraph 10 is added to Article 3 of Law 3892/2010 (Government Gazette, Series I, No 189):
'10. The prescription or referral document may be drawn up in digital format (intangible prescription or intangible referral document). In that case, the intangible prescription or intangible referral document shall be communicated and executed only in digital format, following identification of the patient. A decision of the Minister for Health to be published in the Hellenic Government Gazette shall regulate the more specific matters and technical details relating to the digital communication and execution'.
2. The following paragraph 12 is added to Article 4 of Law 3892/2010 (Government Gazette, Series I, No 189):
'12. The procedure for submitting executed intangible prescriptions or intangible referral documents to social security organizations may be completed only in digital format, i.e. intangible submission. A decision of the Minister for Health to be published in the Hellenic Government Gazette shall regulate the more specific matters and technical details relating to the digital submission'.

Article 8
Entry into force

This Law shall enter into force upon its publication in the Government Gazette, unless otherwise stipulated in its individual provisions.

We hereby order the publication of this Law in the Government Gazette and its enforcement as a Law of the State.

Athens, 6 March 2018
The President of the Republic
PROKOPIOS V. PAVLOPOULOS

The Ministers

Deputy Prime Minister and Minister for the Economy and Development

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Certified and sealed with the Great Seal of the State.
Athens, 6 March 2018

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