Terms and conditions for the manufacture and marketing of final pharmaceutical cannabis products

THE MINISTER FOR HEALTH

Having regard to:

1. The provisions of:

a) Article 2, para. 1, Article 3, para. 1, cases d) and f), para. 3 and para. 5, Article 6, case I, para 6 and case II, paras 1, 8 and 10, Article 8, Article 11 and Article 27 of Law 1316/1983 (Government Gazette, Series I, No. 3);

b) Article 1, para. 9 of Law 4523/2018 "Provision for the manufacture of final pharmaceutical cannabis products and other provisions" (Government Gazette, Series I, No. 41);

c) Articles 2 and 7 of Law 4139/2013 "Law on addictive substances and other provisions" (Government Gazette, Series I, No. 73);

d) Joint Decision No. Γ5γ οικ. 49690/2017 by the Ministers for Justice, Transparency and Human Rights and for Health on the "Supplementation and amendment to the tables of narcotic substances of Law 3459/2013, as in force and amended by Law 4139/2013" (Government Gazette, Series II, No. 2238/29.06.2017);

e) Article 19, paras 1, 2, 5, and 12 of Legislative Decree 96/1973 "On trade in pharmaceutical, dietary and cosmetic products", as in force following its replacement with Article 95, para. 5 o Law 4172/2013 "Income taxation, emergency measures for implementation of Law 4046/2012, Law 4093/2012 and Law 4127/2013 and other provisions" (Government Gazette, Series I, No. 167);

f) Article 90 of Presidential Decree 63/2005 "Codification of the Legislation on the Government and Government Organs" (Government Gazette, Series I, No. 98);

g) Presidential Decree 121/2017 "Internal Regulation of the Ministry of Health" (Government Gazette, Series I, No. 148), as in force, and Presidential Decree 144/2017 ""Internal Regulation of the Ministry of Economy and Development" (Government Gazette, Series I, No. 192);

h) Presidential Decree 73/2015 "Appointment of a Deputy Prime Minister, Ministers, Deputy Ministers and Alternate Ministers" (Government Gazette, Series I, No 116).

2. The Decision-Recommendation by NOM President dated 6/7/2018 and with prot. no. 73075, which was transmitted to the Ministry of Health with cover document dated 6/7/2018 and with prot. no. NOM 73076 .

3. The certificate dated 6/7/2018 and with prot. no. NOM 73151 by the NOM Financial Services Directorate that this decision does not burden the NOM expenses budget.

4. The fact that this decision, pursuant to document with prot. no. Β2(α)/οικ.5338410-7-2018by Financial Services Directorate General of the Ministry of Health, does not burden the budget of the State and of NOM, we hereby decide:

Article 1

Scope - Purpose

1. Final pharmaceutical cannabis products of Article 1 of Law 4523/2018 (Government Gazette, Series I, No. 41) which Article 2A of Law 4139/2013 (Government Gazette, Series I, No. 74) fall within the scope hereof.

2. The terms and conditions for the manufacture of final pharmaceutical cannabis products of para. 1 by the authorization holders of paras 1 and 2 of Article 1 of Law 4523/2018 are determined herby, as well as the terms and conditions for the marketing in the Greek market of final pharmaceutical cannabis products manufactured in Greece, as well as final pharmaceutical cannabis products imported by another European Union Member State or a third country, without prejudice to the provisions of para. 2 of Article 1 and para. 2 of Article 2 of Law 4139/2013 (Government Gazette, Series I, No. 74).

Article 2

Definitions

The following definitions shall apply for the purposes of this ministerial decision:

Final pharmaceutical cannabis product: Any product that contains as active ingredient (active substance) for the indications determined in accordance with the procedure provided for in case a) of para. 1 of Article 4 hereof, the substance of cannabis varieties of the Cannabis Sativa L. species with a tetrahydrocannabinol (THC) content exceeding 0.2% and which falls within the scope of Law 4523/2018 (Government Gazette, Series I, No. 41).

Active ingredient of the final pharmaceutical cannabis product: The substance of cannabis varieties of the Cannabis Sativa L. species with a tetrahydrocannabinol (THC) content exceeding 0.2% intended for use in the manufacture of the final pharmaceutical cannabis product and which, when used in the manufacture of the said product it becomes an active ingredient intended for the indications of case a) of para. 1 of Article 4 hereof.

Name of the final pharmaceutical cannabis product: The name, which may either be a fictional name that does not cause confusion with the common name, or the common or scientific name, accompanied by a trademark or the trade name of the special marketing authorization holder.

Content of the final pharmaceutical cannabis product: The content of tetrahydrocannabinol (THC).

Special marketing authorization holder. The financial entity who has obtained the approval provided for in the provisions of pars 1 and 2 of Article 1 of Law 4523/2018, in the name of which the special marketing authorization for the final pharmaceutical cannabis product shall be issued, and which shall be responsible for all obligations related to the marketing of the said product.

Core Summary of Product Characteristics: The terms for the administration of final pharmaceutical cannabis products that are documented in the respective published international and European scientific literature shall be reviewed and laid down by the Special Committee of Article 3 hereof.

Summary of Product Characteristics: The details of provisions of paras 1 and 2 of Article 7 hereof.

Medical prescription: Any medical prescription of final pharmaceutical cannabis product written by a professional authorized to this end.

Primary packaging: The container or any other form of packaging in direct contact with the medicinal product.

Outer packaging: The packaging in which the primary packaging of the final pharmaceutical product is placed.

Labelling: The information on the outer or primary packaging of the final pharmaceutical product.

Patient Information Leaflet: The information leaflet for the user which shall accompany the final pharmaceutical cannabis product.

Adverse reaction: A response to a final pharmaceutical cannabis product that is harmful and unintended.

Serious adverse reaction: Any adverse reaction which results in death, is life-threatening for the patient, requires hospitalization or prolongation of hospitalization, results in persistent or significant disability or incapacity, or is expressed as a congenital anomaly / malformation.

Main file of the adverse reaction monitoring system: a detailed description of the adverse reaction monitoring system used by the special marketing authorization holder for final pharmaceutical cannabis product.

Article 3

Special Marketing Authorization

1. For all final pharmaceutical cannabis products falling within the scope of the provisions of Article 1 of Law 4523/2018, either for placing on the Greek market under the restrictions of article 2 par. 2 of Law 4139/2013 or for export, as well as for final pharmaceutical cannabis products imported in Greece, either from another European Union Member State, or from a third country, a special marketing authorization shall be required, which shall be granted by NOM pursuant to the provisions hereof and shall be valid for three (3) years, subject to a relevant application by the interested financial entity.

The financial entity applying for the special marketing authorization shall submit, along with the information and documents dossier of Article 6 hereof, the fees provided for in Article 5 of JMD ΔΥΓ3α/Γ.Π. 13907/05/2006 (Government Gazette, Series II, No. 1098).

2. The special marketing authorization shall be granted in writing by NOM, which shall notify its holder for the summary of the characteristics of the final pharmaceutical cannabis product it has approved, as well as for the approved labelling and the approved Patient Information Leaflet, in accordance with the respectively approved Summary of Product Characteristics.

NOM shall adopt all required measures in order to ensure that the labelling and the patient information leaflet are in compliance with the respectively approved summary of product characteristics.

3. The special marketing authorization may be renewed every three years, following a re-evaluation of the risk-benefit relation in accordance with the procedure under Article 4 hereof.

To this end, the special marketing authorization holder shall submit to NOM, at least nine (9) months before the expiry of the validity of the special marketing authorization in accordance with para. 1, all information of the adverse reactions monitoring system in accordance with para. 3 of Article 13 hereof.

Article 4

Evaluation Process

1. A Special Scientific Final Pharmaceutical Cannabis Products Committee shall be established in NOM, by a relevant decision of the its President that shall be issued pursuant to Article 6, case II, para. 10 of Law 1316/1983 (Government Gazette, Series I, No. 3), with the following tasks:

a) the evaluation of the active ingredient (active substance) of the final pharmaceutical cannabis product, as determined in Article 2 hereof, for specific indications and specific pharmaceutical forms;

b) the re-evaluation of the active ingredient (active substance) of the final pharmaceutical cannabis product in view of new scientific data in relation to specific indications and/or pharmaceutical forms or pharmacovigilance data;

c) the preparation of the Core Summary of Product Characteristics, on the basis of the documentation resulting from the outcome of the evaluation under case a) of para. 1 hereof, as well as the revision of the Core Summary of Product Characteristics following the re-evaluation of case b) hereof;

d) the evaluation of the dossier of the financial entity applying for an authorization for manufacture of the final pharmaceutical cannabis product, which shall mandatorily include the inspection report by the materially competent NOM bodies, in accordance with the provisions of Article 8 hereof;

e) the evaluation of the dossier containing the information and the documents laid down in Article 6 hereof that is submitted by the applicant for the special marketing authorization for final pharmaceutical cannabis product;

f) the evaluation of the dossier of final pharmaceutical cannabis products imported from another European Union country or a third country;

g) the re-evaluation of the final pharmaceutical cannabis product dossier for the renewal of the special marketing authorization;

h) the review of grounds for the revocation of the authorization for manufacture or the amendment, suspension or revocation of the special marketing authorization for a final pharmaceutical cannabis product;

i) the recommendation for the Summary of Product Characteristics to be approved, and pursuant thereto the recommendation for the labelling and Patient Information Leaflet to be approved;

j) the recommendation for the classification of the final pharmaceutical cannabis product in accordance with the provisions of Article 96, paras 2 and 3 of JMD 32221/2013;

k) the recommendation for the performance of audits, inspections and samplings regarding final pharmaceutical cannabis products, whenever it considers it necessary for reasons of protection of public health, without prejudice to the provisions of Law 1316/1983 (Government Gazette, Series I, No. 3) that determined the competences of the NOM administration bodies;

l) the recommendation for the imposition of administrative sanctions and fines for infringements of the provisions hereof.

Article 5

Special Marketing Authorization Holders

A special marketing authorization for a final pharmaceutical cannabis product manufactured in Greece in accordance with the provisions of Article 1 of Law 4523/2018 (Government Gazette, Series I, No. 41) shall be granted, subject to the implementation of the provision of para. 2 of Article 2 of Law 4139/2013, exclusively to holders of the authorization laid down in the provisions of paras 1 and 2 of Article 1 of Law 4523/2018 (Government Gazette, Series I, No. 41), either as regards a product to be placed on the Greek market under the restrictions of article 2 par. 2 of Law 4139/2013 or a product to be exported, who has obtained the various approvals required in accordance with the joint ministerial decision 51483/700/ϕ.15/2018 (Government Gazette, Series II, No. 1692) and as long as the terms and provisions hereof are fulfilled, following a relevant application.

A special marketing authorization shall be granted for final pharmaceutical cannabis products imported in Greece, subject to the implementation of the provision of para. 2 of

Article 2 of Law 4139/2013. Where the financial entity applying to NOM for a special marketing authorization for final pharmaceutical cannabis products is registered in a non-EU country, it shall be obliged to appoint a responsible representative in the European Union, who shall have all rights and obligations of the special marketing authorization holder.

Holding a special marketing authorization for final pharmaceutical cannabis products does not have any effect on the civil and criminal liability of its holder and the person appointed in accordance with the previous section as the responsible representative.

Article 6

Special marketing authorization dossier

1. The application for the authorization of Article 3 hereof shall be accompanied by the following information and documents:

a) Name or trade name and home address or registered office of the applicant legal entity;
b) name of the final pharmaceutical cannabis product;
c) qualitative and quantitative composition of the final pharmaceutical cannabis product;
d) methods and specifications of raw materials quality control and verification of control methods;
e) final pharmaceutical cannabis product development designed;
f) 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 that the decision hereof is entered into force are defined by the Joint ministerial Decision ΔΥΓ3α/7567/2008 (Government Gazette, Series II, No. 1562) for the "Adaption of the Commission Directive 2003/94 EC laying down the principles and guidelines of good manufacturing practice in respect of medical products for human use and investigational medical products for human use in greek legislation" without prejudice to article 17 of the Joint ministerial decision Δ3(α)/14709/2017 for the "Adaption of the Commission Directive (EU) 2017/1572 supplementing Directive 2001/83/EC of the European Parliament and of the Counsil as regards the principles and guidelines of good manufacturing practice for medical products for human use in greek legislation" (Government Gazette, Series II, No. 1152/29.3.2018) and the decisions of NOM, published to

the Government Gazette as defined in article 66 of the Joint ministerial decision ΔΥΓ3α/Γ.Π.32221/2013 (Government Gazette, Series II, No. 1049);

g) methods and specifications of final product quality control, verification of control methods, results of test lots analysis;

h) composition, type, characteristics of direct container;

i) 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);

j) therapeutic indications, contra-indications and adverse reactions;

k) dosage, pharmaceutical form, method and route of administration and expected life time of the final pharmaceutical cannabis product;

l) 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;

m) summary of the applicant's adverse reaction monitoring system, which must contain the following information:

1) proof that the applicant has at its disposal a specialized person who shall be responsible to monitor adverse reactions;

2) 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 under Article 13 hereof;

3) reference to the place where the main file of the adverse reaction monitoring system for final pharmaceutical cannabis products is kept;

n) 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;

o) a summary of the product characteristics in accordance with the provisions of Article 7 hereof, a model of the outer packaging, information regarding the primary packaging of the medicinal product that contains the details provided for in Article 9 hereof, as well as the patient information leaflet in accordance with the provisions of Article 9 hereof.

2. The submission of the dossier with the information and documents of para. 1 shall be required in order for all final pharmaceutical cannabis products imported in Greece, either from another European Union Member State or a third country.

Article 7

Core Summary of Product Characteristics -

Summary of Product Characteristics

1. The Core Summary of Product Characteristics of final pharmaceutical cannabis products (Core SmPC), in accordance with the definition of Article 2, shall include, in the following order, the following information:

a. Maximum limit of quantitative composition of tetrahydrocannabinol (THC) from the plants of cannabis varieties of the species Cannabis Sativa L, for which it applies exclusively and restrictively;

b. Pharmaceutical forms, for which it applies exclusively and restrictively;

c. Pharmacological properties -Clinical information;

ca) Medical/Therapeutical uses;

cb) Maximum amounts to be administered and administration route;

cc) Contraindications;

cd) Special warnings and precautions for use;

ce) Interaction with other medicinal products and other forms of interaction;

cf) Administration during pregnancy and breast-feeding;

cg) Effects on ability to drive and use machines;

ch) Adverse reactions;

ci) Overdose (symptoms, emergency actions, antidotes);

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The Core Summary of Product Characteristics of the final pharmaceutical cannabis products shall include a standardized test, which shall explicitly request from doctors, pharmacists and other health professionals to notify any suspected adverse reaction directly to NOM, using the adverse reaction reporting system of para. 1 of Article 13 hereof, and which clarifies the available reporting methods (electronic reporting, by post and/or others).

2. The Summary of Product Characteristics concerning the specific final pharmaceutical cannabis product for which a special marketing authorization is granted shall include, in addition to the information of para. 1, the following information:

a) Product name;

b) Shelf-life;

c) Special precautions for the preservation of the final pharmaceutical cannabis product;

d) The special marketing authorization holder;

e) The number(s) of the special marketing authorization.

Article 8

Manufacturing

1.For manufacturing the final pharmaceutical cannabis products a special manufacturing authorization shall be required, as defined by the provision of case d) of para. 1 of Article 3 of Law 1316/1983 (Government Gazette, Series I, No. 3) which is granted by NOM to authorization holders under the provisions of paras 1 and 2 of Article 1 of Law 4523/2018 (Government Gazette, Series I, No. 41), following a respective application.

The factories for the manufacture of final pharmaceutical cannabis products shall employ a production manager and a quality control manager, in accordance with the specific provisions of case a) of para. 1 of Article 27 of Law 1316/1983, as in force.

2. The production of final pharmaceutical cannabis products shall be mandatorily subject to the terms and conditions of the provisions of Articles 58, 59, 62 section a, 63, 66, 67,68, 69, 70, 71, 72, and 73 of JMD 32221/2013 (Government Gazette, Series II, No. 1049)), applying mutatis mutandis. The administrative procedure for the granting of license for production is under the deadline of articles 60, 61 and 62 of of JMD 32221/2013 (Government Gazette, Series II, No. 1049), as defined in them.

For the purposes of the *mutatis mutandis* application of the provisions laid down in the previous section in respect of products falling within the scope hereof, where reference is made to: a) Medicinal Product, it shall mean the final pharmaceutical cannabis products, b) Active Substance, it shall mean tetrahydrocannabinol (THC), c) Marketing Authorization, it shall mean the special marketing authorization.

3. The final pharmaceutical cannabis products shall be manufactured, within the framework of greek legal order, in accordance with the principles and guidelines concerning the good manufacturing rules for medicinal products intended for human use in force and which at the moment that the decision hereof is entered into force are defined by the Joint ministerial Decision ΔΥΓ3α/7567/2008 (Government Gazette, Series II, No. 1562) for the "Adaption of the Commission Directive 2003/94 EC laying down the principles and guidelines

of good manufacturing practice in respect of medical products for human use and investigational medical products for human use in greek legislation" without prejudice to article 17 of the Joint ministerial decision Δ3(α)/14709/2017 for the "Adaption of the Commission Directive (EU) 2017/1572 supplementing Directive 2001/83/EC of the European Parliament and of the Counsil as regards the principles and guidelines of good manufacturing practice for medical products for human use in greek legislation" (Government Gazette, Series II, No. 1152/29.3.2018) and the decisions of NOM, published to the Government Gazette as defined in article 66 of the Joint ministerial decision ΔΥΓ3α/Γ.Π.32221/2013 (Government Gazette, Series II, No. 1049);

4. NOM shall conduct inspections through its materially competent bodies to the manufacturing (processing) facilities of final pharmaceutical cannabis products of the special marketing authorization holder:

a) Before granting a manufacturing authorization of the final pharmaceutical cannabis products, in order to review the appropriateness of the facility and the operation of the equipment and systems;

b) In order to ascertain compliance with the principles and guidelines of the good manufacturing rules determined in para. 3 and Article 66 of JMD 32221/2013.

Following an inspection under case b), a report shall be drafted on the level of compliance of the inspected entity with the aforementioned principles and guidelines of the good manufacturing rules, which shall be notified to the inspected party, in order for the latter to furnish their opinion within ten (10) days. The inspection report shall be finalized having taken into account the views of the inspected party or upon lapse without action of the aforementioned ten days deadline.

If, according to the findings of the inspection report, the inspected financial entity complies with the principles and guidelines of the good manufacturing rules, a certificate of compliance with the good manufacturing rules shall be granted, as the case may be.

5. NOM shall suspend or revoke the manufacturing authorization for a specific type of the final pharmaceutical cannabis products or for the whole product, in the cases laid down in the provisions of Article 171 of JMD 32221/2013 which shall apply *mutatis mutandis* for products falling within the scope hereof.

6. The Health Directorates and the Health and Care Directorates of the Regions shall conduct on-site inspections in the approved manufacturing units in order to record the production processes of cannabis products, the number of batches and amounts of plants used therein, the number of batches and amounts of the final pharmaceutical cannabis product and the performance of the processing and the justification of deviations. On-site inspections shall be performed every three months and the inspection reports shall be transmitted to NOM.

Article 9

Labelling -

1. The outer packaging or, where no outer packaging exists, the primary packaging of the final pharmaceutical cannabis product shall be approved by NOM and must bear the following indications, in accordance with the information and documents of Article:

a) the name of the medicinal product, accompanied by the content and the pharmaceutical form;

b) the qualitative and quantitative content in tetrahydrocannabinol (THC) or, depending on the administration route, for determined volume or weight, with the use of common names;

c) the pharmaceutical form and the content in weight, volume or number of doses;

d) the administration manner and, if required, the route. Space shall be provided for writing the prescribed dosage;

e) special warning according to which the product must be kept away from children, outside their field of view;

f) other special warnings for the product, where required;

g) the expiration date, in a clear manner (month/year);

h) the special precautions for the preservation of the product, where required;

ha) the name and address of the special marketing authorization holder;

hb) the number of the special marketing authorization;

hc) the manufacturing lot number;

hd) instructions for use.

2. The existence of a patient information leaflet in the packaging of every final pharmaceutical cannabis product shall be mandatory, unless all information required in paragraph 1 are printed directly on the outer packaging or the primary packaging.

3. The information referred to in the previous paragraphs must be legible, easily understandable and indelible.

4. All final pharmaceutical cannabis products that obtain a special marketing authorization shall bear an authenticity strip, in accordance with the applicable legislation.

Article 10

Patient Information Leaflet

The patient information leaflet shall be approved by NOM and shall be prepared on the basis of the summary of the product characteristics. The leaflet shall contain, in the following order:

a) In order to identify the final pharmaceutical cannabis product:

1) the name of the product, accompanied by the content and the pharmaceutical form. The common name shall be listed where the product has only one active substance and its name is a fictional one;

2) the medical/therapeutic use;

b) A list of information that is necessary before taking the final pharmaceutical cannabis product:

1) Contraindications;

2) Precautions in use;

3) Interactions with other medicinal products and other cases of interaction (e.g. alcohol, tobacco, food) that may have an impact on the drug's action;

c) Special warnings, such as:

1) The need to take into account the special conditions of some categories of users (pregnant or breast-feeding women, elderly people, people with a specific pathological condition);

2) Reference must be made, where necessary, to possible effects of the treatment in a person's ability to drive cars or use machinery;

d) The necessary and usual instructions for good use, in particular:

1) maximum dosage;

2) the administration manner and, where required, the route;

3) the required action in case of overdose (e.g. symptoms, emergency treatment);

4) special warning to the users for consulting with their doctor or pharmacist, when necessary, for any clarification for the use of the product;

5) a description of the adverse reactions which may occur under normal use of the final pharmaceutical cannabis product and, if necessary, the necessary action in such a case;

6) reference to the expiration date printed on the packaging (including any lifespan after the first use);

7) where required, the special precautions for the preservation of the medicinal product;

e) The name and address of the special marketing authorization holder.

Article 11

Classification of Final Pharmaceutical Cannabis Products

1. Upon grant of the special marketing authorization of the final pharmaceutical cannabis product, NOM shall classify it in accordance with the provisions of Article 96, paras 2 and 3 of JMD 32221/2013;

2. In addition, the final pharmaceutical cannabis products shall be sold in accordance with the special prescription conditions and the prescription form determined in the decision of the Minister for Health delegated by Article 7 of Law 4139/2013 (Government Gazette, Series I, No. 74).

Article 12

Advertising

1. All advertising of final pharmaceutical cannabis products shall be prohibited as determined by article 118 of JMD 32221/2013 (Government Gazette, Series II, No. 1049).

2. It shall be prohibited to distribute samples of final pharmaceutical cannabis products.

Article 13

Monitoring Adverse Reactions

1. NOM shall implement an adverse reactions monitoring system for collecting information regarding the risks of final pharmaceutical cannabis products to patients' or public health. Such information mainly concerns the adverse reactions to humans from the use of final pharmaceutical cannabis products, within the approved details of the marketing authorization, as well as from the off-label use thereof and the adverse reactions connected to professional exposure.

2. For the purposes of effective monitoring of adverse reactions, in the context of the adverse reactions monitoring system of para. 1, NOM may impose special obligations to doctors, pharmacists, and other health professionals by decisions issued in the Government Gazette.

3. The marketing authorization holder shall implement, in order to comply with the adverse reaction monitoring obligations, a system equivalent to the one of para. 1 and shall be obliged to:

a) Conduct regular internal audits of its adverse reaction monitoring system and place a note concerning the main findings of the internal audit in the main file of the said system and, on the basis of the findings of the internal audit, to ensure the preparation and implementation of an appropriate corrective actions plan;

b) Must have permanently available a specialized person, who shall be responsible for Monitoring Adverse Reactions;

c) Must keep and have available upon request the main file of the adverse reaction monitoring system;

d) Operate a risk management system for each final pharmaceutical cannabis product;

e) Supervise the outcome of the risk minimization measures, which are included in the risk management plan of case d);

f) Update the risk management system and monitor the data collected and recorded in order to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit risk relation of final pharmaceutical cannabis products.

The marketing authorization holder shall submit the full name and the contact details of the specialized person to NOM.

Article 14

Amendment to the Special Marketing Authorization

1. The special marketing authorization holder must:

a) In respect of the methods of manufacture and control provided for in Article 6 cases d) and h), take account of scientific and technical progress and introduce any necessary changes to enable the final pharmaceutical cannabis product to be manufactured and checked by means of generally accepted scientific methods and respectively modify the information of Article 6;

b) Ensure the update of information for the product, taking into account the current scientific knowledge.

All aforementioned modifications shall be subject to the approval of NOM.

2. NOM may amend the special marketing authorization of the final pharmaceutical cannabis product for reasons relating to the safety of the product or where one or more of the information on which the application is based have been modified/updated, in accordance with the provisions of the previous paragraph.

Article 15

Penalties

1. NOM shall suspend or revoke the special marketing authorization when it considers that the final pharmaceutical cannabis product is harmful or the risk-benefit relation is not favorable or when it ascertains with appropriate laboratory tests, conducted by its Laboratories through sampling, that the final pharmaceutical cannabis product does not meet the declared qualitative and quantitative composition or does not meet the approved quality standards.

2. The special marketing authorization may also be suspended or revoked when the data on which the application is based, as determined in Article 6 is erroneous or false, or when the controls referred to in Article 6, para. 1, case g) have not been performed.

The special marketing authorization shall be suspended or revoked where the final pharmaceutical product is not manufactured in accordance with the approved information, in implementation of Article 6 or where the controls are not performed in accordance with the control methods approved in accordance with the aforementioned Article.

Article 16

Administrative Fines

The penalties provided for in Article 19 of Legislative Decree 96/1973 (Government Gazette, Series I, No. 172), , shall be imposed to anyone who infringes the provisions hereof, with the exception of any penalty provided for in other provisions of the applicable legislation.
For the purposes of the implementation of the previous section, where reference is made to the marketing authorization, it shall mean the special marketing authorization and where

reference is made to pharmacovigilance, it shall mean the adverse reactions monitoring system.

Article 17

This decision shall enter into force as of its publication in the Government Gazette.

This decision must be published in the Government Gazette of the Hellenic Republic

Athens, 13 July 2018

The Minister for Health

ANDREAS XANTHOS