

**ORDER**  
**No. 99, dated 23.2.2024**

**FOR THE APPROVAL OF THE REGULATION ON THE ORGANIZATION OF WORK  
AND ACTIVITIES OF THE LICENSING COMMISSION, FOR THE REVIEW AND  
EVALUATION OF APPLICATIONS FOR THE ISSUANCE OF A LICENSE FOR  
CANNABIS CULTIVATION FOR MEDICAL PURPOSES**

Based on Article 102 of the Constitution, and Article 11, point 8, of Law No. 61/2023, "For the control of the cultivation and processing of *cannabis* plant and production of its by-products for medical and industrial purposes,"

I ORDER:

1. The approval of the regulation for the organization of work and activities of the Licensing Commission for the review and evaluation of applications submitted for the issuance of a license for *cannabis* cultivation for medical purposes, according to the attached text to this order.
2. The National Agency for *Cannabis* Control and the members of the Commission are tasked with implementing this regulation.

This order enters into force immediately and is published in the Official Gazette.

MINISTER OF HEALTH AND SOCIAL PROTECTION  
**Albana Koçiu**

**REGULATION**

**FOR THE ORGANIZATION OF WORK AND ACTIVITIES OF THE LICENSING  
COMMISSION, FOR THE REVIEW AND EVALUATION OF APPLICATIONS FOR THE  
ISSUANCE OF A LICENSE FOR CANNABIS CULTIVATION FOR MEDICAL PURPOSES**

Article 1  
**Purpose**

This regulation aims to establish the detailed rules for the organization and operation of the Licensing Commission for the review and evaluation of applications submitted for the issuance of a license, hereinafter referred to as "the Commission," for *cannabis* cultivation for medical purposes.

## Article 2

### **Object**

The object of this regulation is to define the detailed rules for:

- a) organizing meetings, reviewing, and making decisions at the Commission's meetings;
- b) exercising the administrative and procedural activities of the Commission in presenting, reviewing, and managing the documentation related to entities that have applied for a license, and the grounds for suspension or revocation of the license;
- c) processing and managing the documentation that is subject to the Commission's review and decision-making.

## Article 3

### **Duties and responsibilities**

1. The Licensing Commission has the following duties:

- a) administers and verifies the documentation submitted by entities that have applied for a license, made available by the National Agency for *Cannabis* Control;
- b) assesses the fulfillment of conditions related to premises, equipment, and personnel for the issuance of the license;
- c) prepares the list and corresponding report regarding the requesting entities, as well as prepares the proposal for granting or refusing the license;
- ç) in the event of violations being found, according to the provisions of Law No. 61/2023, "For the control of the cultivation and processing of *cannabis* plant and production of its by-products for medical and industrial purposes", proposes to the Minister of Health the adoption of the administrative measure of suspension or revocation of the license.

2. The Licensing Commission is responsible for:

- a) approving requests for the sale of shares by partners of entities holding a license or permit, submitted for approval by the Agency (Article 9, point 2, letter "k");
- b) reviewing measures for suspending or revoking the license, submitted by the Agency (Article 10, point 4);
- c) reviewing requests for changes related to the transfer of ownership of licensed entities, through preliminary approval or refusal, within 3 months of the complete submission of the request, based on the documentation defined in relation to the verification of the entity's background (Article 14, point 5);
- d) deciding on the selection of the winning entity in the competitive licensing procedure (Article 18, point 1);
- e) preparing the final list of entities competing for a license, ranking participants in the competition according to the points received in accordance with the scoring scheme (Article 18, point 3); approving the scoring scheme for evaluating entities applying for licensing (Article 18, point 3);

f) verifying and determining violations specified in points 1 and 2 of Article 21 of Law No. 61/2023, "For the control of the cultivation and processing of *cannabis* plant and production of its by-products for medical and industrial purposes", after hearing the explanations of the license holder (Article 21, point 3);

g) proposing to the Minister of Health the suspension or revocation of the license (Article 21, point 3).

3. In fulfillment of its duties and responsibilities, the Commission drafts, approves, and publishes, no later than 1 month from the constitution of the Commission and, in any case, before opening the procedures for submitting requests for licensing of entities, more detailed rules for evaluating licensing applications and selecting entities, which define:

a) the criteria for evaluating experience in carrying out the core activities for which the license is granted, among participants in the competition with equal evaluation points;

b) the criteria for evaluating ethical-professional experience and integrity based on the provisions of the guideline for verifying the background of the entity;

c) the procedure followed in the case of equal points (Article 18, point 5).

#### Article 4

##### **Rights and duties of the members of the Commission**

1. The Chairman of the Commission is elected from among the representatives of the ministry responsible for health, by secret ballot, with the votes of the majority of the members of the Commission.

2. The Chairman and members of the Commission are independent in their decision-making, which is based solely on the legislation in force.

3. The rights and duties of the Chairman and members of the Commission are:

a) to regularly attend the Commission's meetings;

b) to study the materials of the meeting and actively participate in the meetings;

c) to inform the meeting leader of their non-attendance;

ç) to vote on the issues to be discussed;

d) to declare at the next meeting, before voting on any matter, any conflict of interest, as provided for in Article 37 of Law No. 8485, dated 12.5.1999, "Administrative Procedures Code";

dh) to adhere to the confidentiality of the information obtained during the exercise of their functions.

#### Article 5

##### **Obligation to attend meetings**

The members of the Commission are obligated to attend meetings, except in justified cases, by notifying the Chairman and the Secretariat in advance. In cases where a member fails to attend three consecutive meetings without a valid reason, it is considered that they have resigned as a

member of the Commission. In this case, the Chairman, or in the case where the Chairman does not attend three consecutive meetings, the member elected by the minister responsible for health, immediately notifies the appointing body and the minister responsible for health.

The appointing body begins the procedure for the selection of a new Commission member no later than 5 days from the date of receiving the notification.

## Article 6

### **Organization of meetings**

1. The Commission discusses and makes necessary decisions through its official meetings, which can be held in person or online. As a rule, meetings are held at the premises of the Agency, and if that is not possible, at the premises of the ministry responsible for health or another suitable venue.
2. The Commission meets and carries out its activities based on requests from entities, submitted by the Agency, for obtaining a license to engage in activities related to *cannabis* production for medical purposes.
3. The Commission's meetings are called by the director of the Agency or by the Chairman of the Commission and are led by the Chairman. In the absence of the Chairman, the meeting is led by the most senior member in office, and if there is more than one, by the oldest member in age.
4. Notification of the location, time of the meeting, the agenda approved by the Chairman of the Commission, as well as all necessary documentation according to the provisions of Law No. 61/2023, "For the control of the cultivation and processing of *cannabis* plant and production of its by-products for medical and industrial purposes", is sent to the Commission members by the Secretariat at least 10 (ten) calendar days before the meeting date. In special cases approved by the Agency's director or the Chairman with the proposal of more than 3 Commission members, the time limit is reduced to no less than 2 (two) working days.
5. The meeting notice is sent by the Secretariat in written and/or electronic form to the addresses of the Commission members deposited by each member with the Secretariat/Agency at the time of their appointment. The date of the meeting notice will be considered the date the notice is received in written form or the date the notice is sent electronically.

## Article 7

### **Quorum and decision-making**

1. The Commission's meetings are held when more than half of the members are present.
2. If, at the opening of the meeting, the majority of the members are not present, the Chairman decides to call the meeting on another day, at least 24 hours after the first meeting.
3. The Secretariat of the Commission prepares the attendance list, which must be signed by the present members at the end of the meeting.

4. The decisions of the Commission are made with the majority of the votes of the Commission members. Each member of the Commission has only one vote. In the event of a tie, the Chairman's vote is decisive.
5. A member of the Commission cannot influence the voting of other members.

#### Article 8

##### **Meeting minutes and disclosure of decisions**

1. The documentation of the Commission's meetings is done by the Secretariat of the Commission through the meeting minutes. The Secretariat records the meetings of the Commission for the purpose of transcribing them and preparing the minutes. The minutes should include the location, the start and end time of the meeting, the attendance of the Commission members, discussions, proposals, comments made during the meeting, the decisions taken, as well as the method and results of the voting. The minutes are signed by all Commission members and the Chairman, as well as the Secretariat. The minutes are filed in the Agency's protocol.
2. The Commission's decisions are disclosed within 7 (seven) days from the date of the meeting and signed by all participating members in the meeting. They are then filed in the Agency's protocol. A copy of the decision, which is filed with the Agency, is also countersigned by the Secretariat. A copy of the decision, along with the necessary documentation, is sent to the ministry responsible for health for further processing when provided for by the applicable legislation.
3. The Secretariat of the Commission sends the decisions and approved materials to the members of the Commission and to the structures assigned with their follow-up and implementation, immediately after the documentation.

#### Article 9

##### **The Secretariat of the Commission**

1. The Secretariat is appointed by the order of the Director General of the Agency, which nominates the individuals who will perform the functions of the Secretariat and the duration of their engagement.
2. The Secretariat of the Commission performs functions of assistance and logistical support by facilitating the organization of meetings and the administration of the relevant documentation for the meetings.
3. The Secretariat of the Commission has the following duties:
  - a) to present the materials prepared for the Commission's meeting to the Chairman, according to the procedures outlined in this regulation, and after approval by the Chairman, to send the meeting notice and relevant materials to the Commission members.

In any case, if the meeting has been announced, the Secretariat, even in the absence of a response from the Chairman, will forward the documents to the Commission members within the deadlines specified in this instruction for their transmission;

b) to oversee the preparation and distribution of decisions and other acts of the Commission;

c) to facilitate the organization of meetings by taking measures to ensure the venue, logistics, and online infrastructure;

ç) to keep records of the attendance of the members.

## Article 10

### **Confidentiality**

The evaluations and discussions that take place during the review of the submitted materials and decision-making in the Commission are confidential and will be treated as such even after the termination of the Commission's functions. The Chairman, members, and Secretariat shall sign a confidentiality and conflict of interest declaration in the format specified in Annexes 1 and 2 of this regulation.

## Article 11

### **Selection of members of the Commission and its first meeting**

1. The first constitutive meeting of the Commission is convened by the head of the National Agency for *Cannabis* Control, no later than 15 days from the receipt of the last notification for the appointment of all Commission members and after the entry into force of the by-laws that ensure the functioning of the Commission and enable its decision-making.

2. In the first constitutive meeting of the Commission, the procedure for the selection of the Chairman will be conducted, which is led by one of the employees of the Secretariat of the Commission, designated by the head of the Agency, according to the provisions of Article 4 of this regulation.

3. The employees of the Secretariat of the Commission will be appointed no later than 5 days from the date of the constitutive meeting of the Commission.

## **CONFIDENTIALITY DECLARATION**

### **Object**

This declaration is made by Mr./Ms. \_\_\_\_\_, in their capacity as a member of the Licensing Commission, for the review and evaluation of requests for the issuance of a license for the conduct of activities related to the production of *cannabis* for medical purposes, who has access to information maintained by the National Agency for *Cannabis* Control.

### **Scope of Application**

This declaration applies to all personal data and confidential information that is known during the work in the Licensing Commission for the review and evaluation of the requests for the issuance of a license for activities related to the production of *cannabis* for medical purposes. The relevant provisions apply even after the engagement with this Commission and the institution that has appointed me has ended.

### **Confidentiality Declaration**

1. By means of this declaration, I undertake not to use or transmit personal data or confidential information related to or obtained from the Licensing Commission for the review and evaluation of requests for the issuance of a license for the conduct of activities related to the production of *cannabis* for medical purposes, or the National Agency for *Cannabis* Control, to unauthorized persons, unless required by law. I acknowledge that this obligation remains in effect during my term as a member and after its conclusion.
2. I understand that the use and disclosure of personal data related to individuals are governed by Law No. 9887, dated 10.03.2008, on the "Protection of Personal Data," as amended. I will not use or disseminate any personal data I learn during my work for any purpose that contradicts the objectives of this role.
3. I understand that I am obliged to maintain the confidentiality of personal data and to keep it secure, taking all appropriate organizational and technical measures.
4. I take full responsibility that, in the event it is found that I have acted in violation of the instructions regarding confidentiality or in cases of failure to safeguard the data, appropriate disciplinary measures will be taken against me. I understand that this action is part of maintaining high professional standards in \_\_\_\_\_.

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Signature of Member

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Date

**DECLARATION FORM**  
**(of conflict of interest)**

Declarer: \_\_\_\_\_

I, \_\_\_\_\_, in my capacity as a member of the Licensing Commission, for the review and evaluation of requests for the issuance of a license for the conduct of activities related to the production of *cannabis* for medical purposes, declare that I am not in a conflict of interest as defined by Law No. 9367, dated 7.4.2005, "On the Prevention of Conflict of Interest in the Exercise of Public Functions," as amended, and the applicable legislation in force, in order to perform my duty in this Commission.

In any case provided by the applicable legislation for the prevention of conflict of interest in the exercise of public functions, I will declare, on a case-by-case basis, any conflict of interest, taking on the obligations that arise from such a declaration and the penalties in case of non-declaration.

This declaration is completed with the details as of the date of declaration.

**Date:** \_\_\_\_\_

**Name Surname**

**Signature** \_\_\_\_\_