REPUBLIC OF ALBANIA

MINISTRY OF HEALTH AND SOCIAL PROTECTION

No. 485 ,Prot.,Tirana, on 28.01. 2025

MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT

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INSTRUCTION

No. 4 , Dated 20. 01 . 2025

ON

THE METHOD, QUANTITY OF SAMPLING AND THE LABORATORY FOR CONDUCTING ANALYSES WITH ACCREDITED METHODS FOR QUALITY CONTROL, DOMESTICALLY OR INTERNATIONALLY

Pursuant to Article 102, point 4, of the Constitution, Article 37, point 2, of Law No. 61, dated 21.7.2023, "On the control of the cultivation and processing of the *cannabis plant* and the production of its by-products for medical and industrial purposes",

I HEREBY INSTRUCT :

Article 1
Purpose

The purpose of this instruction is to guarantee quality and safety in the method and quantity of sampling of the *cannabis* plant, its by-products and products .

Article 2
Object

The definition of procedures and criteria for sample collection and the required quantities for conducting quality control analyses.

Article 3
Definitions

1. *Sample* - is a quantity of material taken in accordance with an approved procedure, from a production lot for quality control purposes in the laboratory.
2. *Accredited laboratory* - means a public laboratory certified according to ISO/IEC 17025:2017 standards, in which identification, physico-chemical, and microbiological analyses are performed in accordance with standardized pharmacopoeial methods.
3. *Approved laboratory* - means an accredited public laboratory, which has documented expertise in performing quality control of the *cannabis plant* , its by-products and products in accordance with the methods of the European Pharmacopoeia (Eur.Phar) and is approved to perform these analyses according to the provisions of Law 61/2023.
4. *EU -GACP* - European Good Agricultural and Collection Practices.
5. *EU-GMP* - European Good Manufacturing Practices.
6. *SOP* - Standard operating procedures that contain detailed instructions to achieve uniformity of performance of a specific process.
7. *GLP* - Principles of Good Laboratory Practice, includes a set of rules and criteria for a quality system related to the organizational process and conditions under which laboratory testing is planned, performed, monitored, recorded, reported and archived.

Article 4
Procedure for the quantity and method of sampling

1. The procedure for sample collection for conducting analyses related to the quality control of industrial and medical cannabis plants, by-products, and final products is carried out for each production batch, according to the respective SOPs approved by the Agency, in compliance with the methods of the European Pharmacopoeia (Eur.Phar), Chapter 2.8.20 "For Plant Drugs: Sampling and Sample Preparation" and/or specific monographs of the European Pharmacopoeia depending on the form of the by-product or product; EU-GMP and GLP.

2. The National Agency for Cannabis Control (hereafter referred to as the Agency) authorizes at least two responsible persons for the collection, handling, and delivery of samples to the approved laboratory. The sample collection process for analysis is carried out by persons authorized by the Agency, in the presence of the person responsible authorized by the

entity. Authorized persons are trained in advance by the approved laboratory or another entity with relevant expertise.

3. Before delivery to the approved laboratory, the samples are assigned the corresponding unique identification number generated by the Agency, not in the presence of the entity.

4. The batch being tested is kept in the quarantine area of the entity and remains blocked until the final result is received regarding the passing of quality control tests. In the case of a negative result based on the analysis certificate, the batch is handled according to the provisions of Law No. 61/2023. Quarantine conditions must be such as to ensure the preservation of the quality of the plant, by-product, or product without change and to prevent contamination, in accordance with EU-GACP guidelines.

5. If two or more batches of cannabis plants, by-products, or products are contaminated, the dedicated spaces for each batch and the respective containers should establish a clear separation between the batches to prevent cross-contamination.

6. The sample collection process concludes with the obtaining of a homogeneous and representative initial sample of the entire batch.
7. The initial sample is selected in the following manner:
    a) When the number of containers is 1-3, a sample is taken from all containers;
    b) When the number of containers is greater than 3, a random or systematic sample is taken from $n^* = \sqrt{N} + 1$, where n is rounded to the nearest whole number and expresses the number of containers from which the sample is taken, while N is the total number of containers.
8. The quantity of the initial sample is taken as four times the quantity calculated according to the tables of chapter 2.8.20. of the Eur.Phar pharmacopoeia, or specific monographs, depending on the total quantity produced of a lot.
9. The tools used to collect the sample must be appropriate for its shape, calibrated, and sterile.
10. The entire amount of sample obtained is divided into two equal parts, each placed in sterile containers with hermetic closure, security seal and clear label containing the lot data, the date of sample collection and the amount of sample. One sample is used for testing by the approved laboratory and, before submission, is assigned a unique identification number generated by the Agency to anonymize the origin of the sample, while the other is retained by the subject for possible retesting until the verification procedure and the stages of contesting the test results are completed.
11. The storage of the sample by the subject is carried out in refrigerated conditions at a temperature of -20°C, at controlled humidity levels, in a dark environment, in safe conditions and with limited access.

12. The sampling process is documented through a report approved by the Agency, which is drawn up in two copies and accompanied by video footage, with a distinct date and time. The persons authorized for the process submit a copy of the relevant report to the Agency and one copy is kept by the subject itself.
13. The report is completed at the end of the testing process and includes data such as: date, time, location, subject data, data of the lot to be tested, sample identification number, quantity of the initial sample obtained, and is signed by the persons present. The same procedure is followed in cases of taking a new sample (resampling).
14. In cases of sampling for self-control purposes, the procedure is carried out taking into account the methods provided for in the subject's SOPs. Self-control samples are taken according to the same procedure set out in this instruction.

Article 5
Procedure for sample accompaniment

1. The procedure for accompanying the sample of medical and industrial cannabis plants is carried out with secure transport conditions, hermetically sealed and stamped containers by persons authorized by the Agency, as per point 2 of Article 4 of this Guideline, and is executed by the authorized personnel of the Agency responsible for sample collection. The collection and transport of samples (to prevent tampering) are carried out in bags with a unique serial number and security features that activate if the bag is attempted to be opened. The serial number of the bags used is recorded in the report of the sample collection, as well as in the laboratory's register that will perform the analysis and in the analysis report, ensuring traceability. The transport conditions must ensure the preservation of the sample's quality unchanged, in accordance with the storage conditions requirements for the product.
2. The transport conditions must be such as to ensure the preservation of the sample's quality unchanged, in accordance with the requirements for the storage conditions of the product.
3. Transport is carried out in a container with thermal insulation that ensures the maintenance of the appropriate temperature for the type of sample.
4. Delivery to the laboratory must be completed within 24 hours from sample collection. Apart from the travel time, the sample is kept by the Agency under controlled temperature and humidity conditions.
5. The procedure for accompanying the sample is the same for all cases of testing, retesting, or self-monitoring testing.

Article 6
Procedure for sample acceptance, preparation and storage

1. The procedure for accepting the sample in the approved laboratory involves the delivery of the industrial or medical cannabis plant sample, which is done with an official protocol approved by the Agency, by the authorized persons as per point 2 of Article 4, and the responsible person who will carry out the testing. The data for the delivery and acceptance are recorded in the register of the receiving laboratory.
2. After the arrival of the initial sample, the laboratory is responsible for processing the sample by dividing it into two equal parts, one of which is used for analysis and the other for retesting in cases where confirmation is required in case of dispute over the analysis results.
3. The processing of the sample refers to the procedure according to the relevant pharmacopoeial method for handling the sample, in order to obtain a homogeneous sample ready for further analysis steps.
4. The testing of the sample for analysis begins no later than 2 (two) working days from its arrival.
5. The confirmation sample is used for possible retesting until the verification procedure and the stages of contesting the test results are completed.
6. The sample is stored under refrigeration conditions at -20°C, with controlled humidity levels, in a dark environment, under secure conditions with restricted access.
7. The laboratory must be equipped with internal standard operating procedures (SOPs), specific for testing and retesting cannabis plants in a codified manner, according to ISO 17025, and the personnel engaged in performing the analyses must have expertise in conducting quality control of cannabis plants, its by-products, and its final products.

Article 7
Final Provisions

1. All institutions and entities mentioned in this instruction are responsible for its implementation.
2. If there are suspicions or it is proven that the analyses officially submitted by the laboratory are false or inaccurate, the Agency reports this to the responsible authority of the approved state laboratory and the General Directorate of Accreditation that issued the relevant accreditation. Furthermore, it recommends to the Minister responsible for health, as appropriate, the removal of the laboratory from the list of approved laboratories.

This instruction enters into force upon publication in the Official Gazette.

THE MINISTER OF HEALTH
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MINISTER OF AGRICULTURE
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