

Electronic accounting of medical cannabis in Ukraine

Introduction

1. New terminology
2. How the medical cannabis accounting system will work
3. Objects of medical cannabis accounting in Ukraine
4. Accounting for medical cannabis transactions
5. Register of medical cannabis transactions

B

On 16 August 2024, a law came into force that establishes the rules for the circulation of medical cannabis in Ukraine, as well as the circulation of substances and medicines made from it ("the Law").

Among other things, the Law sets out the principle of traceability of such circulation. The key element for the implementation of this principle is the introduction of an electronic system that will keep records of plants, products of their processing and operations with them at all stages of their circulation.

On 25 July 2024, the Ukrainian government approved the Regulation on the Electronic Information System for Accounting for Cultivated Cannabis Plants for Medical Purposes, Movement of Such Plants, Products of Their Processing, Cannabis Plant Substance, Medicinal Products Manufactured (Produced) from Them at All Stages of Circulation and the Procedure for Its Operation, which will be the primary regulatory act for accounting for the circulation of medical cannabis in Ukraine.

1. New terminology

New terminology is introduced that will become the basis for working with the electronic medical cannabis accounting system in Ukraine. The key terms are as follows:

- accounting entities – business entities (within the meaning of the Regulation, these are companies, legal entities and individual entrepreneurs) that carry out the following activities: cannabis cultivation for medical purposes;
- production or import of cannabis plant substance;
- production of narcotic drugs, psychotropic substances or medicines from hemp for medical purposes;
- manufacturing in a pharmacy based on a doctor's prescription or by order of medical and preventive healthcare institutions, as well as activities related to the circulation of medicinal products manufactured (produced) from cannabis for medical purposes;

electronic account – a personalised web page (web service or other software interface) of an electronic system user having passed electronic identification and

authentication, designed to enable the creation, viewing, submission, exchange of information and documents in the electronic system;

objects of accounting – objects that are subject to accounting in the electronic system through registration of respective transactions (an exemplary list of such objects is provided below);

transactions subject to accounting – transactions related to the objects of accounting to be registered in the electronic system by accounting entities;

harvest of hemp for medical purposes – gross harvest of products obtained as a result of growing hemp for medical purposes, which is suitable for further sorting and use in order to bring it to the state of plant raw materials of hemp for medical purposes;

products of processing of cannabis plant material for medical purposes – products resulting from the processing of plant material suitable for further production of finished medicinal products, cannabis plant material, a narcotic drug, a psychotropic substance or other products of cannabis processing;

cannabis plant material for medical purposes – products formed as a result of sorting the harvested cannabis crop and bringing it to the state of raw materials suitable for further production of cannabis plant material, narcotic drugs, psychotropic substances or processed products.

2. How the medical cannabis accounting system will work in Ukraine

The owner of the electronic system is the state, represented by the State Service of Ukraine on Medicines and Drugs Control, which will also be the administrator of the electronic system and the owner of information therein.

Access to the electronic system and use of the information resources therein will be free of charge.

In addition to the accounting entities, information from the system will be available to authorised persons of the State Service of Ukraine on Medicines and Drugs Control, the Ministry of Health, the National Police, and the Security Service of Ukraine.

The electronic system will collect and process information about:

- electronic system users;
- objects of accounting, transactions in respect of which are registered in the electronic system, their characteristics and properties;
- transactions subject to accounting registered in the electronic system;
- quotas for narcotic drugs and psychotropic substances within which cannabis plants are cultivated; production, manufacture, storage, importation into and exportation from Ukraine of narcotic drugs, psychotropic substances, and medicines produced (manufactured) from them;
- inventory acts, inventory balances, reports submitted by the accounting entities in the electronic system.

Accounting entities shall enter information into the electronic system in the state language. All information entered into the electronic system must be accompanied by a qualified or advanced electronic signature.

Each transaction shall be registered no later than the next day following the completion of such transaction, except for the operations of labelling cannabis plants for medical purposes and units of packaged cannabis plant substance with unique electronic identifiers, which shall be registered immediately before the start of their implementation.

The transaction must be registered by the entity that performed the transaction. There are exceptions to this rule (e.g., a transaction involving notification of the results of a laboratory test of plant samples is registered by the person who cultivates cannabis and received the test results, not by the laboratory that conducted the test).

The system is used through the heads of the accounting entities or their authorised persons. For this purpose, it will be necessary to issue the relevant powers, if, for instance, the head of the reporting department uses the system, by an order or a power of attorney.

Users access the electronic system through an electronic account. An electronic profile is created during registration in the system. Authorisation will be performed using a qualified or advanced electronic signature.

As a result of a transaction registration, depending on its type, information about the object of accounting, its deregistration or change of information about it is reflected in the accounting records. Here, the following rule applies: no transactions can be registered unless the corresponding accounting object required for the transaction is registered in the system.

In addition to registering accounting objects and transactions with them, inventory certificates, inventory balances, reports, etc. are also submitted through the relevant features of the electronic system.

3. Accounting objects with regard to medical cannabis in Ukraine

Information on medical cannabis accounting objects is entered into the electronic system. The list of these objects, in particular, includes:

- seeds of hemp for medical purposes;
- hemp planting material for medical purposes;
- hemp plants for medical purposes;
- hemp harvest for medical purposes;
- hemp plant material for medical purposes;
- processing products;
- cannabis plant material;
- ready-made medicinal products produced from hemp for medical purposes, products of their processing, cannabis plant substance;
- intra-pharmacy preparations;
- medicinal products manufactured in a pharmacy from hemp for medical purposes, products of their processing, and cannabis plant substance;
- narcotic drugs produced from hemp for medical purposes, products of their processing;
- psychotropic substances produced from hemp for medical purposes, products of their processing;
- waste;

- samples of accounting objects.

Accounting shall be carried out in clearly defined units of measurement depending on the objects of accounting (or their groups), namely:

- unit of packaged products – applies to seeds of hemp for medical purposes, cannabis plant substance, intra-pharmacy preparations, medicinal products;
- piece – applied to hemp plants for medical purposes;
- series – applies to cannabis plant material, finished medicinal products (sometimes, if available, to intra-pharmacy preparations);
- batch – applies to planting material, harvest, plant material of hemp for medical purposes, processed products, narcotic drugs, psychotropic substances, waste (if available – to cannabis plant material and finished medicinal products);
- packaging – applies to samples of the accounting objects.

Each unit of measurement of an accounting object must have its own unique number in the electronic system, which accounting entities are obliged to assign when registering transactions subject to accounting, marking the corresponding unit of measurement of the accounting object with it.

4. Accounting of medical cannabis transactions in Ukraine

A wide range of medical cannabis transactions are subject to accounting in the electronic system, in particular:

- producing seeds of hemp for medical purposes;
- sowing seeds of hemp for medical purposes;
- cloning hemp plants for medical purposes;
- planting hemp plants for medical purposes;
- planting of hemp planting material for medical purposes;
- marking hemp plants for medical purposes with unique electronic identifiers;
- sampling hemp plants for medical purposes;
- sending samples of an accounting object for laboratory testing;
- reporting on the results of laboratory testing of samples of hemp plants for medical purposes;
- harvesting hemp for medical purposes;
- sorting hemp harvest for medical purposes;
- production of cannabis plant substance, narcotic drugs, psychotropic substances or processed products from hemp plant material for medical purposes or processing products;
- labelling units of packaged cannabis plant substance with unique electronic identifiers;
- transporting accounting objects;
- sale of accounting objects, etc.

5. Register of medical cannabis transactions in Ukraine

The electronic accounting system includes the Register of Transactions with Seeds, Hemp Plants for Medical Purposes, Products of their Processing, Cannabis Plant Substance, Medicinal Products, Narcotic Drugs, Psychotropic Substances Manufactured (Produced) from Them.

The register information is entered by the heads of the accounting entities and

their authorised persons. They also act as public registrars of the Register.

The list of transactions that must be entered into the Register includes, in particular:

- producing seeds of hemp for medical purposes;
- sowing seeds of hemp for medical purposes;
- cloning hemp plants for medical purposes;
- planting hemp plants for medical purposes;
- planting cannabis planting material for medical purposes;
- marking hemp plants for medical purposes with unique electronic identifiers;
- sampling hemp plants for medical purposes;
- sending samples of an accounting object for laboratory testing (study);
- reporting the results of laboratory testing (research) of samples of hemp plants for medical purposes;
- harvesting hemp for medical purposes;
- sorting hemp harvest for medical purposes;
- bringing the harvest of hemp for medical purposes to the state of plant raw materials of hemp for medical purposes;
- production of a cannabis plant substance, narcotic drugs, psychotropic substance or processing product from hemp plant material for medical purposes or a processing product;
- labelling units of packaged cannabis plant substance with unique electronic identifiers, etc.

The rules for registering transactions in the Register also set out parameters and requirements for registration of each individual transaction.

For instance, in order to register transactions of labelling hemp plants for medical purposes with unique electronic identifiers, the following must be entered into the Register:

- the transaction date;
- the number of labelled hemp plants for medical purposes;
- numbers of unique electronic identifiers assigned to the plants;
- the planting date for each hemp plant, if they have already been planted;
- the type or name (if any), number, and address of the premises where each plant is growing, if they have already been planted;
- the variety and generation of the hemp plants;
- the plant's origin (from seeds, from imported/acquired planting material or by cloning);
- the number of the batch of planting material from which the plants were grown;
- the amount of planting material that has gone to waste (if any), if the planting material originated from planting seeds.

Following the registration of such a transaction, the register shall contain the corresponding number of hemp plants for medical purposes.

There is also a specific requirement for this operation: marking several hemp plants for medical purposes with unique electronic identifiers during one operation is allowed only if all plants are of the same variety and generation and originated from the same batch of planting material.