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## **LAW no. 113 OF 23 June 2021**

### **PROVISIONS ON THE CULTIVATION, PROCESSING, TRADE AND USE OF CANNABIS PRODUCTS INTENDED EXCLUSIVELY FOR MEDICINAL OR THERAPEUTIC USE**

As amended by:

- Delegated Decree no. 28 of 23 February 2023 - Amendments to Law no. 113 of 23 June 2021 - Provisions on the cultivation, processing, trade and use of cannabis products intended exclusively for medicinal or therapeutic use

#### **CHAPTER I GENERAL PRINCIPLES**

##### **Art. 1**

*(General characteristics)*

1. The cultivation of cannabis seeds and plants in technological greenhouses, as well as processing for the production of medicinal products, pharmaceutical grade raw materials or pharmaceutical products of plant origin based on cannabis, herbal substances and preparations, intended exclusively for medicinal or therapeutic use, as well as trade of such medicinal products and pharmaceutical grade raw materials shall be permitted on San Marino territory.
2. For the purposes of this Law, cannabis shall be defined as the Cannabis Sativa L. plant or parts thereof including seeds, flowers and inflorescences, resin, separated, raw or purified resin obtained from all parts of the plant.

##### **Art. 2**

*(Role of the Health Authority)*

1. Pursuant to Articles 23 and 28 of the Single Convention on Narcotic Drugs adopted in New York on 30 March 1961, as amended by the Geneva Protocol of 25 March 1972, to which the Republic of San Marino became a party by means of Decree no. 89 of 18 September 2000, the Authority for the Authorisation, Accreditation and Quality of Health, Socio-Health and Socio-Educational Services referred to in Law no. 69 of 25 May 2004, hereinafter referred to as the Health Authority, shall perform the function of San Marino Cannabis Control Agency (ASCC).
2. More specifically, the ASCC shall:
  - a) authorise applications for the cultivation, processing and wholesale of cannabis, inflorescences, semi-finished goods, galenical preparations and medicinal products derived therefrom pursuant to the second paragraph of Article 1, subject to the granting of the authorisation by the Congress of State referred to in Article 3 paragraph 1;
  - b) authorise the import, export, wholesale distribution, stockholding of cannabis plants and plant material and stocks held by authorised manufacturers of medicinal products;
  - c) authorise manufacturing quotas of the active substance of plant origin based on cannabis and inform the International Narcotics Control Boards (INCB) of the United Nations thereof;

d) supervise and organise quality controls, in agreement with the Police Corps, to ensure that the activities of cultivation, processing and sale of cannabis, inflorescences, semi-finished products, galenic preparations, and medicinal products derived therefrom are carried out in compliance with all the conditions imposed and guarantees required in the authorisation and the provisions subsequently issued by the Health Authority.

3. To perform the functions assigned to it by this Law, the following persons shall be designated to support ASCC activity:

- a reference person of the Pharmacy Complex Organisational Unit;
- a reference person of the Environmental and Agricultural Resources Management Office;
- a reference person of the Gendarmerie.

4. The ASCC may, at its own discretion, rely on specific professionals and experts, also from outside the public administration.

5. The Health Authority shall report annually on its activities as ASCC to the Congress of State and the IVth Permanent Parliamentary Commission.

## **CHAPTER II AUTHORISATIONS**

### **Art. 3 (Authorisations)**

1. Entities or businesses wishing to cultivate, process, wholesale cannabis or medicinal products derived therefrom shall obtain authorisation for their establishment or, in the case of sole proprietorships, for their start-up, from the Congress of State. The authorisation shall be granted following an opinion issued by the ASCC and the submission of a specific business plan. The authorisation shall also be required when the entities and companies change their corporate purpose or the subject of their licence in the case of sole proprietorships, for the purpose of issuing or changing the licence in relation to the activities referred to in this Law.

1 bis. Members, owners and legal representatives of entities and businesses referred to in this Law shall be subject to the provisions governing unfit persons referred to in Article 1 of Law no. 47 of 23 February 2006 and subsequent amendments. For the purposes of this Law, the definition of unfit person pursuant to Article 1 of the aforementioned Law shall also apply, in addition to the cases provided for therein, to any person who has received convictions, even if not final, or is subject to ongoing criminal proceedings for trafficking of narcotic drugs.

2. After obtaining the authorisation from the Congress of State, the request for authorisation to perform such activities shall be forwarded to the ASCC, which, within thirty days, shall finalise the preliminary activities. After verifying the fulfilment of all the necessary requirements, the ASCC shall forward the request to the Congress of State to obtain the acknowledgement. After receiving the acknowledgement, the ASCC shall issue the authorisation requested.

3. For the purposes of obtaining authorisation for the cultivation and processing of and trade in cannabis, semi-finished products, inflorescences and derived medicinal products, a delegated decree shall regulate the following:

- a) ATECO codes that shall already be included in the corporate purpose of the entity or company, the structural, technological and organisational characteristics required, the guarantees and requirements that the applicant entities or companies shall comply with in the performance of the activity, the modalities for submitting the application and other elements useful for the preliminary activities referred to in paragraph 2;
- b) the particular requirements for the owner or legal representative of the entity or company, of the technical director, of the person responsible for keeping the registers, as well as of the employees, aimed at verifying the fulfilment of the professional and reputation requirements.

4. In their application for authorisation to perform such activities, the entities and companies concerned shall indicate the title or office of the person responsible for keeping the registers and complying with the other obligations imposed by the provisions of this Law.

5. The applicant entities or companies shall also submit a "security plan". The plan shall indicate the security systems and facilities, as well as the adequacy of the resources and means of the private security services appointed by the entity or company. The plan shall be authorised by the Command of the Gendarmerie in order to protect the cultivation, processing and storage facilities from unauthorised takings and other types of violations.

6. In authorising the performance of the activity referred to in paragraph 1, the ASCC, subject to the positive opinion of the Congress of State, may establish specific conditions and guarantees for the protection of health and public order.

7. The Congress of State, upon indication of the ASCC, shall also authorise, by means of a decision, the maximum annual quantity of cannabis intended for the production of medicines or pharmaceutical grade raw materials and the corresponding quantities for cultivation intended for individual authorised entities and companies.

#### **Art. 4**

##### *(Revocations/Suspensions)*

1. The ASCC, with the prior authorisation of the Congress of State, may revoke the authorisation referred to in Article 3, paragraph 1:

a) in the event of verified irregularities during the cultivation, harvesting, production, processing, synthesis, use, storage, trade of cannabis, semi-finished products or medicinal products derived therefrom;

b) in the event that the requirements defined in the delegated decree referred to in Article 3 paragraph 3 are wholly or partially not met;

c) in the event of a technical incident, theft, deterioration of substances derived from cannabis;

d) in the event of theft, only if the judicial authority establishes gross negligence or liability of the entity or company.

2. The Congress of State may revoke the licence in the event of serious and/or repeated violations of the provisions issued by the ASCC, as well as for the causes provided for in Article 29 paragraph 2 of Law no. 40 of 31 March 2014.

3. Reasons shall be given for the revocation measure and the persons concerned shall be promptly notified thereof through the Command of the Gendarmerie.

4. In the case referred to in Article 19 paragraph 2, a temporary suspension of the licence shall be applied until the ASCC has carried out its investigations.

5. If the ASCC and the authorised entity reconstitute the content of the registers as a result of the investigations, the suspension shall be lifted; otherwise the suspension shall be turned into the revocation of the licence.

6. Following a report by San Marino or foreign judicial authorities, pending the conclusion of the investigations referred to in paragraph 1 letter a), the ASCC shall, as a precautionary measure, suspend any authorised commercial activity of the reported entity or company pursuant to this Law. In this case, the ASCC shall appoint a Special Administrator to manage ordinary activities to ensure business continuity.

#### **Art. 5**

##### *(Acquired or confiscated substances)*

1. Cannabis plants and seeds, or substances derived therefrom, stored after revocation of the authorisation or otherwise confiscated, shall be acquired by the State, which may order their use or destruction.

2. In the case of different use or destruction of seized substances, the ASCC shall oversee the procedure, assisted by the Gendarmerie and the competent health and territorial offices, according to a guarantee and security protocol established by the ASCC.

3. The costs of disposal or destruction of the confiscated substances shall be borne by the entity or company.

**Art. 6**  
*(Supervision)*

1. The ASCC, in cooperation with the Police Corps, shall carry out periodic controls of entities or companies authorised to cultivate, process or trade cannabis or medicinal products derived therefrom, in order to verify compliance with the conditions established, the provisions laid down for the performance of the activities, and the existence of the guarantees underlying the authorisation decision.

2. The ASCC shall issue provisions to authorised entities and companies so that activities are managed by establishing and maintaining an adequate quality and security system, with reference to GACP (Good Agricultural Cultivation Practice), GMP (Good Manufacturing Practice) and the international standards governing ISO (International Standardisation Organisation) quality management systems. The cultivation and production of the active substance shall be regulated by the ASCC in compliance with the Active Substance Master File. For clinical and healthcare activities, reference shall be made to GCP (Good Clinical Practice) and the guidelines of International Health Organisations and Scientific Societies.

3. Any serious incident, whether due to accident or error, related to the production, harvesting, control, processing, storage, distribution and allocation of each product, likely to jeopardise ordinary activities, shall be reported to the Police Corps and to the ASCC by the entity or company.

4. Entities or companies authorised to cultivate, process or wholesale cannabis, semi-finished products, inflorescences or medicinal products derived therefrom shall, upon request, promptly transmit the requested data, information and documents to the ASCC.

5. Authorised entities or companies shall inform in advance the ASCC and the Operations Centre of the Police Corps, by means of a notice, including telematic, of any movement of cannabis materials into or out of the plant by giving adequate prior notice to allow them to inspect it when they deem it appropriate.

**Art. 7**  
*(Surplus production)*

1. Any surplus production not exceeding 10 percent of the permitted quantities shall be allowed as long as it is reported to the ASCC within 15 days of its verification.

2. Surplus production shall be counted in the quantities to be produced in the following year.

**Art. 8**  
(Annual estimates of Cannabis for cultivation purposes)

1. On an annual basis, the ASCC, in compliance with relevant International Conventions and the bodies deriving therefrom, shall send the annual estimate of the need for cannabis to the UN International Narcotics Control Board (INCB) for the following year.

**CHAPTER III**  
**TRADE AND USE**

**Art. 9**  
*(Retail sale)*

1. The retail sale of medicinal or pharmaceutical products of plant origin based on cannabis shall be permitted only in State pharmacies and upon presentation of a doctor's prescription, as provided for in a special regulation drawn up by the Social Security Institute.

2. The Pharmaceutical Service and pharmacies of the SSI shall not need any further authorisation for the trade of medicinal products based on cannabis.

**Art. 10**  
*(Wholesale)*

1. The wholesale within the Republic of San Marino of cannabis, semi-finished products, inflorescences or medicinal products derived therefrom shall only be allowed between authorised entities and companies, or by authorised entities and companies to the State Pharmaceutical Service.

2. Without prejudice to compliance with the general rules governing trade and the distribution network, as referred to in Law no. 130 of 26 July 2010, any wholesale or transfer for any reason of cannabis, semi-finished products, inflorescences or medicinal products derived therefrom shall be submitted to the ASCC for prior authorisation and the Police Corps shall be notified in accordance with the provisions of Article 6, paragraph 5.

3. The products referred to in paragraph 1 shall be delivered in the following manner:

a) to the headquarters of the entity or company, or to the State Pharmaceutical Service;

b) personally to the holder of the authorisation to trade, after verification of his/her identity, or to a duly authorised employee of the entity or company.

**Art. 11**  
*(Use of cannabis products for therapeutic use)*

1. The use of cannabis products for therapeutic use shall only be permitted upon presentation of a doctor's prescription, also electronically, issued by an authorised doctor or veterinarian.

2. The SSI Health Directorate, in agreement with the Health Authority, shall provide for special guidelines or protocols for doctors concerning the verification of diseases to be treated, the therapies to be adopted, and the modes of administration of the cannabis-based medicinal product. 3. The therapeutic use of medicinal cannabis preparations, duly prescribed according to the treatment needs of the person's particular pathological conditions, shall be permitted.

4. Any serious undesirable reaction observed during or after the administration of cannabis-derived products for therapeutic use shall be reported to the ASCC in accordance with the regulations on clinical risk related to these events (near misses), adverse events and sentinel events.

**CHAPTER IV**  
**IMPORT, EXPORT AND TRANSIT**

**Art. 12**  
*(General provisions)*

1. The import, export and transit of cannabis, semi-finished products, inflorescences or medicinal products derived therefrom shall only be carried out by the pharmaceutical service, entities and companies authorised to cultivate plants, produce, process, use and trade these goods.

2. Without prejudice to compliance with the general rules on import and export, from and to the Republic of San Marino, from and to EU and non-EU Countries, both with regard to the documents accompanying the goods and to the fulfilment of tax and customs obligations, each import, export and transit operation of cannabis, semi-finished products, inflorescences or medicinal products derived therefrom shall be authorised in advance by the ASCC, pursuant to Article 2, paragraph 2, letter b) of this Law.

3. The import or export of cannabis, semi-finished products, inflorescences or medicinal products derived therefrom via the ordinary public postal service shall be prohibited.

4. During transit, it shall be prohibited to tamper with or in any way alter packages containing cannabis, inflorescences, semi-finished products or medicinal products derived therefrom, except for customs or police operations by qualified and authorised personnel.

**Art. 13**  
*(Import)*

1. In addition to the fulfilment of tax, customs and documentation obligations for the import of goods, the entity or company authorised to cultivate, process or trade cannabis or medicinal products derived therefrom, interested in importing seeds, plants, semi-finished products, inflorescences or cannabis-based medicinal products, shall submit an application for import authorisation to the ASCC, in accordance with the procedures indicated by the ASCC through a specific regulation, drawn up by the ASCC.
2. Once the ASCC has issued the import permit in accordance with international conventions, it shall promptly notify the Command of the Fortress Guard- Uniformed Unit and the Tax Office thereof, for the relevant controls.
3. The ASCC's authorisation decision shall indicate, on the basis of the application received, the exact weight, quality and quantity of the goods and the reasonable time frame for delivery.
4. Upon arrival of the goods at their destination, the importer shall request to the Uniformed Unit of the Fortress Guard a certification relate to the transport documents, which shall be issued after verifying the compliance of the documents, the intactness of the package and the seals of the goods.
5. The Civil Police, upon indication by the ASCC or on its own initiative, may order the taking of samples of the imported goods. This operation shall be carried out in the presence of the importer or legal representative thereof, who shall sign the report of the operations. Every sample shall be promptly transmitted to the ASCC, which shall arrange for the appropriate investigations.

**Art. 14**  
*(Export)*

1. In addition to the fulfilment of tax, customs and documentation obligations for the export of goods and the recording referred to in Article 18, the entity or company authorised to cultivate, process or trade cannabis or medicinal products derived therefrom, interested in exporting seeds, plants, semi-finished products, inflorescences or cannabis-based medicinal products, shall submit an application for authorisation to the ASCC, in accordance with the procedures indicated by the ASCC through the specific regulation referred to in Article 13, paragraph 1.
2. Once the export permit has been issued, the ASCC shall give prior notice to the San Marino Command of the Gendarmerie and to the Department of Foreign Affairs for notification to the competent authorities of the country of destination, through diplomatic channels.
3. The export permit of the ASCC, numbered consecutively, shall indicate the exact weight, quality and quantity of the goods exported, as well as the details of the authorisation by the authority of the country of destination.

**Art. 15**  
*(Transit)*

1. Authorisation for the transit of seeds, plants, inflorescences, semi-finished products or cannabis-based medicinal products shall be granted by the ASCC, subject to the submission of an application by the entity or company that produced the goods, or by the carrier, in accordance with the procedures set out in the regulation of the ASCC referred to in Article 13, paragraph 1.
2. The application shall in all cases be accompanied by the import permit issued by the competent authorities of the country of destination and the export permit issued by the competent authorities of the country of origin.
3. The ASCC's authorisation decision shall be promptly forwarded to the Operations Centre of the Police Corps.

**CHAPTER V**  
**DOCUMENTATION AND STORAGE**

**Art. 16**  
*(Entry and exit register)*

1. The entity or company authorised to cultivate, process or trade cannabis or medicinal products derived therefrom shall keep a register, without any omissions, abrasions or additions, in chronological order, according to a unique numerical progression for each substance or medicinal product. Such register shall record the movement into or out of the plant of seeds, plants, semi-finished products, inflorescences or cannabis-based medicinal products.
2. This register shall be numbered and signed on each page by the Director of the Health Authority or his/her delegate, shall indicate on the first page the details of the authorisation and on the last page the number of pages of the register. The register shall be kept by the authorised entities and companies for a period of five years from the day of the last registration.

**Art. 17**  
*(Register of the cultivation of cannabis seeds and plants)*

1. Entities or companies authorised to cultivate cannabis seeds, inflorescences and plants, in accordance with this Law, shall be obliged to record each incoming and outgoing operation or processing operation in the register referred to in Article 18.
2. The records of outgoing or processing operations shall also show the number of the operation under which the substance was registered as incoming.
3. The substance obtained from processing, even through synthesis, shall be recorded as incoming with indications that allow the connection with the data contained in the processing register.
4. Quantitative variations in the stocks of each substance shall be registered, in the appropriate column of the substance, under the registration relating to the operation by which they were determined.

**Art. 18**  
*(Register of the use and trade of cannabis products or medicinal products)*

1. Entities or companies authorised to use and trade cannabis products or medicinal products shall close the register referred to in this Article on 31 December of each year. They shall do so by recording in summary all data showing the total of the qualities and quantities of the products handled and the quantities and qualities of the products used or traded during the year, with an indication of any difference or surplus.
2. For the processing of cannabis products, a processing register shall also be kept, numbered and signed on each page by the Director of the Health Authority or an official delegated by him/her. It shall indicate the quantities of raw materials processed, their exact name and date of entry into the processing department, as well as the products obtained from each processing. This register shall be kept for five years from the date of the last registration.
3. The Health Directorate of the Social Security Institute may establish supplementary procedures for the registration and management of cannabis medicinal products by State pharmacies, or for regulating their sale.

**Art. 19**  
*(Data transmission)*

1. Entities and companies authorised to cultivate, process or trade cannabis or medicinal products derived therefrom shall transmit to the ASCC, no later than 31 January of each year, the summary data for the previous year, namely:
  - a) the final results of the loading and discharge register;
  - b) the quantity and quality of substances used in the production of medicinal products and/or preparations for therapeutic use during the year;
  - c) the quantity and quality of medicinal products sold during the year;
  - d) the quantity and quality of stocks as of 31 December.
2. In the event of loss, disappearance or theft of the registers, of parts of them or of their supporting documents, the persons concerned shall, within twenty-four hours of their discovery, report this in writing to the Gendarmerie and notify the ASCC thereof.

**CHAPTER VI**  
**FINAL PROVISIONS**

**Art. 20**  
*(Provisions of the ASCC)*

1. The ASCC shall keep all application forms, provisions, guidelines, operational procedures, reporting forms required by this Law at its headquarters. These shall be made available to interested entities or companies and to the public.

**Art. 21**  
*(Decriminalisation - Repeal)*

1. All the provisions on punishability contained in the Criminal Code and in Law no. 139 of 26 November 1997, and subsequent amendments, concerning narcotic substances shall remain unaffected, without prejudice to the cases of production, use, processing and trade of cannabis in accordance with this Law and of medical prescription issued or recognised as effective by the Social Security Institute, as provided for in Article 1, paragraph 2 of Law no. 139/1997, and subsequent amendments.

**Art. 22**  
*(Tax provisions)*

1. A subsequent delegated decree shall establish the 'cannabis cultivation' tax to be paid by subjects authorised to cultivate cannabis.
2. The Congress of State shall be delegated to introduce by means of a delegated decree any other taxes connected with the processing or any other tax provisions.

**Art. 23**  
*(Sanctions)*

1. Anyone who, without the mandatory authorisation, carries out activities of cultivation, processing or trade of cannabis, semi-finished products, inflorescences or medicinal products derived therefrom shall be subject to the criminal and administrative sanctions laid down for the performance of the same activities with regard to narcotic substances.
2. Failure to comply with the provisions and guarantees set forth in the authorisation, unless the act constitutes a criminal offence, shall give rise to an administrative sanction ranging from euro 15,000.00



(fifteen thousand/00) to euro 60,000.00 (sixty thousand/00), imposed by the Police Corps also upon indication/report by the ASCC.

3. Failure to comply, in whole or in part, with the lawful provisions of the ASCC, unless the act constitutes a criminal offence, shall entail the application of an administrative pecuniary sanction, imposed by the Police Corps also upon indication/report by the ASCC, from euro 5,000.00 (five thousand/00) to euro 30,000.00 (thirty thousand/00). In the most serious and repeated cases, it may constitute grounds for requesting the Congress of State to revoke the licence.

4. Illegally or unlawfully possessed cannabis seeds and plants, inflorescences, semi-finished products or cannabis-based medicinal products shall be seized and confiscated by the Gendarmerie, according to a guarantee and security protocol established by the ASCC.

5. With the exception of the cases referred to in paragraphs 1 and 2 of Article 7 of this Law, anyone who, through negligence or wilful intent, produces cannabis substances in quantities exceeding those permitted or tolerated shall be punished by imprisonment of up to one year or a fine of up to EUR 15,000.00 (fifteen thousand/00).

6. Unless the act constitutes a more serious criminal offence, anyone who fails to comply with the rules on the keeping of entry and exit, loading and discharge, and processing registers, as well as with the data transmission and reporting obligation referred to in this Chapter, shall be punished with imprisonment of up to two years or with a fine ranging from Euro 1,500.00 (one thousand five hundred/00) to Euro 25,000.00 (twenty-five thousand/00).

#### **Art. 24**

*(Entry into force)*

1. This Law shall enter into force on the fifteenth day following that of its legal publication.

*Done at Our Residence, on 23 June 2021/1720 since the Foundation of the Republic.*