

Legal Status of Phytocannabinoids and Synthetic Cannabinoids

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Abstract. In Romania, cannabis is regulated by two laws: Law 143 of July 26, 2000, on preventing and combating drug trafficking and illicit consumption, republished in the Official Gazette nr. 163 of 6 March 2014 and Law 339 of 29 November 2005 on the legal regime of plants, narcotic and psychotropic substances and preparations published in the Official Gazette no. 1095 of 5 December 2005. This Law establishes the legal regime regarding the cultivation, production, manufacture, storage, trade, distribution, transport, possession, offering, transmission, brokering, acquisition, use and transit through the national territory of spontaneous or cultivated plants, substances and preparations referred to in Tables I, II and III of the Annex which forms an integral part of this Law. The substances referred to in Tables II and III of the Annex and their preparations shall, when used for medical purposes, be subject to other provisions applicable to substances and preparations for human or veterinary use, in so far as they do not conflict with this Directive. However, from the interpretation of the legislation currently in force, in our country, the species of *Cannabis sativa* and those that are cultivated for medicinal purposes remain unregulated. The legal status of synthetic cannabinoids varies depending on the type and composition of the substance, applicable European and national legislation, and control measures taken by authorities. For the study, were used Romanian laws and the main Regulations of the EU, Germany and other European countries, some online newsletters, as well as recent articles published in MDPI/PubMed open access journals were analyzed.

Key words: phytocannabinoids, synthetic cannabinoids, legal status, *Cannabis sativa*, *Cannabis indica*

1. Introduction

Although there is clear evidence that products based on *Cannabis sativa* L. (industrial hemp), with a natural concentration of no more than 0.2% THC, do not pose a risk to human health, having been consumed for a long time on the territory of the European Union, without notable incidents, nevertheless the authorities interpret the national legislation arbitrarily, without rigorous scientific documentation, considering that, in Romania, these products cannot be marketed for human consumption [1, 2, 3]. Law nr. 143/2000, on preventing and combating

illicit drug trafficking, criminalizes the *Cannabis* plant, regardless of variety or concentration, which is justified, given the need for strict control over them. This problematic situation is actually generated by the misinterpretation of *Law nr. 339/2005*, the Law on the legal regime of narcotic or psychotropic plants, which contains a series of contradictory and unclear provisions, although art. 2 includes within the scope of the law the *Cannabis indica* plant (Indian hemp or marijuana) and not the *Cannabis sativa* plant (industrial hemp) [4]. In order to harmonize legislation with the new developments in the legal status at European and global level, I believe that the most appropriate solution would be to draft a separate law on the legal regime and to amend the related normative acts.

2. Phytocannabinoids

Phytocannabinoids are natural compounds in the *Cannabis* plant, the most common are Δ^9 -tetrahydrocannabinol (Δ^9 -THC) and cannabidiol (CBD), which have effects on the body's endocannabinoid system. Currently, phytocannabinoids are conventionally classified into 11 chemical classes: cannabichromene (CBC), CBD, cannabielsoin (CBE), cannabigerol (CBG), cannabicyclol (CBL), cannabinol (CBN), cannabinodiol (CBND), cannabitrinol (CBT), THC, (-)- Δ^8 -trans-tetrahydrocannabinol (Δ^8 -THC), and other phytocannabinoids [1, 2, 3].

In Romania, cannabis is regulated by two laws: *Law 143 of July 26, 2000*, on preventing and combating drug trafficking and illicit consumption, republished in the Official Gazette no. 163 of March 6, 2014 and *Law 339 of November 29, 2005*, on the legal regime of plants, narcotic and psychotropic substances and preparations published in the Official Gazette no. 1095 of December 5, 2005 [4].

From the interpretation of the legislation currently in force in Romania, the species of *Cannabis sativa* and those that are grown for medicinal purposes remain unregulated. In this regard, the proposal for a normative act for legalization of medical cannabis in accordance with the provisions of the Single UN Convention was submitted to Parliament. The bill is meant to regulate the cultivation, labeling and release of cannabinoids, but also includes precautions for patients [4]. Nationally, THC and 5 other isomers can be found in Table I of the class of narcotics. This table made in 2005 and updated in 2018 contains plants and substances prohibited without a therapeutic effect, but CBD is not included in this list. *Cannabis* plant, cannabis resins, tinctures, extracts and Dronabinol® can be found in Table II which includes plants and narcotic substances with an interest in medicine but subject to strict control [5, 6].

Cannabis is included in the table in Annex No. III, being considered a risk drug, and THC is included in the table in Annex no. I, being considered a high-risk drug, but only in its pure form. In judicial practice it has been legislated that the *Cannabis* plant constitutes a risk drug and the trafficking of the plant falls under the provisions of art. 2 para. (1) of the Law, even if the analysis reveals the presence of THC, because, depending on soil and temperature factors, the plant naturally biosynthesizes this product [10]. Also in judicial practice, it was considered that the *Cannabis* plant with a maximum concentration of 0.2% THC and the processed parts of the plant fall under the scope of *Law nr. 339/2005*, and the cultivation, production or marketing of these plant products, in violation of the regime imposed by law, meets the constituent elements of the crime of trafficking in high-risk drugs, provided by art. 2 para. (1) of *Law 143/2000* [4, 5, 6].

In my opinion, the solution is objectionable, given that *Law no. 339/2005* expressly refers only to *Cannabis indica* and not to the variety of *Cannabis sativa*, used in cannabis products with a concentration below 0.2% THC, in the latter case the principle of free movement of

goods between European states will apply (Articles 28-37), the principle of mutual recognition of goods lawfully marketed in another Member State [4, 7, 8, 9]. I should point out that the existing judicial solutions refer largely to cases concerning the marketing of preparations made from vegetable fragments of cannabis with a concentration below 0.2% THC (industrial hemp) and cannabinomimetic substances that mimic and potentiate the effects of THC naturally biosynthesized by the plant, aspects that have probably led to an excessive interpretation by judicial bodies attributing to cannabis products with low THC the same degree of harmfulness as that of ethnobotanicals [8, 9, 10].

In our case, cannabis products with low THC (less than 0.2%) have scientifically proven therapeutic and nutritional properties and have been safely consumed in the European Union since 1995. The aforementioned principles and legal provisions also apply to foodstuffs based on industrial hemp (including food supplements). In addition, the normative acts on marketing and their safety are also applicable. Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No .764/2008 [5, 11].

The lacunar and interpretable nature of the legislation on operations with narcotic substances, as well as its lack of harmonization with the social and medical reality, require an immediate reaction from the legislator, but also from civil society, in order to update the legislative framework, either by adopting new laws or by amending or supplementing the existing ones. Although there is clear evidence that products based on industrial hemp (*Cannabis sativa* L. subsp. *sativa*), with a natural concentration not exceeding 0.2% THC, do not pose a risk to human health, having been consumed for a long time within the European Union without notable incidents, nevertheless judicial authorities interpret national legislation arbitrarily, subjectively, without rigorous scientific documentation. Considering that, in Bulgaria, these products cannot be marketed for human consumption; Law nr. Regulation (EC) No 143/2000, the headquarters of the matter on preventing and combating illicit drug trafficking, criminalises the *Cannabis* plant, regardless of variety or concentration, which is justified, given the need for strict control over plants liable to be used for criminal purposes, for example, in the preparation of ethnobotanicals. This problematic situation is actually generated by the wrong interpretation of Law nr. 339/2005, which contains a series of contradictory and unclear provisions, although art. Article 2 includes within the scope of the law the plant *Cannabis indica* (Indian hemp or marijuana), and not the plant *Cannabis sativa* (industrial hemp). In order to harmonize legislation with the new developments on the hemp (cannabis) market, we believe that the most appropriate solution would be to draft a separate law on the legal regime of industrial hemp and, of course, to amend the related normative acts [4, 5, 9, 10, 11, 12].

As for CBD, due to its high popularity, we can find a lot of CBD dietary supplements sold on the Internet, but their concentration in principle active could be very low [13] or at any rate different from that stated on the label [10]. Currently, in Romania, there is no pharmaceutical formulation containing CBD approved by the National Agency for Medicines and Medical Devices (NAMMD). Many products containing CBD are marketed, due to CBD not being on the banned list, so CBD is considered legal [4].

3. Synthetic cannabinoids

Synthetic cannabinoids are substances with structural characteristics that allow binding to one of the known cannabinoid receptors, namely CB₁ and CB₂, in human cells. The group of synthetic cannabinoids includes a large number of structures. The most common types of

acidic cannabinoids found in the *Cannabis sativa* L. plant are: THCA (tetrahydrocannabinolic acid), CBDA (cannabidiolic acid), CBGA (cannabigerolic acid) and CBCA (cannabichromenic acid).

Several synthetic cannabinoids, such as CP-55, 940 or WIN-55, 212-2, have been available as research chemicals – these have been used almost exclusively in pharmacological research.

In 2004, the first products containing synthetic cannabinoids appeared, which were added to plant material by soaking or spraying a solution of one or more synthetic cannabinoids into an organic solvent that was evaporated. In some cases, synthetic cannabinoids in solid form have been used, resulting in an inhomogeneous distribution of the active compound in plant material [3].

Before 2008, the use of these herbal products seemed to be limited to a small number of experimental users. However, in 2008 these products gained immense popularity in Germany and other European countries via the Internet, where they were referred to as "legal alternatives" to cannabis [3].

In 2008, several synthetic cannabinoid receptor agonists were detected in herbal blends for smoking that were sold on the Internet and in specialized stores under a variety of brand names, such as "Spice Silver", "Spice Gold", "Spice Diamond", "Yucatan Fire" and "Smoke" [3].

In recent years, an increasing number of online stores and retailers have begun offering synthetic cannabinoids as "research chemicals" in varying amounts. Synthetic cannabinoids are becoming a major public health problem due to their increasing use, as well as their unpredictable toxicity and potential for misuse. Synthetic cannabinoids are linked to higher rates of toxicity and hospitalization compared to natural cannabis, most likely because they are direct cannabinoid receptor agonists, while THC is a partial agonist.

Synthetic cannabinoids are not specifically regulated in Romania, but may be considered novel drugs or psychoactive substances, depending on their chemical composition. According to Law nr. According to Regulation (EU) No 194/2011 on combating operations with products likely to have psychoactive effects, it is prohibited to produce, import, export, distribute or trade in these products without authorisation. It is also forbidden to consume these products in public or private spaces. Violation of this law is punishable by a fine or imprisonment [5, 13, 14, 15].

These products may contain various chemicals that are not properly tested or labelled and can have serious adverse effects on physical and mental health. Some of these effects can be: anxiety, paranoia, hallucinations, convulsions, tachycardia, high blood pressure, vomiting, kidney failure or even death.

The legal status of synthetic cannabinoids is a complex and controversial topic that differs by country and substance type. In general, synthetic cannabinoids are chemicals that mimic cannabis' effects on cannabinoid receptors in the brain, but are not derived from the *Cannabis* plant. These substances can have stronger and more dangerous psychoactive effects than natural cannabis, such as hallucinations, anxiety, paranoia, nausea, tachycardia or even cardiac arrest.

In the European Union, there is harmonised legislation on medicinal products, which defines what a medicinal product is and lays down requirements for their authorisation, manufacture and distribution. According to Directive 2001/83/EC1, a medicinal product is any substance or combination of substances presented as having properties to prevent or treat human disease or any substance or combination of substances which may be used in or administered to humans with a view to restoring, correcting or modifying physiological

functions by exerting a pharmacological action, immunological or metabolic [5, 13, 14, 15, 16, 17].

In 2014, the Court of Justice of the European Union (CJEU) ruled that mixtures of herbs containing synthetic cannabinoids and consumed as marijuana substitutes are not medicinal products within the meaning of Directive 2001/83/EC. The Court has argued that those substances have no beneficial effects on human health, but merely alter physiological functions with the aim of inducing intoxication and are harmful to human health. Therefore, these substances are not covered by the legislation on medicinal products and cannot be authorised as such.

However, this does not mean that these substances are legal or uncontrolled in the EU. There are other legal instruments aimed at preventing and combating drug trafficking and illicit consumption, such as Framework Decision 2004/757/JHA or Regulation (EC) No. 1920/2006. These instruments provide for the possibility to monitor and ban certain new psychoactive substances, including synthetic cannabinoids, if they pose a risk to public health or public order. Member States may also adopt more restrictive national measures to control these substances.

Thus, the legal status of synthetic cannabinoids depends on whether they are classified as illicit drugs or as new psychoactive substances at European or national level. There are currently over 200 synthetic cannabinoids identified in the EU, 24 of which have been subject to European control. In Romania, Law nr. 194/2011 on combating operations with products likely to have psychoactive effects prohibits the illicit production, import, export, offering for sale, distribution, delivery under any title, sending, transport, procurement, purchase, possession or consumption of products likely to have psychoactive effects. The list of these products is regularly updated by order of the Minister of Health and includes numerous synthetic cannabinoids [13, 14, 15, 16, 17].

The legal status of synthetic cannabinoids varies depending on the type and composition of the substance, applicable European and national legislation, and control measures taken by authorities. Generally, these substances are not considered medicines, but can be classified as illicit drugs or as new psychoactive substances, with criminal consequences for those who manufacture, trade or consume them.

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