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# Cannabis use: CEE regulatory update

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Significant changes in the regulation of cannabis use have occurred in some countries in Central and Eastern Europe since our last report.

In addition to a number of countries gradually legalising the use of cannabis for medical purposes, increasing efforts by some countries are being seen to also legalise the use of cannabis for recreational use, as well as the use of other products containing various cannabinoids, most importantly cannabidiol (CBD).

Below, we present a summary of recent changes related to the national regulation of this rapidly growing sector across Central and Eastern Europe.



## Czech Republic

### Cannabis for medical use

The use of cannabis for medical treatment has been permitted in the Czech Republic since April 2013. Although it is still strictly regulated, the rules are becoming more relaxed and cannabis for medical use is now more accessible.

Certain restrictions apply on the prescription of cannabis for medical use: (i) the strains of cannabis that can be prescribed, i.e. *Cannabis indica* and *Cannabis sativa L.*; (ii) the types of medical problems it can be used for (mainly as a supportive treatment to relieve symptoms associated with serious illnesses); (iii) the amount that can be prescribed (180 grams of dried cannabis for medical use per person per month); and (iv) the areas of expertise required from physicians authorised to prescribe medical cannabis. According to publicly available information, prescriptions of medicinal products containing cannabis increased by 50% in 2022 compared to the previous year.

Growing medical cannabis is only permissible on the basis of a licence granted by the State Institute for Drug Control. The licence may be granted to any applicant that fulfils the statutory requirements (unlike previously where only one operator could be granted a licence for growing cannabis). Medical cannabis may also be imported and is subject to strict import control rules similar to the other addictive substances.

Currently, 90 percent of the cost of an individually prepared medicinal product containing medical cannabis in a quantity not exceeding 30 grams per month is covered by public health insurance.

### Recreational use of cannabis

The recreational use of cannabis is not yet legal, although it is widely tolerated in the country unless used excessively. At the moment, an expert group appointed by the Czech government is working on a draft law that should legalize recreational use of cannabis. However, very different views are still found amongst experts and politicians on how the regulation should look – so we expect a very long discussion and it is not yet clear whether, and if so when, the new regulation will enter into force.

### Other products containing cannabinoids

In the Czech Republic, the current statutory limit of THC content for industrial hemp is 1%, which is far above the typical limit set by many other countries. Hemp may be freely marketed and used in the Czech Republic without any permission or licence. The only obligation is to notify the competent customs authority of the cultivation of hemp over an area of more than 100 sq m.

In recent years, the popularity of some other products containing cannabinoids, in particular CBD, has grown significantly. Various products containing CBD are widely available in the Czech Republic, such as cosmetics, oil and tinctures.

In July 2023, an amendment to the Addictive Substances Act was submitted to the Czech parliament, which would subject so-called psychomodulants (including many cannabinoids, such as HHC) to stricter supervision, but the fate of this proposal is presently uncertain.



## Bulgaria

### Cannabis for medical use

Cannabis is classified in Bulgaria as a plant constituting a high risk to public health due to the harmful effect of its abuse, and it is prohibited for use in human and veterinary medicine.

More specifically, the Act on Narcotic Substances and Their Precursors also bans the cultivation, production, processing, trade, storage, import, export, re-export, transit, transfer, transport, supply, acquisition, use and possession of cannabis. However, this is subject to two notable exceptions, namely when:

(i) the cultivation of cannabis is intended for fibre, seeds for animal feed and sowing, provided the plants contain less than 0.2 per cent of THC; or

(ii) limited quantities of cannabis are used for medical, scientific or laboratory research, for educational purposes, as well as for maintaining the ability of dogs uncovering narcotic substances.

The activities under (i) and (ii) above are subject to separate licences, which are issued by the Minister of Agriculture and the Minister of Health, respectively. The maximum cannabis quantity allowed for the medical purposes as per item (ii) is 30,000 grams. The plants grown must be of varieties entered in the Official Variety List of the Republic of Bulgaria and/or in the Common Catalogue of Varieties of Agricultural Plant Species of the European Union, or of varieties for which authorisation has been granted by the Minister of Agriculture.

A draft amendment to the Act on Narcotic Substances and Their Precursors is currently being considered by the National Assembly of the Republic of Bulgaria. The amendment introduces new rules regarding cannabis and its production, specifically enabling the cultivation of cannabis intended for the production of non-psychoactive products with a weight percentage less than 1%. Interest in industrial cannabis is increasing and the amendments, if passed by the National Assembly, will represent a further step forward for the legalised usage of the cannabis.

### **Recreational use of cannabis**

The use of cannabis for recreational purposes is not permitted. A person found to be acquiring or possessing cannabis is subject to imprisonment of up to five years or a fine ranging from BGN 1,000 to 5,000 (this applies to smaller quantities).

### **Other products containing cannabinoids**

Currently in Bulgaria the production of medicinal products and other products containing CBD is not explicitly permitted. However, as there is no explicit prohibition on the import and export of products containing CBD, such as cosmetics, essential oils, food supplements, etc., products containing CBD can be legally traded in and from Bulgaria.



## **Croatia**

### **Cannabis for medical use**

Cannabis has been used for medical purposes in Croatia since 2015, but is strictly limited. Medicinal products containing THC can be prescribed only by general physicians or specialists (e.g., neurologists) for certain illnesses (multiple sclerosis, cancer, epilepsy and AIDS). Medicinal products containing THC may be administered as a supportive treatment on the basis of a single prescription. The cost for this kind of therapy is not covered by the Croatian health insurance fund, so the use of medical cannabis can be quite expensive for patients. Moreover, in the case of magistral/galenic preparations physicians must prescribe, among other things, exact amounts of THC for a single dose, and the amount can be prescribed for a maximum of 30 days. The total amount of THC prescribed for 30 days of treatment must not exceed 7.5 g.

The production and cultivation of cannabis for medical use is permitted. Cultivation requires an additional approval of the Ministry of Health, provided that the manufacturer has already obtained a license for the production of medicines and active substances from the Agency for Medicinal Products and Medical Devices (HALMED) in accordance with the Medicinal Products Act.

### **Recreational use of cannabis**

In Croatia, cannabis is not authorised for recreational purposes.

The draft Act on Exploiting the Full Potential of Hemp from 2022 aimed to regulate the production and use of hemp in more detail and to legalise its use for personal needs, as many countries have started to legalise or liberalise usage of this substance. The draft Act provided for the cultivation and consumption of hemp for personal use; each adult would be allowed to grow up to nine plants in flower and to grow chemotype 3 varieties (CBD chemotype: THC < 0.3%; CBD > 0.5%). However, the draft Act was not adopted by the members of the Croatian parliament and no new initiatives to stimulate the discussion on this topic have occurred since.

## Other products containing cannabinoids

Both food and cosmetic products containing industrial hemp are becoming increasingly popular due to their high nutritional value and medical benefits (e.g. hemp seeds, oil, tinctures). In Croatia, the maximum limit for the total THC content of industrial hemp is 0.2%.

Legal entities and natural persons may only cultivate industrial hemp if they are registered in the Register of Industrial Hemp Manufacturers at the Ministry of Agriculture. Furthermore, the applicable legislation does not differentiate between the different parts of the plant. Accordingly, the legal regulation and status of hemp is the same for all parts of the plant. Also, the relevant processing and extraction licences depend on the final product; the requirements differ depending on the final product, e.g. food or other products.



## Hungary

### Cannabis for medical use

No regulatory regime enables the use of cannabis for medical purposes in Hungary. It is possible for doctors to prescribe already registered pharmaceutical products containing CBD as an active ingredient under certain circumstances. However, in practice this occurs very rarely, as obtaining pharmaceutical products containing CBD typically requires individual import from foreign countries.

### Recreational use of cannabis

The use of cannabis for recreational purposes is not permitted and is currently criminalized.

### Other products containing cannabinoids

Hungary only permits the processing of industrial hemp for CBD oil subject to notification and license requirements.

No detailed Hungarian legal framework is in place that is applicable to the use of CBD. The Hungarian Pharma Authority published a standpoint concerning products containing hemp and hemp derivatives (e.g. CBD) falling under its competence (the “**Standpoint**”).

According to this Standpoint, in relation to food supplements distinction must be made between “pure hemp seed oils” (which do not contain added CBD) and CBD oils (which do contain added CBD). Foods containing “pure hemp seed oils” or CBD oils (which contain added CBD) are considered novel foods that are not currently authorised, regardless of their THC content. Non-authorised novel foods cannot be legally marketed in Hungary.

Food supplements containing only “pure hemp seed oils” may be permitted, provided that their CBD content does not exceed the threshold of 25 mg/kg.

According to the Standpoint, “pure hemp seed oils” can be used in cosmetics up to certain thresholds; however CBD oils cannot be used.



## Romania

### Cannabis for medical use

The use of cannabis for medical purposes is permitted in Romania, based on a medical prescription. The cultivation of cannabis for medical use is authorised via a permit issued by the Ministry of Agriculture and Rural Development. In addition, the Ministry of Health issues authorisations for the purchase, distribution and use of cannabis products. However, such authorisations are limited to specific medical, scientific or technical needs. As regards imports of cannabis into Romania, every individual import activity must be authorised by the Romanian Ministry of Health.

In July 2019, a draft law regarding the legal framework for medical cannabis and mixtures which contain cannabis was submitted in the Romanian parliament, providing for, among others, the establishment of the Romanian Agency for Cannabis, responsible for issuing authorisations for the activity of growing or processing medical cannabis, as well as ensuring the control, verification and monitoring of operations and transactions of medical cannabis.

After years of relative inactivity, this draft law was debated, on 13 March 2023, at the Health Committee of the Chamber of Deputies, seemingly gaining support from certain parliamentary groups. However, its potential entry into force and related timeline remain uncertain.

### Recreational use of cannabis

The recreational use of cannabis is prohibited and is a criminal offence. Given the authorities rather unfavourable position on the matter and general public opinion, it is difficult to predict if or when the recreational use of cannabis will be legalised in Romania.

In this respect, a few recent developments have occurred regarding the sanctioning regime for cannabis:

- certain legislative acts were adopted recently, increasing the current criminal sanctions for activities related to cannabis usage (i.e., imprisonment). Recently, a public debate took place on further severely increasing sanctions applicable to drivers that commit traffic accidents under the influence of drugs, including cannabis (e.g. imprisonment and impounding vehicles involved in such incidents).
- conversely, a legislative proposal was submitted with the Romanian parliament in May 2023, providing, among others, that (i) the possession of up to 3 grams of cannabis for personal use is an administrative offence (i.e., as opposed to a criminal offence, as currently legislated), punishable by fine of up to EUR 600 and (ii) the possession of cannabis for medical use, justified by a medical prescription, is not sanctioned and will be further regulated following the adoption of this law. The proposal recently met with a negative opinion from the Romanian Parliamentary Health Committee, and thus any timeline for enactment remains uncertain, especially given the current public outcry against the use of drugs in Romania due to several very recent traffic accidents with casualties involving drivers under the influence of drugs.

### Other products containing cannabinoids

Cannabis-derived CBD products containing THC (regardless of concentration) are prohibited and subject to criminal enforcement. THC is a strictly regulated substance, listed as a narcotic and/or psychotropic substance, as per the currently applicable legal framework and the official stance of the national police authorities.

In this context, as a result of criminal investigations into the activities of several companies marketing so-called CBD food products – which in fact contained THC – the police authorities issued a press release, on 19 January 2021, stating that any product containing any level whatsoever of THC was to be classified as a high-risk drug and its distribution was, therefore, subject to criminal enforcement. The police authorities also stated that a THC level of 0.2% was only permissible for raw plants grown in an authorised manner, and not for the finalised products that result from the plants.

The police authorities have also emphasized that in Romania no specific laws exist concerning the placement on the market of food products containing different components/derivatives of the cannabis plant (e.g. seeds, oil, flour); nor have any minimum/maximum permitted limits or daily intake levels been set/agreed for the CBD content of food products (including food supplements). No additional official interpretations on the marketing of CBD products by other Romanian authorities have been identified at present.



## Serbia

### Cannabis for medical use

The use of cannabis for medical purposes is currently not authorised in Serbia. Several attempts have occurred in the past to legalize cannabis for medical use, albeit without success. It appears that the issue of the decriminalization of cannabis in Serbia, including its potential use for medical purposes, is completely outside of the focus of Serbian authorities. No wider debates have taken place in relation to this topic in Serbia, and occasional initiatives in this respect, even when raised by politicians who are members of the Serbian ruling coalition (as evidenced during the session of the Serbian parliament in October 2022), are being dismissed by the government without consideration.

## Recreational use of cannabis

The use of cannabis for recreational purposes is not permitted, and is considered a criminal offence. In accordance with Article 246a of the Serbian Criminal Code, possessing even minor amounts of opioids for personal use is punishable by a monetary fine or imprisonment of up to three (3) years, whereas no definition is found in the Criminal Code for the amount considered sufficient to constitute a criminal offence. Therefore, possession of any amount of cannabis (or any other opioid) bears the risk of criminal liability.

## Other products containing cannabinoids

In accordance with applicable regulations, the cultivation of industrial hemp of the type *Cannabis sativa* L, containing less than 0.3% of THC in the produced hemp is authorised, subject to special permit issued by the Serbian Ministry of Agriculture. However, in practice, it appears that obtaining the relevant permit is burdened by a number of obstacles, and that Serbian state bodies are very restrictive in issuing such permits.

However, it does appear that certain companies in Serbia are offering certain hemp products containing various levels of CBD (whose use is not prohibited).



## Slovakia

### Cannabis for medical use

Medicinal products containing cannabinoids (the chemical compounds that give cannabis its medical and psychoactive properties) are classified as 1st category narcotics and psychotropic substances and treated as controlled substances. The import, production, distribution and research into medicinal products containing cannabinoids are subject to a licence issued by the Slovak Ministry of Health. The cultivation of cannabis in Slovakia is only permitted for industrial production and research purposes, and is subject to a licence issued by the Slovak Ministry of Health.

As of 1 December 2022, no licence is required if a farmer cultivates varieties of cannabis listed in Article 9(1) of the delegated Commission Regulation (EU) 639/2014 of March 11, 2014, supplementing the Regulation of the European Parliament and of the Council (EU) no. 1307/2013, as amended.

Medicinal products containing certain controlled substances, namely cannabis compounds, are available only on prescription and are subject to additional prescription restrictions (e.g. the prescribed number of packages cannot exceed the amount required for 30 days of treatment). Possession of registered medicinal products containing certain cannabis substances (delta-9-THC) is only authorised in doses intended for personal use.

### Recreational use of cannabis

The recreational use of cannabis is not legal in Slovakia.

Recreational cannabis possession in Slovakia is illegal. Breaches of this prohibition are subject to up to five years' imprisonment under the Slovak Criminal Code. Cannabis production, import or sale is punishable by three to ten years' imprisonment. In aggravating circumstances, the perpetrator can face imprisonment of up to 25 years or even life imprisonment.

### Other products containing cannabinoids

As of 1 May 2021, Slovak law does not classify CBD as a narcotic substance and its sale, purchase and possession are legal. However, CBD, as part of the group of cannabinoids, is considered a novel food and may be legally included in foodstuffs or food supplements until a safety assessment has been completed and the use as a novel food has been approved. Therefore, products containing CBD can only be marketed as cosmetic products in accordance with Regulation (EC) No. 1223/2009 on cosmetic products. Some e-shops and distributors have sought to circumvent this ban on food supplements by stating that the food supplement is not intended for ingestion and is classified as a cosmetic product. Such conduct is illegal under Slovak law and subject to fines of up to EUR 100,000.



## Ukraine

### Cannabis for medical use

Cannabis treatment is not currently permitted in Ukraine – with some exceptions, as outlined below. The free use and cultivation of cannabis is prohibited.

In April 2021 the Cabinet of Ministers of Ukraine legalised the limited circulation of cannabis-based medical products, namely Nabilone (a synthetic cannabinoid, mimicking the effect of THC), Nabiximols (a specific cannabis extract with the same content of THC and CBD) and Dronabinol on the Ukrainian market. Yet, these psychotropic substances are authorised only as medicines (on prescription), or as substances intended for the production and manufacture thereof.

On 13 July 2023 Draft Law No. 7457 (“**Draft Law**”) aimed at regulating the process of obtaining the necessary licenses and permits and establishing the rules for laboratory testing, traceability, labelling, transportation, medical use, prescribing and selling of cannabis-based medicinal products to patients was adopted in the first reading (three readings are required for the draft to become the law). On 10 October 2023 the revised version of the Draft Law was approved by the Committee on Public Health, Medical Assistance and Medical Insurance and recommended to the Ukrainian parliament for adoption.

It is expected that Draft Law will be adopted; however, no public information is presently available on the expected timeline.

### Recreational use of cannabis

The recreational use of cannabis is prohibited in Ukraine.

The manufacture, purchase, storage, transportation and sale of cannabis and its derivatives are subject to administrative and/or criminal liability depending on the volume and nature of the activity.

The recreational use of cannabis is out of scope of the Draft Law and is not expected to be legalised.

### Other products containing cannabinoids

The cultivation of hemp for industrial purposes is permitted in Ukraine – albeit, within quotas established by the Ukrainian government, and is subject to licensing and other approvals. The current statutory limit of THC content for industrial hemp is 0.08% in dried straw, which is far below the typical limits set by many other countries.

The Draft Law will further regulate the cultivation of hemp for medicinal purposes.

CBD use is not subject to a clear regulatory framework in Ukraine. Starting from April 2021 CBD has not been subject to state controls (e.g. restrictions applicable to controlled substances are not applicable). At the same time, all cannabis resins, extracts and tinctures (including CBD) continue to be prohibited in Ukraine. Nevertheless, various CBD-based products are commonly used in Ukraine (produced locally or imported), i.e. cosmetics, essential oils, food supplements, etc.

## SUMMARY



Most countries in Central and Eastern Europe covered by this report maintain a conservative approach to cannabis use. Despite this, there have been some positive recent developments in this field.

Cannabis for medical use is available upon a prescription in the Czech Republic, Croatia and Romania, and to some extent also in Slovakia and Ukraine.

The recreational use of cannabis is still prohibited and subject to criminal or administrative sanctions in the countries covered by this report. The Czech Republic shows a positive trend towards legalisation, but this is still in its infancy, as no consensus has been found on this issue yet.

Other products containing cannabis appear to be appearing on the markets; but in most cases their production, distribution and use are not explicitly regulated by local legislation. Some restrictions, however, apply to the THC content, or on general licensing requirements for hemp.

We will continue to monitor developments in this field and will publish updates on a regular basis.



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