

Current legislation on medical cannabis in the European Union: historical background, movements, trends, and counter-trends lessons for Brazil

Legislação atual sobre cannabis medicinal na União Europeia: históricos, movimentos, tendências e contratendências. Lições para o Brasil

Ricardo Ferreira de Oliveira e Silva¹, Emilio Nabas Figueiredo²

DOI 10.5935/2595-0118.20230052-en

ABSTRACT

BACKGROUND AND OBJECTIVES: The growing interest in the medical use of cannabis and phytocannabinoids has led European Union (EU) countries to regulate the production and access to cannabis products for their citizens. This regulation is based on international conventions, the European Medicines Agency (EMA) guidelines and legal loopholes that grant autonomy to EU member countries to authorize the production and marketing of cannabis-based drugs and foods. This summary aims to present the current status of medical cannabis legislation in the EU, highlighting the authorization of drugs, regulatory processes and the autonomy of member states in the production of magistral formulas.

CONTENTS: Most EU countries allow, in some form, the legal use of cannabis and its derivatives as a drug. Since 2019, three drugs containing nabiximols, dronabinol or nabilone have been authorized on the markets of EU member states. In addition to the EMA centralized procedure for marketing authorization, cannabinoid-based products can also be authorized through regional or national processes in EU countries. This autonomy extends to the production of magistral formulas in compounding pharmacies, allowing pharmacists to prepare formulas containing cannabis for use according to a specific medical prescription and, in some situations, at scale.

CONCLUSION: While it is not possible to conclude which is the ideal approach to the regulation of medical cannabis that all countries should adopt, the experience of the EU provides valuable lessons. The autonomy granted to the member states

allows the expansion of the medical use of cannabis through the authorization of drugs and the production of magistral formulas. These experiences can be used as a basis for reformulations in Brazilian regulations, aiming to expand access and medical use of cannabis in the country.

Keywords: Drug and narcotic control, Europe, Medical marijuana, Pharmaceutical preparations.

RESUMO

JUSTIFICATIVA E OBJETIVOS: O crescente interesse no uso medicinal da cannabis e fitocanabinoides tem levado os países da União Europeia (UE) a regulamentarem a produção e acesso a produtos canábicos para seus cidadãos. Esta regulamentação se baseia em convenções internacionais, orientações da Agência Europeia de Medicamentos (EMA) e brechas legais que concedem autonomia aos países-membros da UE para autorizar a produção e comercialização de fármacos e alimentos à base de cannabis. Este estudo teve o objetivo de apresentar a situação atual da legislação sobre cannabis medicinal na UE, destacando a autorização de fármacos, os processos de regulamentação e a autonomia dos estados-membros na produção de fórmulas magistrais.

CONTEÚDO: A maioria dos países da UE permite, de alguma forma, o uso legal da cannabis e seus derivados como fármaco. Desde 2019, três fármacos contendo nabiximols, dronabinol ou nabilona foram autorizados nos mercados dos estados-membros da UE. Além do procedimento centralizado da EMA para a autorização de comercialização, os produtos à base de canabinoides também podem ser autorizados por meio de processos regionais ou nacionais dos países da UE. Essa autonomia se estende à produção de fórmulas magistrais em farmácias de manipulação, permitindo que os farmacêuticos preparem fórmulas contendo cannabis para uso de acordo com prescrição médica específica e, em algumas situações, em escala.

CONCLUSÃO: Embora não seja possível concluir qual é a abordagem ideal para a regulamentação da cannabis medicinal que deve ser adotada por todos os países, a experiência da UE fornece lições valiosas. A autonomia concedida aos estados-membros permite a ampliação do uso medicinal da cannabis por meio da autorização de fármacos e da produção de fórmulas magistrais. Essas experiências podem ser utilizadas como base para reformulações na regulamentação brasileira, visando ampliar o acesso e uso medicinal da cannabis no país.

Descritores: Cannabis, Controle de medicamentos e entorpecentes, Europa, Preparações farmacêuticas, Regulamentação Governamental.

Ricardo Ferreira de Oliveira e Silva – <https://orcid.org/0000-0002-6354-8546>;
Emilio Nabas Figueiredo – <https://orcid.org/0000-0001-8799-4586>.

1. Vertebralis Spine Center, Spinal Surgery and Pain Management, Rio de Janeiro, RJ, Brazil,
2. Legal Reform Network, Legal Department, Rio de Janeiro, RJ, Brazil.

Presented on July 09, 2022.

Accepted for publication on June 21, 2023.

Conflict of interest: none - Sources of funding: none.

HIGHLIGHTS

- Expansion of access to medical cannabis in recent years in several European states.
- Particularities of regulatory models in European Union countries.
- Challenges and counter-trends in regulatory frameworks for cannabis as a drug in Europe, and lessons for Brazil.

Correspondence to:

Ricardo Ferreira de Oliveira e Silva

E-mail: ricfos@gmail.com

© Sociedade Brasileira para o Estudo da Dor

INTRODUCTION

Different varieties of *Cannabis sativa* have been and continue to be used by humans since ancient times. In the European Union (EU), cannabis varieties are defined as industrial cannabis or food (hemp) and drug cannabis (marijuana), based on the amount of their main psychoactive compound, Δ^9 -tetrahydrocannabinol (THC). It is considered as hemp when the amount of THC measured in the plant reaches a maximum of 0.2% of its total weight¹, as this understanding is derived from the 1961 United Nations Single Convention on Narcotic Drugs, which excludes the cultivation of cannabis “exclusively for industrial (fiber and seed) or horticultural purposes” from its controls.

Hemp is usually grown for the production of various industrial products such as paper, fibers in textiles, and different materials used in various manufacturing industries. Hemp is also traditionally used in food through its seeds in its natural form or through its oil extraction. Conversely, the drug form of cannabis has a long history of cultivation for its psychoactive use in recreational, religious, or medicinal contexts^{2,3}.

However, with the emergence of the pharmaceutical industry and the establishment of contemporary regulatory frameworks in the early 20th century, the medicinal use of cannabis drastically decreased. However, in the past 20 years, partly due to the discovery of the endocannabinoid system, interest in the potential therapeutic use of various cannabis derivatives has been growing exponentially⁴.

According to most European lawmakers and regulators, the issue with cannabis is related to its psychoactive effects and potential risks to public health, asserting that these risks justify maintaining cannabis with more than 0.2% of THC in the category of illicit drugs under strict control¹.

However, new laws are being instituted in EU countries regulating the therapeutic use of cannabis, phytocannabinoids, and their analogues. These laws differ greatly among countries, reflecting their different historical, political, and cultural origins^{3,4}.

MEDICAL USE OF CANNABIS AND DERIVATIVES

Currently, most EU countries allow, in some way, the legal use of cannabis and its derivatives as drug^{1,4}, also based on the 1961 UN Single Convention on Narcotic Drugs, which stipulates in its preamble that medical use continues to be “indispensable for the relief of pain and suffering”.

This can be simplified by saying that cannabinoids are substances that bind to animal cannabinoid receptors and trigger effects similar to those caused by the *Cannabis sativa* plant. Cannabinoids are classified according to their origin and molecular structure^{5,6}. Endocannabinoids are endogenous neurotransmitters produced by the body that bind to CB1 and CB2 cannabinoid receptors present in the central and peripheral nervous systems of animals. In recent years, connections between endocannabinoids and receptors outside the endocannabinoid system have also been shown, crediting them with important regulatory roles in various physiological processes⁵⁻⁷.

This regulation includes interference in multiple aspects of pain physiology, cognition, motor coordination, appetite, nausea, and some endocrine, inflammatory, and immune processes. Thus, manipulations of the endocannabinoid system may be useful in treating various diseases and symptoms such as pain, nausea, depression, anxiety, and various neurological disorders⁶.

Phytocannabinoids are cannabinoids derived from plants. Among the known plants, cannabis synthesizes this class of substance in the greatest quantity. Over 100 phytocannabinoids with different properties and concentrations have already been documented, varying according to the plant species and cannabis variety⁸.

In general, the most abundant phytocannabinoid is the psychoactive Δ^9 -tetrahydrocannabinol (THC). However, depending on the *Cannabis sativa* variety, other non-psychoactive phytocannabinoids may be dominant, such as cannabidiol (CBD), cannabigerol (CBG), and others⁸.

Synthetic cannabinoids have been used in medicine since the second half of the 20th century. They are based on the chemical structure of phytocannabinoids and there are currently two products containing synthetic cannabinoids that have been approved for medicinal use in some EU member states: dronabinol, which is synthetic THC, and nabilone, which is a synthetic analogue of THC^{9,10}.

Other synthetic cannabinoids have been marketed in an unregulated manner as a means to avoid being characterized as trafficking or using illicit drugs. For many years, these cannabinoids have been sold in Europe through electronic means and smartshops as legal options for recreational cannabis, with names like K2, Spice, or as room freshener. Because they are not regulated, science knows little about their effects on humans, but on the other hand, reports multiply that they cause more distress, anxiety, and panic than phytocannabinoids from cannabis, representing a significantly greater health risk than cannabinoids from nature¹¹.

EUROPEAN UNION LEGISLATION AND ITS MEMBER STATES

Cannabis and cannabinoids currently have regulation for medicinal use in most EU member states. They are mainly indicated for the treatment of chronic pain, nausea, and vomiting resulting from chemotherapy or for spasticity related to multiple sclerosis^{7,12}.

Several cannabis products have already received different types of authorizations for commercialization within the European territory, and the EU legal issues for authorizing drugs for human use are established by Directive 2001/83/EC of the European Parliament and Council¹³.

All cannabinoid-based drugs go through the same centralized procedure for marketing authorization as other drugs. Once approved, they can be marketed in all EU member states, provided they are prescribed by doctors and within the clinical indications and dosage indicated in the package leaflet.

In 2019, the European Medicines Agency (EMA) approved the first product based on cannabinoids. This drug is based on isolated CBD and was approved for the treatment of children with intractable epilepsy with the designation of an orphan drug, with no similar products available.

In addition to the centralized EMA procedure for marketing authorization, cannabinoid-based products can be authorized through regional or national processes of EU member states, with these authorizations restricting their scope only to states or regions that grant this license. Regardless of whether the authorization is regional or for the entire EU, having marketing authorization implies that the product has been tested for safety and efficacy through extensive clinical and pharmacological trials.

Until now, there are three authorized drugs containing nabiximols, dronabinol, or nabilone in the markets of EU member states¹⁴⁻¹⁸. Other cannabinoid-based drugs are in different stages of development but have not yet been authorized for marketing by the EMA. Of those that have been authorized, only nabiximols is formulated with phytocannabinoids (CBD and THC) directly derived from the Cannabis plant; the other two are synthetic and semi-synthetic products.

Due to national sovereignty, some EU countries have regulated the prescription and sale of products containing cannabinoids on their own terms and independently from EMA approval. This autonomy is based on the absence of EMA influence in the regulation of magistral and officinal formulas, leaving the regulation for compounding pharmacies at the discretion of each EU member state^{1,13}.

In most EU countries, this exemption allows pharmacists to prepare magistral formulas for use according to a specific medical prescription for each patient. It also allows for production on a larger scale (official formulas with stock or standardized preparations independent of individual prescription), according to the pharmacopeia of each country, as occurs with vitamins and supplements in Brazil.

Croatia, Czech Republic, Denmark, Finland, Germany, Italy, Luxembourg, Netherlands, Poland, and Sweden allow patients to access cannabis preparations through official formulas, meaning no prescription is necessary for patients who meet certain indications and therapeutic protocols; patients can be offered natural cannabis flowers or plant extracts^{1,19-23}. Magistral preparations, prescribed with a formula and presentation specified by the prescriber, are also available through special access schemes in the Czech Republic, Germany, Italy, and the Netherlands.

There are also programs for accessing cannabis and its derivatives for exceptional/compassionate use in Croatia, Denmark, Finland, Poland, and Sweden. These programs depend on medical approval and supervision, limit medicinal use to a specific set of medical conditions, and usually restrict use in the form of cannabis extracts for oral use.

Although there are legal prerogatives, the use of cannabis as a drug may be unfeasible in some countries such as Slovenia and Estonia. This is due to the local regulatory bureaucracy and lack of health insurance coverage²⁴⁻²⁶.

SPECIFIC SITUATIONS IN COUNTRIES WITH HIGHER PRESCRIPTION RATES OF CANNABIS

Medical use of cannabis in Germany

In Germany, medical cannabis was regulated in March 2017. Before that, around 1000 patients had been granted special permission for use on German territory. Since the 2017 regulation, the number of prescriptions has drastically increased, making Germany the EU country with the highest official number of patients using medical cannabis. In 2018 alone, approximately 80000 patients received prescriptions for some form of cannabis derivative in Germany²⁷⁻³⁰.

Fourteen varieties of cannabis flowers can be prescribed for any medical condition, provided refractoriness to therapeutic alternatives is proven, either due to a lack of positive response or adverse effects²⁸.

The German regulatory framework comprises a policy that offers broad access to medicinal cannabis. Health insurers are required to reimburse the cost of treatment for patients who prove refractory to other treatment options, but, so far, there are no standardized protocols defining universal criteria for reimbursement approval. Therefore, each case is assessed individually and according to each insurer³⁰.

Medical use of cannabis in Italy

After Germany, Italy has the highest number of prescriptions for medicinal cannabis in the EU. Since 2006, doctors in Italy can prescribe magistral preparations mandatory manipulated by pharmacists in pharmacies, using dronabinol or natural active principles of cannabis under medical prescription³¹.

Plants to supply pharmacies are cultivated in Italian territory under the authorization and supervision of a national cannabis agency. In addition to Italian plants, since 2013, doctors registered in Italy can also prescribe an imported extract from England: nabiximol (THC:CBD), for spasms and pain related to multiple sclerosis.

Recently, imports of five varieties of cannabis flowers cultivated in Canada and the Netherlands (Bedrocan, Bediol, Bedica, Bedrobinol and Bedrolite) have been allowed for specific conditions: chronic pain, spasms, palliative care, the control of side effects from oncological treatments, complications, cancer and AIDS-related anorexia, as well as other medical conditions refractory to conventional treatments²⁸.

In Italy, doctors need to describe the variety of cannabis, quantity, dosage, and the most suitable method of administration for each patient on an individualized prescription. The Italian healthcare system provides full reimbursement for the cost of cannabis treatment. As of January 2019, approximately 13000 patients have received cannabis prescriptions as drug treatments in Italy³¹.

Medical use of cannabis in the United Kingdom

In the United Kingdom, medicinal cannabis was legalized and made available under a special license from the regulatory agency for drugs and healthcare products in November 2018. However, since then, only a very small number of patients with a limited range of conditions have received treatment within the English public healthcare system (NHS), meaning that medi-

cial cannabis remains inaccessible to most patients. Current guidelines from the National Institute for Health and Care Excellence (NICE) recommend the prescription of two cannabis-based drugs produced in England (isolated CBD) and nabiximols (THC:CBD) for the treatment of three main conditions: chemotherapy-induced nausea and vomiting, multiple sclerosis spasticity, and severe epilepsy³².

Many question the restricted choice of recommended products and the lack of recommendation for medicinal cannabis for the treatment of chronic pain. In contrast to the current NICE guidelines, people are using medicinal cannabis for a wide variety of indications ranging from pain, depression, anxiety, insomnia, arthritis, fibromyalgia, muscle spasms, irritable bowel syndrome, migraines, headaches, and other conditions³³.

A ray of hope for English citizens is that the National Academy of Sciences (NASEM) has recently published that there is conclusive evidence that cannabis and its derivatives are effective in the treatment of chronic pain in adults³⁴.

Medicinal use of cannabis in the Netherlands

In 2003, the Netherlands became the second country in the world, after Canada, to regulate the medicinal use of cannabis. Cannabis flowers from four varieties with distinct cannabinoid profiles can be prescribed by any doctor for spasticity caused by multiple sclerosis, spinal cord trauma, any type of chronic pain, palliative care, and complications of cancer, acquired immunodeficiency syndrome, and hepatitis C²⁸.

Outside of official programs, since 1976, cannabis is widely available in cafes due to the liberal recreational cannabis policy in the Netherlands. It is estimated that around half a million people use cannabis for medicinal purposes in the Netherlands, the majority without a prescription or medical supervision³¹.

Legislation for the cultivation of cannabis for medicinal purposes and food products

International law does not prohibit the cultivation of cannabis for medicinal use. On the contrary, the 1961 UN Convention paved the way for cultivation for medical and scientific purposes. The UN also provides for the use of cannabis for industrial and food purposes³⁵.

Each country has the prerogative to purchase the cannabis produced on its territory. As the cultivation and processing of cannabis directly affect the quality, type and proportion of phytocannabinoids, it is necessary to comply with the provisions of the United Nations Conventions and WHO guidelines on good agricultural practices, harvesting, and handling of medicinal plants to minimize differences in each crop or batch³.

For EU member countries, the EMA also provides guidelines on good agricultural and processing practices that include a quality control system for medicinal plants and herbal substances from cultivation to patient³⁷.

Currently, cultivation of medical cannabis in the EU takes place in Austria, Czech Republic, Italy, Germany, Greece, Malta, Netherlands and Portugal. Before starting their cultivation, each of these countries was obliged to establish a regulatory authority for the cultivation of cannabis in their territories^{1,38-41}.

Cannabis can also be grown in the EU for food purposes, provided that the cannabis variety is registered in the EU common catalog of varieties of agricultural plant species, and that this variety does not exceed the content of 0.2% THC⁴².

Unlike in the United States, where the sale of extracts with any concentration of CBD has been legal since 2018, the European Commission's food catalogue lists Cannabis sativa extracts with a CBD content higher than 2% as prohibited for use in food and dietary supplements⁴³.

CONCLUSION

The growing interest in the medicinal use of cannabis and phytocannabinoids is forcing EU countries to regulate the production and access to cannabis products for their citizens. In this journey, there is a dispute between two regulatory models: first, the model that emerges from the medicinal cannabis industry, where one company dominates the entire production cycle from seed to shelf; and second, the more recently adopted model of the pharmaceutical industry, where each company takes care of a part of the cycle from raw material to finished product.

The variety of approaches to regulating medicinal cannabis and their practical results in making medication accessible to patients demonstrate the benefits and deficiencies of different regulatory regimes. In Europe, as well as other continents, countries adopt different approaches that reflect various historical, political, and cultural factors.

Although it is still difficult to conclude which is the "ideal approach" that should be adopted by all countries, valuable lessons can be learned for reformulation of regulation that allows for the expansion of medicinal cannabis use in Brazil. Despite the differences in their regulatory approaches to medicinal cannabis, all countries agree on the need for continued education for doctors and other healthcare professionals. In addition, it is important to expedite policy formulation and improve communication between policy makers, doctors, and patients.

Regulations need to be developed in a timely and efficient manner. If this is neglected, it creates a regulation vacuum that will be filled by other interest groups. On the other hand, if regulation is too conservative, it will feed the black market with all the risks that it entails. Therefore, it is important to have an appropriate regulatory framework that takes into account scientific knowledge, risks, and patient needs. There is a need to develop guidelines and regulations that can be followed, that are neither too strict nor too permissive.

The foundations of cannabis regulation as a drug in EU countries are based on UN conventions, the European Medicines Agency (EMA), and legal loopholes that give autonomy to each EU member country to authorize the production and marketing of drugs and food on their territories. The absence of marketing authorization by the EMA does not prevent patients from accessing various cannabis products in different EU countries, as many countries exercise their sovereignty by authorizing magistral and officinal preparations.

AUTHORS' CONTRIBUTIONS

Ricardo Ferreira de Oliveira e Silva

Data Collection, Conceptualization, Project Management, Research, Methodology, Writing - Preparation of the original, Writing - Review and Editing, Supervision

Emilio Nabas Figueiredo

Writing - Review and Editing, Supervision

REFERENCES

- European Monitoring Centre for Drugs and Drug Addiction. Medical use of cannabis and cannabinoids: questions and answers for policymaking. Luxembourg: Publications Office of the European Union; 2018. http://www.emcdda.europa.eu/publications/rapid-communications/medical-use-of-cannabis-and-cannabinoids-questions-and-answers-for-policymaking_en.
- Congressional Research Service. Report R44742. Defining Hemp A Fact Sheet. 2019. <https://crsreports.congress.gov>.
- Zuardi AW. History of cannabis as a medicine: a review. *Braz J Psychiatry*. 2006;28(2):153-7.
- Abuhasira R, Shbiro L, Landschaft Y. Medical use of cannabis and cannabinoids containing products - Regulations in Europe and North America. *Eur J Intern Med*. 2018;49(1):2-6.
- Schurman LD, Lu D, Kendall DA, Howlett AC, Lichtman AH. Molecular mechanism and cannabinoid pharmacology. *Handb Exp Pharmacol*. 2020;258:323-53.
- Lowe H, Toyang N, Steele B, Bryant J, Ngwa W. The endocannabinoid system: a potential target for the treatment of various diseases. *Int J Mol Sci*. 2021;22(17):9472.
- N, Steele B, Bryant J, Ngwa W. The endocannabinoid system: a potential target for the treatment of various diseases. *Int J Mol Sci*. 2021;22(17):9472.
- Di Marzo V, Piscitelli F. The Endocannabinoid system and its modulation by phytocannabinoids. *Neurotherapeutics*. 2015;12(4):692-8.
- Rock EM, Parker LA. Constituents of Cannabis Sativa. *Adv Exp Med Biol*. 2021;1264:1-13.
- Pertwee RG. Targeting the endocannabinoid system with cannabinoid receptor agonists: pharmacological strategies and therapeutic possibilities. *Philos Trans R Soc Lond B Biol Sci*. 2012;367(1607):3353-63.
- Tsang CC, Giudice MG. Nabilone for the management of pain. *Pharmacotherapy*. 2016;36(3):273-86.
- Castaneto MS, Gorelick DA, Desrosiers NA, Hartman RL, Pirard S, Huestis MA. Synthetic cannabinoids: epidemiology, pharmacodynamics, and clinical implications. *Drug Alcohol Depend*. 2014;144:12-41.
- Aizpurua-Olaizola O, Elezgarai I, Rico-Barrio I, Zarandona I, Exebarria N, Usobiaga A. Targeting the endocannabinoid system: future therapeutic strategies. *Drug Discov Today*. 2017;22(1):105-110.
- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use <https://eur-lex.europa.eu/eli/dir/2001/83/oj>.
- European Medicines Agency. Orphan designation: Cannabidiol for: the treatment of Dravet syndrome. 2019. <https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3141339>.
- European Medicines Agency. Epidyolex. EPAR. 2019. <https://www.ema.europa.eu/en/medicines/human/EPAR/epidyolex>
- Electronic Medicines Compendium (EMC). Sativex Oromucosal Spray. SmPC. 2018. <https://www.medicines.org.uk/emc/product/602/smpe>.
- Danish Medicines Agency. Medicinal use of Cannabis, 3rd ed. Copenhagen: Medicines Control & Inspection; 2015 <https://laegemiddelstyrelsen.dk/en/news/2015/updated-memo-on-medicinal-use-of-cannabis/-/media/CA79D52432AC4045A999C-6C183FB173B.ashx> File no.2013113424.
- Cesamet. 2020. Drugs.com <https://www.drugs.com/cesamet.html>.
- Álvares M. After legalisation, what next for medical cannabis in Portugal? *Health Europa*. 2020. <https://www.healtheuropa.eu/medical-cannabis-in-portugal/90986>.
- Státní agentura pro konopí pro léčebné použití (SAKL). 236/2015 Coll. Decree of 4 September 2015 stipulating the conditions of prescribing, preparation, distribution, dispensing, and use of magistral formulas containing medical cannabis. <http://www.sakl.cz/assets/user/Decree%20No%20236-2015.pdf>.
- Federal Institute for Drugs and Medical Devices. Annual Report 2017/2018. Bonn: Federal Institute for Drugs and Medical Devices; 2018. https://www.bfarm.de/SharedDocs/Downloads/EN/BfArM/Publikationen/AnnualReport2017-18.pdf?_blob=publicationFile&cv=4.
- Office of Medicinal Cannabis. Medicinal cannabis. The Hague: Institute for Responsible Medicine Use and the Office of Medicinal Cannabis of the CIBG; 2011. <https://english.cannabisbureau.nl/medicinal-cannabis>.
- Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.
- Zakon o lekarniški dejavnosti [Pharmacy Practice Act, in Slovenian] Uradni list RS, št. 2020;85(16) <http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO7375>
- Čufar A. Regulatorni vidik predpisovanja kanabinoidov [Prescribing of cannabinoids – a regulatory view, in Slovenian] *Farm Vestn*. 2016;67:91-6..
- Partners P. The European Cannabis Report Edition 4. January. 2019. <http://prohibitionpartners.com/report-uploads/The%20European%20Cannabis%20Report%204th%20Edition.pdf>.
- Krcovski-Skvarc N, Wells C, Häuser W. Availability and approval of cannabis-based medicines for chronic pain management and palliative/supportive care in Europe: A survey of the status in the chapters of the European Pain Federation. *Eur J Pain*. 2018;22(3):440-54.
- Dobush G. Why can't Germany get its medical marijuana industry going? *Das Handelsblatt*. 01/02/2019. <https://www.handelsblatt.com/today/companies/cannabis-why-cant-germany-get-its-medical-marijuana-industry-going/23811676.html?ticket=ST-2507447-OtcWATLyUdlzVqUSdd50-ap4>.
- Pascual A. Germany's medical cannabis market prioritizes efficacy over unfettered access. June 12th. 2019. <https://mjbizdaily.com/germanys-medical-cannabis-market-prioritizes-efficacy-over-unfettered-access/>.
- Da Cas R. The use and safety of Cannabis for medical use in Italy. Presentation given at the 2nd International Annual Congress on Controversies on Cannabis-Based Medicines. May 23rd-24th. 2019 Barcelona, Spain.
- National Institute for Health and Care Excellence (NICE) Cannabis-based medicinal products. NICE Guidelines [NG144] November 2019. <https://www.nice.org.uk/guidance/ng144>.
- United Patient's Alliance (UPA) UPA Patients' Survey. 2018. <https://www.upalliance.org/patient-survey-2018>.
- Health Canada Market data under the Access to Cannabis for Medical Purposes Regulations. 2019. <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/licensed-producers/market-data.html>.
- Convenção Única de 1961 sobre Narcóticos - Alterado pelo Protocolo de 1972 para modificar a Convenção Única de 1961 sobre Estupefacientes http://www.tjmt.jus.br/intranet.arq/cms/grupopaginas/105/975/convention_1961_es.pdf.
- World Health Organization (WHO). WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants. Geneva: WHO; 2003. <http://apps.who.int/medicinedocs/pdf/s4928e/s4928e.pdf>.
- European Medicines Agency. Guidelines on Good Agricultural and Collection Practices (GACP) for starting materials of herbal origin. 2006. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-agricultural-collection-practice-gacp-starting-materials-herbal-origin_en.pdf Feb. EMEA/ HMPCC/246816/2005.
- Malta Medicines Authority. General Guidelines on the Production of cannabis for medicinal and research purposes. 2018. <http://www.medicinesauthority.gov.mt> Dec. Ref No: GL-CAN01/01.
- Manifava D. Greece grants country's first medical cannabis licenses. 2018. <http://www.ekathimerini.com/234842/article/ekathimerini/news/greece-grants-country-s-first-medical-cannabis-licenses>.
- Nanaimo BC. Tilray® Increases International Export Capacity with New Outdoor Cultivation Site in Portugal. 2019. <https://www.tilray.com/tilraynews-master/2019/8/7/tilray-increases-international-export-capacity-with-new-outdoor-cultivation-site-in-portugal>.
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia. Andreja Čufar. Stališče JAZMP v zvezi s predlogom o spremembi razvrstitve konoplje in ureditvi gojenja konoplje [JAZMP's position on the proposal to amend the classification of cannabis and the regulation of cannabis cultivation, in Slovenian] https://www.jazmp.si/fileadmin/datoteki/dokumenti/Stalisce_JAZMP_glede_konoplje.pdf.
- Publications Office of the EU. C/2017/4132 Common catalogue of varieties of agricultural plant species - fifth supplement to the 35th complete edition. <https://op.europa.eu/en/publication-detail/-/publication/3d31e818-5715-11e7-a5ca-01aa75ed71a1>.
- European Commission. EU Novel food catalogue. http://ec.europa.eu/food/safety/novel_food/catalogue/search/public/?event=home&seq=72&ascii

