РЕПУБЛИКА БЪЛГАРИЯ
Изпълнителна агенция по лекарствата
REPUBLIC OF BULGARIA
Bulgarian Drug Agency

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ДО
Д-Р ПЕТЪР МОСКОВ
МИНИСТЪР НА
ЗДРАВЕОПАЗВАНЕТО

ГР. СОФИЯ 1000
ПЛ. „СВЕТА НЕДЕЛЯ“ № 5

МИНИСТЕРСТВО НА ЗДРАВЕОПАЗВАНЕТО
Регистрационен индекс
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ОТНОСНО: проучване на прилагането на марихуаната и нейните деривати за медицински цели в държави от ЕС

УВАЖАЕМИ Д-Р МОСКОВ,

Във връзка с обсъждане на позиция по темата за необходимостта и терапевтичното значение на употребата на марихуаната и нейните деривати за медицински цели на първото редовно заседание на Националния съвет по наркотичните вещества от 09.02.2015 г., Изпълнителна агенция по лекарствата извърши проучване сред държави-членки на ЕС относно регулаторната практика и контрол. В резултат от направеното проучване чрез проведена писмена анкета-отворен тип бяха получени отговори от 13 държави-членки /ДЧ/. Обобщаването на резултатите показва, че използването на марихуаната за медицински цели е разрешено в Австрия, Германия, Естония, Исландия, Испания, Италия, Лихтенщайн, Холандия, Чехия, Швейцария и Швеция. Марихуаната не се използва за медицински цели в Унгария. Латвия посочва, че употребата на канабис, канабисова смола, масла, екстракти и тинктури като продукти от растителен произход с наркотичен ефект са класифицирани в съответствие с Единната конвенция по упойващите вещества от 30 март 1961. Поради това употребата на марихуана/канабиноиди за медицинска или друга цел е забранено в Латвия.

Съгласно швейцарското законодателство канабис и неговите препарати могат да бъдат използвани с изключителна лицензия на швейцарската Федерална служба за обществено здраве, но в определени случаи, а именно: научни изследвания; разработване на лекарствени продукти; забранена медицинска употреба. Законът е приложим за канабис, дронабинол или дронабинол–THC (вещества и препарати). Лекарствени продукти обаче, обхванати от разрешение за употреба, не се нуждаят от тази изключителна лицензия. Разрешен лекарствен продукт е Sativex. Относно другите препарати отговорна е Федералната служба за обществено здраве.

В Испания екстракти и тинкури от канабис могат да бъдат част от лекарствени продукти, за които са приложими общите правила за получаване на разрешение за употреба. В Германия, Исландия и Швеция лекарствени продукти с разрешение за употреба в държавата, съдържащи определени канабиноидни активни вещества, посочени в списък, могат да бъдат законно пуснати на пазара.

В Чешката република през 2013 г. е създаден специфичен надзорен орган Държавна агенция за канабис за медицински цели - SAKL (www.sakl.cz). Само SAKL има право да закупи и отглежда медицински канабис от производителя за разпределяне, както и за извършване на износ извън Чехия. Производителят е длъжен да продаде всичкия отглеждан и бран медицински канабис на SAKL. SAKL може да представя и продава медицински канабис само за аптеките единствено чрез лицензиран дистрибутор. Медицински канабис, отглеждан

в Чешката република, към момента на проучването, се сочи, че не е на разположение, като се очаква неговата наличност до края на тази година. Наличният медицински канабис в Чешката република е внос от Холандия. Съгласно законодателството медицинският канабис не е предмет на чешкото обществено здравно осигуряване. Дозира се изключително на електронна рецепта.

В Холандия действа специален закон за опиума, който прави разграничение между I категория (твърди наркотици) и категория II (леки наркотици). Законът гласи, че е престъпление да:

- се вземат наркотици от всяка категория през границите на територията на Холандия;
- подготовка, лечение, продажба, доставка, предоставяне, транспортиране на наркотици от всяка категория;
- притежание на наркотици от която и да е категория или
- произвеждане на наркотици от всяка категория.

Законът за опиума предоставя списък за I и II категория.

Налична е възможност за кандидатстване за освобождаване от тази забрана. Това освобождаване се нарича *„opiumontheffing“* на нидерландски език. Изключенията са предназначени за предприятия или агенции, които желаят да работят с лекарства, посочени в закона. При определени условия забраната не се прилага и за фармацевтите, общопрактикуващи и ветеринарните лекари. Също така не се прилага по отношение на правителствените-филиал агенции, на лица или агенции относно запаси от наркотици за медицински или стоматологични цели или за тяхна собствена употреба.

Изключения се допускат за определени цели: общественото здраве, здравето на животните, аналитични изследвания, обучения.

В Италия се изисква специално разрешение и контрол от централната наркотична служба на италианското министерство на здравеопазването за внасяне на Bedrocan, Bediol, Bedrobinol, служещи за приготвяне на магистрални препарати за пациент. ДЧ сочи, че в момента е налице правителствен проект да бъде започната култивация на канабис в строго регулирана среда от италианското министерство на отбраната с цел достъпност на употребата му за медицински цели.

Използване на канабиса за индивидуално лечение предвиждат и чешкото (при месечно ограничение на потреблението на един пациент), германското (при липса на алтернативни терапии) и естонското (с мотивирано предложение от лекар и одобрение от съответна специализирана комисия на естонското министерство по социалните въпроси) законодателство. Холандското законодателство предвижда предписване от лекар, ако стандартните лечения и лекарства не са регистрирани, нямат необходимия резултат или причиняват прекалено много странични ефекти.

Австрия, Германия, Исландия, Испания, Италия, Чехия, Швейцария и Швеция сочат разрешен за употреба лекарствен продукт, а именно Sativex - разтвор за използване като оромукозен спрей, съдържащ комбинация от делта-9-тетрахидроканабинол и канабидиол. Sativex е показан за лечение за подобряване на симптомите при възрастни пациенти с умерена до тежка спастичност, дължаща се на множествена склероза, които не са отговорили адекватно на други антиспастични медикаменти и които демонстрират клинично значимо подобрение на симптомите, свързани със спастичност по време на първоначалния процес на терапията.

Австрия сочи, че законодателството в момента е в процес на преразглеждане във фаза на обществено допитване.

Допитаните държави сочат, че отглеждането на марихуаната за лична употреба не е разрешено на тяхна територия. Холандия изисква прилагането на специални правила, ако холандски пациент желае да използва канабиса като лекарство при пътуване в чужбина, както и застрахователни политики при възстановяване на направените разходи от използването на канабиса за медицински цели.

ДЧ не сочат лицензиран производител на тяхна територия.

Естония предвижда специални условия за производството на такива вещества, Испания – специфични функции на безопасност по отношение на етикетирането, а Чехия - сертификат от сертифицирана лаборатория за проверка на съдържанието на THC и канабидиол (CBD), микробиологична чистота, загубата при сушене, отсъствие на пестициди и тежки метали.

В световен мащаб ООН сочи нови регулаторни рамки в Колорадо и Вашингтон, САЩ и Уругвай, вкл. за веригите за доставки и лична култивация - http://www.unodc.org

Наличната информация показва, че лекарственият канабис може да помогне за облекчаване на:

- болка и мускулни спазми/крампи, свързани с множествена склероза или увреждане на гръбначния мозък
- гадене, намален апетит, загуба на тегло и отслабване, свързана с рак и СПИН
- гадене и повръщане, причинени от лекарства или лъчетерапия за рак и ХИВ / СПИН
- дългосрочни неврогенни болки (т.е. произход на нервната система), причинени от увреждане на нервите, фантомна болка, лицева невралгия или хронична болка при атака на херпес зостер
- тикове, свързани със синдром на Турет

Използването на канабиса за медицински цели не може да излекува посочените показания, но е в състояние да облекчи симптомите, свързани с тях и да намали страничните ефекти на други лекарства.

Видно от проведеното проучване, в 11 от 13 държави-членки, подали отговор, е видно, че при строг държавен контрол и ограничения чрез специализирана нормативна уредба е разрешено използването на марихуаната за медицински цели.

Приложение: таблица с получени отговори от ДЧ – Приложение № 1.

С уважение,

ДОЦ. АСЕНА СТОИМЕНОВА, ДФ
Изпълнителен директор

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Приложение 1

Country	Is the use of marijuana / cannabinoids for medical purposes legalized? Please specify the applicable legislative act and attach it as a text in English, if there is no English version - in the national language.	If the answer to the first question is "yes", please answer the next questions: What type of use of marijuana/cannabinoids for medical purposes is allowed? What kind of treatment is it used for?	Please specify the authorized route of administration - vaporizer, consumption of extracts, capsules, etc.?	Is the cultivation of the plant allowed? Is cultivation for personal use allowed? If "yes", what is the authorized quantity?	Is the incorporation of marijuana's/ cannabinoids' extract into composition of medicinal products permitted? Is there a licensed manufacturer in your country? What is the licensing procedure?	Are there any concerned special rules of quality control and/or specific standards and/or additional guidelines on quality?
AUSTRIA	Yes. According to Narcotic Ordinance § 14 Cannabisextracts which are used as components of licensed medicinal products are legal.	According to Narcotic Ordinance § 14 Cannabis extracts which are used as components of licensed medicinal products are legal.	Oromucosal spray	Yes, acording to § 6a Narcotic Act the cultivation is exclusively allowed for the Austrian Agency for Health and Food Safety; the cultivation for personal use is banned.	There is a Marketing Authorisation for Sativex Spray (UK/H/2462) which is manufactured by GW Pharma Linited, UK. The legislation is currently under revision in the public consultation phase and it is intended to have extratemporaneous use as well.	In general the rules of governing medicinal product apply. Narcotic legislation provides tight documentation requirements and records for the supply and disposal.
CZECH REPUBLIC	The use of medical cannabis for medical purposes is legal in the Czech Republic since April 2013. The supervising authority in the Czech Republic is SAKL (State Agency for Cannabis for Medical Purposes, www.sakl.cz), which was established in 2013 according to Act No. 167/1998 Coll. The activities of SAKL include granting of licenses to grow medical cannabis. Only SAKL is entitled to purchase the grown and harvested	Medical cannabis varieties are listed in the law (see the chart below). Varieties of medical cannabis are not specified for individual diseases by the law. It is always on the doctor's decision. The law limits prescribing of medical cannabis for selected specializations of physicians, selected diagnosis and determines month limit of consumption for a single patient. Medical Cannabis is not covered by public health insurance. Medical	The permitted way of application is inhalation and oral application. Recommende d way of inhalation is vaporization. There is no pharmaceutica	Growing for research purposes is permitted (two subjects are currently authorised). Growing for personal use is not allowed.	Medical cannabis extract is not available in the Czech Republic and use of extract is not described nor permitted in any standard. Thus there are not prepared any pharmaceuticals with content of cannabis extract in	The quality rules and standards for grown and harvested medical cannabis purchased by SAKL are described in the law (No. 221/2013). Before SAKL purchase the grown and harvested medical cannabis from the grower, the grower must get a

	medical cannabis from the grower and to distribute it, as well as export outside the Czech Republic. The grower is obligated to sell all grown and harvested medical cannabis to SAKL. SAKL may deliver and sell medical cannabis only to pharmacies exclusively through a licensed distributor. Medical cannabis grown in the Czech republic is not available yet. We expect its availability by the end of this year. Medical cannabis which is currently available in the Czech republic was imported from the Netherlands. In addition, according to the above mentioned act SAKL also fulfils all reporting obligations towards the Ministry of Health of the Czech Republic and the Police of the Czech Republic. http://www.mzcr.cz/Cizinci/dokumenty/act-no167/1998-coll-_8933_3108_23.html http://www.vlada.cz/en/ppov/protidrogova-politika/government-council-for-drug-policy-coordination-72748/	cannabis is dispensed exclusively on an electronic prescription in pharmacies.Cannabis variety kontent of THC a CBD Code Cannabis sativa L. THC 12%, CBD<1% Content of THC (Δ-9-tetrahydrocannabinol) 12 % a CBD (cannabidiol) less than 1 % 9000001 Cannabis sativa L. THC 19%, CBD<1% Content of THC (Δ-9-tetrahydrocannabinol) 19 % a CBD (cannabidiol) less than 1 % 9000002 Cannabis sativa L. THC 6%, CBD 7,5% Content of THC (Δ-9-tetrahydrocannabinol) 6 % a CBD (cannabidiol) 7,5 % 9000003 Cannabis indica Lam. Content of THC (9Δ-tetrahydrocannabinol) 14 % a CBD (cannabidiol) less than 1 % 9000004 Sativex is registered in the Czech Republic, is available on a prescription and is indicated as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate ~~clinically significant improvement in~~ spasticity related symptoms during an initial trial of therapy.	I form of oral dosage yet.		pharmacies and there is no manufacturer of such product in the Czech Republic.	certificate from a certificated laboratory to verify the content of THC and CBD, microbiological purity, loss on drying, absence of aflatoxines, pesticides and heavy metals.
ESTONIA	Yes, under the Act on Narcotic Drugs and Psychotropic Substances and Precursors thereof. According to the article 3 paragraph 1 the handling of narcotic drugs and psychotropic substances is prohibited except for medical or scientific purposes. Substances (in Schedule I as	Types of use are not specified in the legal act as all decisions are made case-by-case basis only, taking into account the justification of a doctor (in previous answer).	It depends on the justification of a doctor.	No.	Yes, it will be permitted if the application for marketing authorisation complies with all the requirements stated	There are special conditions for the manufacturing of such substances.

	marijuana/cannabinoids are) and medicinal products containing such substances shall be imported and exported on the basis of the import or export authorisation of the State Agency of Medicines (§ 4 (1)) and unauthorised medicinal products (such as marijuana/cannabinoids are) may be imported and distributed on the basis of a single import authorisation and a single distribution permit issued by the State Agency of Medicines at the medically justified written request of a doctor qualified to prescribe the medicinal product for the treatment of a person treated by the doctor (Medicinal Products Act § 21 (1)). According to the Regulation of Minister of Social Affairs from 18.05.2005 annex 73 "Conditions and Procedure for Handling of Narcotic Drugs and Psychotropic Substances for Medical and Research Purposes, and Conditions and Procedure for Maintaining Records and Reporting in that Area and Schedules of Narcotic Drugs and Psychotropic Substances" article 5 paragraph 2: An application				in the EU and national laws.	
	reasoned by a doctor and the approval of a member of the corresponding specialist commission of the Ministry of Social Affairs is required for the use for medical purposes of substances specified in Schedule I and medicinal products containing such substances. (Updated version of the regulation is only in Estonian, but previous versions					

	are also available in English – the referred paragraph is unchanged).					
GERMANY	Yes, to some extent. Please find attached the non-official translation of the German Act on the Trade in Narcotic Drugs - Narcotic Drugs Act - and the narcotic drugs under this act listed in Annexes I to III. Annex III lists the marketable and prescibable narcotic drugs. Cannabis (Marihuana, plants and parts of plants belonging to the Cannabis genus) are prescribable only in preparations covered by a marketing authorization as finished medicinal products. That means that medicinal products covered by a marketing authorizations in Germany containing those substances can be legally marketed in Germany. Also listed as marketable and prescribable narcotic drugs in Annex III are Dronabinol and Nabilone. Individual preparations from this substances made by pharmacies are prescribable. In the absence of alternative therapies (Section 13 (1) Narcotic Drug Act) it is possible to apply for an exception permit from the Federal Institute for Drugs and Medical Devices (BfArM) (Section 3 Narcotic Drug Act) for the purchase of Cannabis for medicinal purposes apply for use as part of a medically attended self-therapy.	As stated above, cannabinoids for medical purposes is only allowed in certain medicinal products covered by a marketing authorization. The only product currently authorised in Germany is Sativex. Sativex is indicated as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.	The only authorised medicinal product in Germany , containing cannabinoids, is Sativex, marketed in the form of oromucosal spray.	No.	No.	No.
HUNGARY	in Hungary marijuana is not used for medical purposes at all.					

ICELAND	Yes, to some extent. Special exemption has been made in Regulation No. 233/2001 on habit-forming and narcotic substances and other controlled substances, for Tetrahydrocannabinol (THC) and Dronabinol (δ-9-tetrahydrocannabinol and stereoisomers). Those substances are marked with exemption No 4 in Annex I to the regulation which means that medicinal products covered by a marketing authorisation in Iceland containing those active substances can be legally marketed in Iceland. The following links will direct you to an English translation (unofficial) of aforementioned regulation. http://eng.velferdarraduneyti.is/media/Reglugerdir-enska/Regulation-on-habit-forming-and-narcotic-substances-and-other-controlled-substances-No-233-2001.pdf	Marijuana/cannabinoids for medical purposes is only allowed in certain medicinal products covered by a marketing authorisation. The only product currently authorised is Sativex. Sativex is indicated as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.	The only authorised medicinal product in Iceland, containing cannabinoids, is Sativex, marketed in the form of oromucosal spray.	No.	No.	No.
ITALY	Yes.	The only medicinal product authorized in Italy through a mutual recognition procedure is Sativex, a solution for use as an oromucosal spray containing a combination of two extracts from ~~Cannabis sativa L., delta-9-~~ tetrahydrocannabinol and cannabidiol. Sativex is indicated as add-on treatment, for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis who have not responded adequately to other antispasticity medication and who demonstrate clinically significant improvement in spasticity related	Sativex is a spray for oromucosal use. Magisterial ~~preparations~~ are used as a decoction or for inhalation through a special device that heats the herbal substances in order to vaporize it.	No. Currently a governmental project is going to be ~~initiated~~ in order to cultivate cannabis in a strictly regulated environment (by a national Agency of the Ministry of Defence) to		The quality guidelines of herbal substances/preparations/medicinal products published on the EMA website apply: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000217.jsp&mid=WC0b01ac0580033a9e

		symptoms during an initial trial of therapy. Magisterial preparations are made on a patient named basis containing cannabis inflorescences (for this purpose Bedrocan, Bediol, Bedrobinol are currently imported under specific authorisation and control of the Central narcotic office of the Ministry of Health).		make it available for magisterial preparations for medicinal use.		
LATVIA	Regulations of the Cabinet of Ministers No.847 "Regulations Regarding Narcotic Substances, Psychotropic Substances and Precursors to be Controlled in Latvia" of november 8, 2005 prescribes narcotic substances, psychotropic substances and precursors to be controlled in Latvia. The article 2 of Regulations states: „The following shall be controlled in Latvia in accordance with regulatory enactments regulating the circulation of narcotic and psychotropic medicinal products and substances: 2.1. prohibited especially dangerous narcotic substances and equivalent psychotropic substances and plants (Schedule I of Narcotic Substances, Psychotropic Substances and Precursors to be Controlled in Latvia) (Annex 1)." So Narcotic Substances, Psychotropic Substances and Precursors to be Controlled in Latvia Schedule I (Prohibited especially dangerous narcotic substances, equivalent	In general terms, the answer is NO, nevertheless extracts and tinctures of Cannabis may be part of registered and authorized medicinal products, such as SATIVEX®, as detailed below: 1.- EXTRACTS and TICTURES OF CANNABIS are narcotic drugs under audit and control of the Spanish Medicines and Medical Devices Agency, by article 2.1 of the "Law 17/1967, of april 8th, updating the current regulations on narcotic drugs and adapting them to the provisions of the United Nations Single Convention on Narcotic Drugs, 1961" as these substances are included in the List of Drugs Included in Schedule I, but not IV, of the Convention: Article 2.1 (in Spanish): "A los efectos de la presente Ley, se consideran estupefacientes las sustancias naturales o sintéticas incluidas en las listas I y II de las anexas al Convenio Único de mil novecientos sesenta y uno de las Naciones Unidas, sobre estupefacientes y las demás que adquieran tal consideración en el ámbito internacional, con arreglo a dicho Convenio y en el ámbito				

	psychotropic substances thereof and plants, illegal handling and abuse of which endangers health) states that cannabis, cannabis resin, oil, extracts and tinctures are products of plant origin with narcotic effect: classified in conformity with the Single Convention on Narcotic Drugs of 30 March 1961. Therefore use of marijuana/cannabinoids for medical or any other purpose is prohibited in Latvia.	nacional por el procedimiento que reglamentariamente se establezca." 2.- The use of CANNABIS AND CANNABIS RESIN, with or without medical purposes, is forbidden in Spain by article 2.2 of the "Law 17/1967, of april 8th", as these substances are included in the List of Drugs Included in Schedule IV of the Convention: Article 2.2 (in Spanish): "Tendrán la consideración de artículos o géneros prohibidos los estupefacientes incluidos o que se incluyan en lo sucesivo en la IV de las listas anexas al citado Convenio, que en consecuencia no podrán ser objeto de producción, fabricación, tráfico, posesión o uso, con excepción de las cantidades necesarias para la investigación médica y científica, incluidos los experimentos clínicos con dichos estupefacientes que se realicen bajo la vigilancia y fiscalización de la Dirección General de Sanidad." 3.- Finally, the use of some PSYCHOTROPIC SUBSTANCES (Tetrahydrocannabinol, the following ~~isomers and their stereochemical~~ variants: 7,8,9,10-Tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol 8,9,10,10atetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol 6a,9,10,10a-Tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol				

		6a,7,10,10a-Tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol 6a,7,8,9-Tetrahydro-6,6,9-trimethyl-3-pentyl- 6H-dibenzo[b,d]pyran-1-ol 6a,7,8,9,10,10a-Hexahydro-6,6-dimethyl-9- methylene3-pentyl-6H-dibenzo[b,d]pyran-1-ol) is forbidden in Spain by article 2.1 of the "Royal Decree 2829/1977, of October 6th, regulating psychotropic substances and psychotropic medicinal preparations, as well as the control and inspection of its manufacturing, distribution, prescription and dispensation," as these substances are included in the List of substances in Schedule I of the Convention: Article 2.1 (in Spanish): "Quedan prohibidos, incluso a los efectos de la Ley de Contrabando, el uso, la fabricación, importación, exportación, tránsito, comercio, distribución y tenencia, así como la inclusión en todo preparado de las sustancias incluidas en la Lista I." Therefore, EXTRACTS and TICTURES OF CANNABIS can be part of medicinal products, for which the general rules for obtaining a marketing authorization must be applied as stated in the Additional Disposition First of the "Royal Decree 1345/2007, of October 11th, governing the procedure for authorization, registration, and dispensing conditions of industrially produced medicinal products for human use" (in Spanish):				

		"Disposición adicional primera. Aplicación a otros medicamentos fabricados industrialmente. El presente real decreto se aplicará, en lo que no se establezca en su norma específica, a los medicamentos con sustancias psicoactivas con potencial adictivo." Nowadays, in Spain there's only one authorised medicinal product containing extract of cannabis: SATIVEX®. All the current legislation in Spain relating this issue is available in the following link: http://www.aemps.gob.es/legislacion/espana/medicamentosUsoHumano/estupefacientesPsicotropos.htm				
LIECHTENSTEIN	In Liechtenstein the Swiss legislative act is applicable, see http://www.bag.admin.ch/themen/drogen/00042/00643/15378/index.html?lang=de					
NETHERLANDS	Since 1 January 2001 the Office for Medicinal Canabis Research (OMC) has been the government agency responsible for implementing the Single Convention on Narcotic Drugs. It is also responsible for overseeing the production of cannabis for medicinal and scientific purposes. The OMC has a monopoly on supplying medicinal cannabis to pharmacies, and on its import and export. The OMC also processes applications for exemptions from the Opium Act relating to cannabis and cannabis resin. The quality of the medicinal cannabis is guaranteed by a constant					You can find all information relevant to answer your question on the website of the OMC agency, which is fully in English: www.cannabisbureau.nl/en

	supervision of the grower and the distributor. The Opium Act makes a distinction between category I drugs (hard drugs) and category II drugs (soft drugs). The Act states that it is an offence to: • take drugs of either category across the borders of the territory of the Netherlands; • prepare, treat, process, sell, supply, provide or transport drugs of either category; • possess drugs of either category; or • manufacture drugs of either category. The Opium Act provides a list of category I and category II drugs. You may apply for an exemption from this prohibition. This exemption is called an opiumontheffing in Dutch. Who can apply for an exemption? Exemptions are intended for businesses or agencies wishing to work with drugs referred to in the Opium Act. Under certain conditions the prohibition does not apply to pharmacists, dispensing GPs and veterinarians. Nor does it apply to					
	government-affiliated agencies, or to persons or agencies that stock drugs for medicinal or dentistry purposes or for their own medicinal use (see article 5 of the Opium Act). Exemptions are granted for the following purposes: • public health					

	• animal health (with a distinction between exemptions for training sniffer dogs and other exemptions) • academic or chemical analytical research • training • trade-related purposes What is the legal basis for exemption? Section 8, paragraph 1 (a-c) of the Opium Act.					
SPAIN				No.	YES SATIVEX SATIVEX® is indicated as an add-on treatment of moderate to severe spasticity in multiple sclerosis. SATIVEX® is a medicinal product for Hospital Diagnosis and must be dispensed by the hospital pharmacy services, requiring Official Narcotic Drug Prescription. Each 100 µL pump-action oromucosal ~~Sativex spray~~ actuation provides 2.7 mg of THC and 2.5 mg of CBD. Same procedure as any medicinal product as established in the Royal Decree 1345/2007	Medicinal products containing narcotic drugs have to comply with the same quality, safety and efficacy standards as the rest of the products. However, they are prescribed with special prescriptions and they are subject to special safety features on labelling.

SWEDEN	Iceland's answer seems to reflect the situation in Sweden. It's legal when used in authorized medicinal products.	As in Iceland, the only product currently authorized is Sativex.	Sativex is an oromucosal spray.	No.	It's allowed if you have permission from the Swedish Medical Products Agency. Today no one have permission.	No.
SWISS	Cannabis, its formulations (oil, resin, extract, tincture), cannabis seeds, Dronabinol, Tetrahydrocannabinol are scheduled in schedule d (Betäubungsmittelverzeichnisverordnung; BetmVV-EDI) German: https://www.admin.ch/opc/de/classified-compilation/20101220/index.html French: https://www.admin.ch/opc/fr/classified-compilation/20101220/index.html Italian: https://www.admin.ch/opc/it/classified-compilation/20101220/index.html For Cannabis, Dronabinol or THC (substances and preparations), Article 8 of the Federal Act on Narcotics and Psychotropic Substances (Narcotics Act, NarcA) applies. English: https://www.admin.ch/opc/en/classified-compilation/19981989/index.html Concerning medical use of cannabis Article 8 paragraphs 5, 6 and 7 NarcA are relevant. Art. 8 para. 5 NarcA: Cannabis and its preparations could be used with exceptional licence of the Federal Office of Public Health, but only in the following cases: - scientific research	Only authorised medicinal product is Sativex. Concerning other preparations the Federal Office of Public Health is responsible (See 1)	Responsability of the Federal Office of Public Health (See 1)	Yes, with exceptional licence of the Federal Office of Public Health, Article 8 paragraph 6 (see as well 1)	See 1, in the responsability of the Federal Office of Public Health	According to the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act) English: https://www.admin.ch/opc/en/classified-compilation/20002716/index.html German: https://www.admin.ch/opc/de/classified-compilation/20002716/index.html French: https://www.admin.ch/opc/fr/classified-compilation/20002716/index.html Italian: https://www.admin.ch/opc/it/classified-compilation/20002716/index.html

	- development of medicinal products - restricted medical use Art. 8 Prohibited narcotics1 NarcA 1 The following narcotics may not be cultivated, imported, produced or placed on the market:2 a. opium for smoking and the residues created in its production or use; b. diacetylmorphine and its salts; c. hallucinogens such as lysergide (LSD 25); d.3 narcotics containing an effective concentration of cannabinoids.4 2 ...5 3 The Federal Council may prohibit the import, production and placing on the market of further narcotics if international agreements prohibit their production or the most important producer countries cease their production.6 4 Any stocks of prohibited narcotics must be transformed under the supervision of the relevant cantonal authority in to a legally-permitted substance or, if this is not possible, destroyed. 5 The Federal Office of Public Health may issue exceptional licences for cultivating, importing, producing and placing on the market the narcotics mentioned in paragraphs 1 and 3, where this is not prohibited by an international agreement and these narcotics are needed for scientific research, the development of medicinal products or for restricted medical use.7					

	6 For the cultivation of a narcotic mentioned in paragraphs 1 and 3 that is an active ingredient in an authorised medicinal product, an exceptional licence is required from the Federal Office of Public Health.8 7 For the import, production and placing on the market of a narcotic mentioned in paragraphs 1 and 3 that is an active ingredient in an authorised medicinal product, a licence is required from the Agency in accordance with Article 4.9 8 The Federal Office of Public Health may grant exceptional licences, provided the substances mentioned in the paragraphs 1 and 3 are used in control measures.10 Decision and under which conditions this exceptional licence could be granted is in the responsibility of the Federal Office of Public Health. Further information concerning exceptional licences the Federal Office of Public Health published under (German, French, Italian): http://www.bag.admin.ch/themen/drogen/00042/00643/15378/index.html?lang=de					
	According to Article 8 paragraph 7, medicinal products covered by a marketing authorisation do not require this exceptional licence. The only product currently authorised is Sativex.					