



**E.M.C.D.D.A.**

European Monitoring Centre  
for Drugs and Drug Addiction

# European Legal Database on Drugs

<http://eldd.emcdda.org/>

## Medicinal cannabis and derivatives

*A legal analysis of the options, their limitations,  
and current practice in the EU*

EMCDDA

ELDD Comparative Study

May 2002

Published at

[http://eldd.emcdda.org/databases/eldd\\_comparative\\_analyses.cfm](http://eldd.emcdda.org/databases/eldd_comparative_analyses.cfm)

# Medicinal cannabis and derivatives

## Introduction

This report has been produced by the EMCDDA as a practical development of its legal database on drugs. Medicinal cannabis is one of the topics in the field of drugs that produces lively debates in the political and scientific arenas. In this brief paper, the EMCDDA looks at the issue of medicinal cannabis and derivatives from a legal viewpoint, both internationally and nationally. The assistance of the ELDD Legal Correspondents has once again been invaluable in the development of this document, and we are especially grateful to Dr Willem Scholten of the Dutch Bureau of Medicinal Cannabis for his advice on scientific matters throughout the drafting process. Information has also been gathered from the final Report and Reader of the International Conference on Medicinal Cannabis, held in the Hague, Netherlands, on 22-23 November 2001, and the European Agency for Evaluation of Medicinal Products (EMA).

## Background and definitions

For some years now, cannabis or its derivatives has been advocated for medical use by various sources – political and scientific – due to the apparent relief of certain symptoms brought about by it. A number of countries<sup>1</sup> are experimenting with its use to counter symptoms of:

- Nausea and vomiting during chemo- and radiotherapy
- Glaucoma
- Multiple Sclerosis (spasticity)
- AIDS-related wasting and appetite loss
- Spinal cord injury or disease
- Chronic pain management such as severe arthritis; and
- Tourette's Syndrome.

Arguments against its use include that there are already similar or more efficient and already tested drugs on the market for these purposes, but this argument is based on scientific merits and so cannot be adequately addressed in this legal analysis.

## Substances

The term “medicinal cannabis” in fact can encompass a number of different adaptations of the drug, which create different consequences both legally and medically. These include:

1. Cannabis Herb and Resin – any part of the plant *Cannabis Sativa L.*, or the resin extracted from the tops of the plant;
2. Cannabis extract – any extract, usually an oil, extracted from the plant, and any preparation consisting mainly of it, also known as hashish oil;
3. Cannabinoids. These are a class of chemical compounds that have the typical cannabinoid skeleton in common. In nature cannabinoids are only known to occur in cannabis, which contains over 60 cannabinoids. Cannabinoids include:
  - THC, a group of very closely related compounds called isomers, one of which is Delta 9 THC. The WHO name (International Non-proprietary Name, INN)

---

<sup>1</sup> Belgium, France, Germany, Netherlands, UK, Finland

for the particular variant of delta-9-THC which occurs naturally in the cannabis plant ((-)-trans-delta-9-THC) is dronabinol, and in much literature the terms are used interchangeably. Chemically synthesized dronabinol is marketed as Marinol;

- nabilone (marketed as Cesamet), a synthetic cannabinoid not occurring in nature;
- other naturally occurring cannabinoids, not controlled under international law, because they seem to have no psychotropic action. These include cannabidiol (CBD), cannabinol (CBN), cannabichromene (CBC), and cannabigerol (CBG).

These substances can be administered in a number of ways, primarily:

- Spray or vaporiser
- Capsules
- Eye-drops.

Smoking is also possible.

### ***Levels of permission***

Distribution and use of certain cannabis derivatives may require some form of licence or permission from the national government, depending on how that medicine or substance is classified under national criminal and pharmaceutical law.

Permission may be for **research purposes** only, for **clinical trials**, **limited medical use** (limited by licence or criteria), or **general medical use**. It may or may not permit prescription by doctors, magistral (self-made) preparations by pharmacists, or dispensing of already-prepared / finished products by pharmacists.

### **1. Research**

Some legislations allow studies for laboratory research purposes only, but a wealth of research material has been published over recent years as to the scientific nature of cannabis. Therefore the permission for research has been interpreted to include research via clinical trials (eg. in Ireland and UK).

### **2. Clinical studies**

Clinical studies may be governmental responsibility, or carried out by private companies under licence to conduct the research. These trials may be with only one form of cannabinoid listed above, or comparisons of effects between them.

Practical issues at this point include legal supply of the substance for the trials, controlling the dose of the substance, finding the most appropriate form for each indication (illness), and minimising and controlling the active ingredients and additives that accompany the substance.

### **3. Limited medical use**

Following trials, the next phase of development would be to permit some medical use, but specifically limited by, for instance, requiring licences for each individual doctor or pharmacy involved. It may also require legal changes for some substances which are, up to now, excluded from medical use except for research purposes, as above. It is usually at this point that the drugs may be made available on prescription, and perhaps kept by pharmacies for either magistral use (self-prepared medicines kept in stock) or

extemporaneous use (prepared for each individual patient). Alternatively, but more expensively, drugs could be privately imported from another country where they are more available. The drugs could not be marketed.

#### **4. General medical use**

It is generally considered that general medical use would involve finished drugs manufactured by pharmaceutical companies with authorisations for marketing, once reproducible quality, safety, and efficiency is proven. This is already the case for dronabinol and nabilone, drugs which have been licensed for medical use as Marinol in the USA and Cesamet in Canada respectively.

### **Legal frameworks**

The legislation on medicinal cannabis and derivatives can be roughly divided into two categories. Firstly, there is the framework which controls the substance in the criminal and medical spheres – its classification, limits on use and distribution, etc. Secondly, and complementary to these controls, is the legal framework for the infrastructure and distribution of the product; establishment of agencies, licensing of growers, and control of doctors and pharmacies. With these two concepts in mind, this paper now looks at international, European, and national legal frameworks respectively.

#### ***International legal framework***

It should be remembered at all times that the international legal framework, primarily the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances, is effectively a minimum requirement. Signatory Parties are permitted to apply more restrictive laws or procedures as in their opinion are necessary or desirable for the protection of the public health or welfare<sup>1</sup>.

#### **Current classifications**

Cannabis and cannabis resin are classified under Schedule I and Schedule IV of the 1961 Single Convention. Extracts and tinctures of cannabis are classified under Schedule I of the same Convention. THC is listed in Schedule I of the 1971 Convention on Psychotropic Substances, and delta-9-THC and its stereochemical variants, including dronabinol, is listed in Schedule II of that Convention. Nabilone, another INN, is a THC derivative but not a stereochemical variant of delta-9-THC and so is not controlled in international law. The leaves of the cannabis plant are barely covered by the 1961 Convention, but that is because they have comparatively low THC yield, and therefore they are unlikely to have a risk of abuse. The seeds of the plant are also not controlled.

#### **The 1961 Single Convention**

The criteria for classification under the 1961 Convention are twofold: the substance's "degree of liability to abuse" and its "risk to public health and social welfare"<sup>2</sup>.

Substances must be listed in Schedule I or Schedule II. Preparations are listed in Schedule III, and substances may be additionally listed in Schedule IV.

<b>Schedule</b>	<b>Guidelines for included substances</b>	<b>Cannabinoids currently included</b>
Schedule I	Those which are, inter alia, having, or convertible into substances having, “a liability to abuse comparable to that of cannabis, cannabis resin, or cocaine” <sup>3</sup> .	<ul style="list-style-type: none"> <li>• Cannabis and cannabis resin</li> <li>• Extracts and tinctures of cannabis</li> </ul>
Schedule II	Substances 1. “Having addiction-producing or addiction-sustaining properties not greater than those of codeine but at least as great as those of dextropropoxyphene; or 2. Convertible into a substance having addiction-producing or addiction-sustaining properties with an ease and yield such as to constitute a risk of abuse not greater than codeine.” <sup>4</sup>	
Schedule III	Preparations which are intended for legitimate medical use, and which the WHO considers not liable to abuse and cannot produce ill effects, and the drug therein is not readily recoverable <sup>5</sup> .	
Schedule IV	Substances that are particularly liable to abuse and to produce ill effects, and such liability is not offset by substantial therapeutic advantages not possessed by substances other than drugs in Schedule IV <sup>6</sup> .	<ul style="list-style-type: none"> <li>• Cannabis and cannabis resin</li> </ul>

It is unlikely, though not impossible, that a Schedule III preparation will contain a drug listed in Schedule IV, as the latter is supposed to have little therapeutic value <sup>7</sup>.

An extra level of control is proposed for substances in Schedule IV, whereby the “Party shall, *if in its opinion* the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare, prohibit the production, manufacture, export and import of, trade in, possession or use of any such drug *except for amounts which may be necessary for medical and scientific research only, including clinical trials therewith...*”<sup>8</sup> (emphasis added). There are therefore no international legal prohibitions on clinical trials with cannabis that are authorised by national governments. Such a wide prohibition by a Party depends on the bona fide (not just declared) opinion of that Party<sup>9</sup>.

In a similar way, a party is expected to prohibit the cultivation of cannabis only if it considers this to be the most suitable measure for protecting the public health and welfare and preventing the diversion of drugs into the illicit traffic<sup>10</sup>. When interpreting “public health”, the public can also be the public of another country<sup>11</sup>.

For substances other than those in Schedule IV, Parties are permitted, subject to the provisions of the 1961 Convention, to undertake the production, manufacture, export, import, distribution of, trade in, use and possession of drugs for medical purposes<sup>12</sup>. The sphere of “medical purposes” is clearly wider than the “medical research including clinical trials” specified for Schedule IV substances. The term “medical purposes” should be interpreted at the stage of medical science at the time in question, and can be interpreted differently by different governments<sup>13</sup>.

If a party permits the cultivation of cannabis plants for the production of cannabis or cannabis resin, a national agency is required to have the exclusive right of importing, exporting, wholesale trading and maintaining stocks of cannabis and cannabis resin<sup>14</sup>. It

is not yet clear at what stage a national agency should be established. Some Member States consider that it should be as soon as the country requires cultivation of cannabis for clinical trials, others think it is only necessary for trade. The INCB has been asked for clarification<sup>15</sup>.

As extracts and tinctures of cannabis are effectively preparations for the purposes of the above, it is assumed that manufacturers are allowed to keep stocks of cannabis and cannabis resin in order to make the “preparations” of extracts and tinctures of cannabis<sup>16</sup>. Manufacturing should be under licence when it is not carried out by a State enterprise<sup>17</sup>. Licensed manufacturers should require periodical permits, though this need not apply for manufacture of preparations<sup>18</sup>. Similarly, retail pharmacists and medical practitioners should not need this manufacturing licence for compounding preparations<sup>19</sup>.

Regarding trade and distribution, there are 4 types of authorisation defined under the Convention<sup>20</sup>. These are for:

- the right to trade,
- the right to use premises for trade and distribution,
- those persons duly authorised to perform therapeutic and scientific functions without the above two licences, and
- a prescription to supply drugs to individuals.

As with manufacture, a licence is not required for trade and distribution by a State enterprise, though it would require a licence for the right to use premises<sup>21</sup>. Preparations also require licences for trade and distribution, though not for the use of premises<sup>22</sup>. Medical practitioners are exempt from both trade and premises licences, though pharmacists are not<sup>23</sup>.

Parties should require medical prescriptions for the supply of drugs to individuals (except to medical practitioners)<sup>24</sup>. Sale of drugs to patients other than the physician’s would not be a therapeutic function, and so would require the prescription of another medical practitioner. For international trade and distribution, general authorisation under the 1961 Convention is not required for medical practitioners who occasionally import small quantities of substances for medical purposes, or for patients who import minor amounts for their own medically prescribed use<sup>25</sup>.

## The 1971 Convention on Psychotropic Substances

The criteria for classification under the 1971 Convention are as follows:

<b>Schedule</b>	<b>Guidelines for included substances</b>	<b>Cannabinoids currently included</b>
Schedule I	Substances whose liability to abuse constitutes an especially serious risk to public health and which have a very limited, if any, therapeutic usefulness	<ul style="list-style-type: none"> <li>• THC, specified isomers and their stereochemical variants</li> </ul>
Schedule II	Substances whose liability to abuse constitutes a substantial risk to public health and which have little to moderate therapeutic usefulness	<ul style="list-style-type: none"> <li>• Delta-9-THC and its stereochemical variants</li> </ul>
Schedule III	Substances whose liability to abuse constitutes a substantial risk to public health and which have moderate to great therapeutic usefulness	
Schedule IV	Substances whose liability to abuse constitutes a smaller but still significant risk to public health and which have a therapeutic usefulness from little to great	

Schedule I substances are subject to the most strict controls under the 1971 Convention. Import and export, and manufacture, trade, distribution and possession of Schedule I substances should be under a special licence<sup>26</sup>. Use under such a licence is permitted only for very limited medical purposes by duly authorised persons, in State or licensed medical or scientific establishments<sup>27</sup>. Note that this limit does not apply only to clinical trials – as the option of control for substances in Schedule IV of the 1961 Single Convention – but to the wider sphere of “very limited medical purposes”. In fact, it may be that Parties follow different rules in implementing their obligation to permit only a “very limited medical use” of substances. They may be guided by their own values of medical use, degree of harmfulness, and principles of freedom of medical practice<sup>28</sup>. But individual medical practitioners should be licensed, and quantities available should not exceed those necessary<sup>29</sup>.

For a substance in Schedule II, III or IV, import and export, manufacture, trade, and distribution should be under licence or special control<sup>30</sup>. However, governmental authorisation is not required for a medical practitioner who occasionally imports, manufactures, trades or distributes small quantities of substances for medical purposes<sup>31</sup>, nor for preparations of such substances that have been exempted under Art 3.3.

These substances and their preparations should only be supplied pursuant to medical prescription, which must be addressed to an individual, except when used for authorised medical or scientific functions<sup>32</sup>. Licensed pharmacies and retailers can supply small quantities of Schedule III and IV substances without prescription in exceptional circumstances<sup>33</sup>. No governmental authorisation is required for compounding a preparation of substances in Schedules II, III, IV in pharmacies on prescription, or compounding by a medical practitioner for a patient<sup>34</sup>. There is not even a requirement to limit such dispensing to the most highly qualified medical practitioners<sup>35</sup>. In fact, preparations under these Schedules can be exempted from the requirement of prescription if there is only a negligible risk of abuse<sup>36</sup>.

## Amendments to the Conventions

Schedules can be amended for, *inter alia*, the purpose of facilitating the availability of substances for therapeutic purposes. This may happen when a Party or the World Health Organisation (WHO) has information justifying the transfer of a substance between Schedules, or even its deletion from them. The procedure may be initiated by a Party or by the WHO<sup>37</sup>.

In the 1961 Convention, the Commission for Narcotic Drugs (CND) is able to transfer a substance from Schedule I to Schedule II or vice versa, or delete a drug or preparation from a Schedule, in accordance with the recommendation of the WHO; it may also take no action<sup>38</sup>.

In the 1971 Convention, the CND is not legally bound to act only on WHO recommendations, and can schedule, reschedule or deschedule a substance according to factors of an economic, social, legal or administrative nature, even when such a change has not been recommended by the WHO. In this procedure the CND has a much wider discretion under the 1971 Convention than the 1961 Convention. However, the CND must still consider the WHO assessments to be determinative as to medical and scientific matters<sup>39</sup>. In this way, an objection on grounds of danger to public health would be unlikely to be sustained.

If results of research warrant it, cannabis, its resin, and extracts and tinctures of cannabis could be transferred from Schedule I to Schedule II and deleted from Schedule IV<sup>40</sup>. However, one should be aware that these substances are part of the main benchmark for Schedule I, implying the benchmark may also need adjusting if they are rescheduled.

Under the 1971 Convention, it is theoretically possible to keep a substance in Schedule I and use it therapeutically<sup>41</sup>. However, the CND would be acting *ultra vires* if a substance was kept in Schedule I despite WHO finding that it had more than a “very limited” therapeutic usefulness and expressly or impliedly recommended removal from that Schedule. This is because it “would unduly restrict its availability for medical and scientific purposes, and thus conflict with requirements of sound principles of public health and also with basic aims of the [1971] Convention”<sup>42</sup>.

As regards preparations, the CND can exempt those listed in Schedule III of the 1961 Convention from certain controls applied to the substances therein<sup>43</sup> – such an exemption is valid for all Parties. Under the 1971 Convention, this blanket exemption is not available to the CND, only for one Party, and is not possible at all for preparations containing substances in Schedule I. The exemptions may be granted if the preparation is compounded in such a way that it presents no, or a negligible, risk of abuse and the substance cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health problem<sup>44</sup>. There are therefore legal implications for including cannabis products in preparations, rather than distributing the substance itself.

In the 2001 Annual Report of the International Narcotics Control Board (INCB), the body responsible for promoting government compliance with the provisions of the drug control treaties, the INCB addressed the topic of medicinal cannabis. It welcomed the research into possible therapeutic properties and medical uses of cannabis or cannabis extracts, reiterating that any decision on their medical use should be based on clear scientific and medical evidence. It also took the opportunity to remind governments of those countries



conducting research of the control requirements of the treaties to reduce the risk of diversion and abuse of the substances<sup>45</sup>.

## ***EU legal framework***

With competence only recently extended to the EU in the field of Justice and Home Affairs, where classification of cannabinoids is usually addressed, the main Community legislation on medicinal cannabis and derivatives is in the sphere of medicine and pharmacology.

The EU legal framework regarding medicinal products for human use was codified by the Directive 2001/83/EEC of 6 November 2001<sup>46</sup>.

Under this Directive, a medicinal product is defined as “Any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product<sup>47</sup>. A substance is defined as including “Any matter irrespective of origin which may be vegetable (e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts)”.

Nevertheless, this Directive does not apply to magistral or official (extemporaneous) preparations that have been prepared in a pharmacy, as well as medicinal products intended for research and development trials<sup>48</sup>. In most countries this exemption is used for enabling pharmacists to make tailor-made medicines, though the degree to which it is used varies between countries. It is therefore possible to state that the system of regulation established by EU pharmaceutical law does not disallow magistral and extemporaneous preparations of certain cannabinoids.

Should any cannabis-based medicinal product be placed for sale or distribution on the market in a Member State, it will require marketing authorisation, and on this issue the EU legislation is comprehensive. Article 6 of Directive 2001/83/EEC states that “no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EEC) Nr 2309/93”.

In fact, these two options may result in marketing authorisation valid for all Member States.

In the first scenario, the manufacturer who registered the product can apply to a national Medicine Evaluation Agency for authorisation for the national market. If this is granted, the manufacturer or that Member State can then request marketing authorisation in all Member States on the basis of mutual recognition of the national authorisation in each Member State, under Art 28 of the above Directive (the Mutual Recognition Procedure). If a Member State objects due to a perceived risk to public health, then either the application can be withdrawn, in which case the product will not become available in that specific Member State, or the European Agency for the Evaluation of Medicinal Products (EMA) will act as arbiter. If the application is withdrawn, the applicant is not allowed to submit a national application subsequently, an independent national marketing authorisation for a medicinal product already authorised in another Member State being illegal. If it comes to arbitration by EMA, a scientific evaluation by the Committee for

Proprietary Medicinal Products should lead to a decision that will be binding on all Member States, and so the product may become available in all Member States.

In the second scenario, the Centralised Procedure, the EMEA would be the EU agency directly responsible for the granting of marketing authorisations for medicinal products, which are derived from biotechnology or are “Innovative medicinal products”. The latter class includes products containing a new active substance, or those presented for an entirely new indication which in the opinion of the EMEA are of significant therapeutic interest, “new” in both cases meaning not authorised before in the EU. Based on this, it would be possible for cannabis herb/extract, THC, and delta-9-THC to be classed as innovative medicinal products.

Finally, the EMEA released a Public Statement on 18 Sept 2001<sup>49</sup> in which it outlined the possibility for accelerated evaluation of products indicated for serious diseases. This might be initiated in exceptional cases to provide an answer to a major public health need, defined by three cumulative criteria:

- The seriousness of the disease to be treated (examples given include AIDS, cancer),
- The absence of an appropriate alternative therapeutic approach, and
- The anticipation of exceptional high therapeutic benefit.

This might be relevant to certain applications for approval of a cannabinoid medicine.

### ***National legal frameworks***

EU Member States are at varying stages of trials, manufacture, distribution and prescription of cannabinoids for therapeutic purposes.

### **National agencies**

Regarding cannabis and cannabis resin, the only country in Europe so far to establish a national agency, as required by the 1961 Convention, for the monopoly of wholesale and stock is the Netherlands. The Dutch Bureau of Medicinal Cannabis came into force in January 2001 and its monopolies will be confirmed in an amendment to the Opium Act that will almost certainly come into force in September 2002. The UK, though licensing the growing of cannabis for medicine, has not yet established an agency, considering that it is not necessary while it is only undertaking clinical trials.

It is notable that the Dutch Bureau of Medicinal Cannabis is established in the Health Ministry in the Department of Pharmaceutical Affairs and Medical Technology, and not in the Department of Addiction Affairs and Mental Health. This is because the users should be treated as patients taking medicine, rather than people abusing illegal drugs, and in order to control conformity with all standard pharmaceutical requirements<sup>50</sup>.

### **Clinical trials**

EU Member States already undertaking clinical studies are Germany, Netherlands, Finland, and the UK, with Belgium, France and Spain considering the matter.

Under UK legislation, s7(3) of the Misuse of Drugs Act 1971 allows medical use of drugs, unless they are “designated” as non-medical by s7(4) if the Secretary of State is of the opinion that this is in the public interest. Cannabis is so designated, so it can only be licensed for cultivation etc for the purposes of research or other special purposes. In fact, the UK government has licensed a private company, GW Pharmaceuticals, to grow cannabis and carry out clinical trials of a sub-lingual spray containing cannabis extract.

Phase I (tests in healthy volunteers) and Phase II (tests in a limited number of patients) have been successfully completed, and the company is now undertaking Phase III, a comprehensive evaluation of safety and efficacy in a large number of patients, over 120 so far.

Doctors in Norway can apply to National Board of Health and to the Norwegian Medicines Agency for exemption to perform a controlled trial, but such applications are unknown<sup>51</sup>.

In the Netherlands, an amendment to the Opium Act in 1999 allowed clinical trials with cannabis and prescriptions. At present, the Dutch government is planning clinical trials comparing high dronabinol cannabis with dronabinol and CBD containing cannabis, plus placebo<sup>52</sup>. The Royal Decree on Prescribing and Ordering Opium Act Related Medicinal Products (Besluit voorschrijven en bestellen opiumwetmiddelen - Staatsblad 1999;256) lists controlled substances that may be prescribed. Any controlled substance which is not listed may only be used in clinical trials with a special licence<sup>53</sup>. Should the clinical trials prove successful, an amendment to the Royal Decree will add the appropriate substance to the list of those which may be prescribed.

In Belgium, the Royal Decree "Arrêté royal déterminant les conditions pour la délivrance des médicaments contenant un ou des tétrahydrocannabinol(s)" of 19 July 2001 established the legal framework for clinical trials. Such research with medicines containing one or more THC is likely to start in the second half of 2002, and will be conducted by GW Pharmaceuticals, the same company who are trialling products in the UK, rather than the Ministry of Health. Special preparations containing dronabinol as the only active substance are excluded from the coverage of this latest Decree.

Clinical trials with Marinol will start in France in September 2002<sup>54</sup>. Temporary Use Authorisations (ATUs) have been issued to allow specified doctors to prescribe to specified patients the substances dronabinol, nabilone, or delta-9-THC plus cannabidiol (this last substance being the sublingual spray developed in the UK) since September 1999<sup>55</sup>. Production, marketing and use of cannabis and THC (except synthetic delta-9-THC) is prohibited, but special authorisations can be issued for research by the Head of AFSSAPS, the French Health Products Safety Agency, under Article R.5181 of the Code de la Santé Publique.

In Germany, the Narcotics Act s.3.2 states that cannabis could be used only on the basis of authorisation for scientific or other purposes which are in the public interest. This has been granted for trial in May 1999<sup>56</sup>, and some 60-80 patients are participating in a trial with cannabis extract over the next three years.

Finland is carrying out studies on the effectiveness of cannabinoids on glaucoma<sup>57</sup>.

In Italy, there is no movement at the national level, but in early 2002 three regions – Lombardy, Umbria and Tuscany – raised motions to request the national government and parliament to regulate the medical use of cannabis and its derivatives.

## **Pharmacies and prescription systems**

In Germany, the Narcotics Act s.5.1.6 states that the purpose of the Act is to secure required medical care for population, and preclude the development of maintenance and addiction. The Federal High Court stated in 1999 that medicinal use of cannabis could be the subject of a licence in accordance with Art 3.2 of the Narcotics Act, but 120

private applications have been refused so far as use would be of illegal non-standard cannabis, whose effectiveness cannot be proved<sup>58</sup>. Nevertheless, if reproducible quality, safety and efficiency is proven, the active ingredient THC might be included in Schedule III (licit narcotics available on special prescription)<sup>59</sup>, and it is possible also for natural mixtures (eg cannabis extract). However, it would not be possible for hashish or marihuana as the content or additives cannot be controlled. Meanwhile, one can import and prescribe Marinol or Cesamet in individual cases on the basis of s.73.3 of the Medicines Act, though private importing is expensive. Marinol is also now authorised for sending to pharmacies for use in the magistral preparation of drugs.

Doctors in Norway can apply to the National Board of Health for an exemption to use certain drugs in treatment if needed, but such an exemption is seldom applied for<sup>60</sup>.

The Netherlands permits prescription of dronabinol. It is available as Marinol only, a pharmaceutical product which can be imported on special licence of the Health Care Inspectorate<sup>61</sup>. For cannabis, the Dutch government is operating two policies. In the long term they wish to develop a registered medicine, but in the short term, once the legal framework is in place, they will temporarily prescribe cannabis herb through pharmacies<sup>62</sup>. An amendment will add hemp to the list of prescribable substances in the Royal Decree, so it is not prohibited for doctors to prescribe and pharmacists to deliver, and this will come into force as soon as the new Bureau of Medicinal Cannabis has organised the legal supply to pharmacies, expected in 2003<sup>63</sup>.

UK doctors can prescribe medicine based on cannabis or cannabis extracts to patients under licence from the Home Office. This must only be for the purposes of research, though research includes clinical trials<sup>64</sup>. Legislative changes would be required to prescribe such medicine to patients without a licence. Marinol (dronabinol) can be prescribed without a licence.

In Austria, Marinol can be prescribed, as can dronabinol in magistral preparations in capsules, which is cheaper than importing Marinol privately. However, neither THC, nor cannabis or its preparations are used in medicine, so prescription of medication containing it is prohibited by the Austrian Narcotic Drug Ordinance (SV)<sup>65</sup>. Nevertheless, in April 2001, the district court of Wels, Upper Austria, acquitted a defendant of growing cannabis because he only used it to relieve his AIDS symptoms. In the oral statement the court gave the explanation that the superior legal interest of a life worth living should override the inferior legal interest of the Austrian Criminal Code<sup>66</sup>.

Similarly, in Italy, a court ruling in Venice on 13 March 2002 declared that the constitutional right to health could not be limited by Italy's ban on cannabis use in the case in question. The judge ruled that the patient's use of cannabis to alleviate symptoms of terminal lung cancer should be tolerated, and the local medical authorities of San Dona di Piave should obtain the drug abroad free of charge and provide it to the patient.

## Discussion

For 40 years, and with much research, cannabis and cannabis resin have been officially classified as substances with little therapeutic value. The same substances are also a benchmark by which other similar controlled substances are measured. The international Conventions have required governmental permission on a politically sensitive subject for research and trials. In practice, if we look carefully at the letter of the Conventions, there has been no official ban on medical use, but such a ban may have been perceived by some governments as following logically from the other restrictions. There has also been the argument used that legalising cannabis for medicinal purposes is in fact a back-door method of legalising it for non-medicinal (recreational) purposes – already a problem with benzodiazepenes – thus confusing the spheres of medicine and controlled non-medicinal substances. Yet, as can be seen above, the drugs involved and their forms of administration are far more complex than the issue of smoking cannabis herb.

Now, an increasing number of trials in different countries are being conducted in the EU (and outside), within a similar timescale, with the full support of the national governments. They aim to objectively prove or disprove the therapeutic benefits of various cannabis derivatives. Some of those trials already appear to show clear therapeutic benefits from cannabis products for certain indications. Opposition due to fears of “back-door legalisation” may note the common finding to date that smoking is shown to be one of the least reliable methods of administration for therapeutic purposes, as it has poor dosage control and a high number of pollutants. As outlined above, some of those countries are moving to alter their legal frameworks to facilitate the use of cannabinoids for medical purposes.

Use of many cannabis derivatives for medical purposes is already permitted by the international legal framework, and it is hoped that the legal analysis given above may clarify this. Nevertheless, the international legal framework as it stands places restrictions on some substances which may unduly hinder their manufacture, production, distribution and use in the medical sphere. If cannabinoids were to be shown to have some therapeutic value, and a Party’s application to the CND were supported by the WHO’s medical and scientific assessment to this effect, it appears from the Commentaries to the Conventions that the CND would be bound to amend the Schedules of the 1971 Convention accordingly<sup>67</sup>. Required amendment of the 1961 Convention is less clear<sup>68</sup>, and also may hinge on the possible alternatives available for therapeutic purposes. Should there be such an amendment, controls on cannabis and cannabis resin as a substance “that is particularly liable to abuse and to produce ill effects” could continue, but it would no longer be subject to the particularly stringent controls reserved for substances which have little therapeutic usefulness. Such amendments to the Conventions would mark a major change of 40 years of the international view of the medical properties of cannabinoids.

---

<sup>1</sup> Single Convention on Narcotic Drugs, 1961 [1961 Convention] Art.39; Convention on Psychotropic Substances 1971 [1971 Convention], Art 23

<sup>2</sup> Commentary on the Single Convention on Narcotic Drugs, 1961. United Nations, New York, 1973 [1961 Commentary] p.86

<sup>3</sup> 1961 Commentary n.2, p.86

- 
- <sup>4</sup> 1961 Commentary n.2, p.86  
<sup>5</sup> 1961 Convention, n.1, Art.3.4; 1961 Commentary, n.2 p. 92  
<sup>6</sup> 1961 Convention, n.1, Art.3.5  
<sup>7</sup> 1961 Commentary, n.2 p. 92  
<sup>8</sup> 1961 Convention, n.1, Art. 2.5.b  
<sup>9</sup> 1961 Commentary, n.2 p. 65-6  
<sup>10</sup> 1961 Convention, n.1, Art. 22  
<sup>11</sup> 1961 Commentary, n.2 p. 275  
<sup>12</sup> 1961 Convention, n.1, Art. 4.1; Art 21  
<sup>13</sup> 1961 Commentary, n.2 p. 111  
<sup>14</sup> 1961 Convention, n.1, Art. 28 in conjunction with Art 23  
<sup>15</sup> International Conference on Medicinal Cannabis, 22-23 November 2001, The Hague – Report [ICMC Report] p. 42  
<sup>16</sup> 1961 Commentary, n.2 p. 314  
<sup>17</sup> 1961 Convention, n.1, Art.29.1  
<sup>18</sup> 1961 Convention, n.1, Art.29.2.c  
<sup>19</sup> 1961 Commentary, n.2 p. 317  
<sup>20</sup> 1961 Convention, n.1, Art.30  
<sup>21</sup> 1961 Convention, n.1, Art.30.1  
<sup>22</sup> 1961 Convention, n.1, Art.30.1.b  
<sup>23</sup> 1961 Convention, n.1, Art.30.1.c; 1961 Commentary, n.2 p. 333  
<sup>24</sup> 1961 Convention, n.1, Art.30.2.b.i  
<sup>25</sup> Commentary on the Convention on Psychotropic Substances. United Nations, New York, 1976 [1971 Commentary] p. 215  
<sup>26</sup> 1971 Convention n.1, Art 7.f; 1971 Convention Art 7.b  
<sup>27</sup> 1971 Convention n.1, Art 7.a  
<sup>28</sup> 1971 Commentary n.26, p. 148  
<sup>29</sup> 1971 Convention n.1, Art 7.d  
<sup>30</sup> 1971 Convention n.1, Art 8.1  
<sup>31</sup> 1971 Convention n.1, Art 8.3; 1971 Commentary n.26, p. 215  
<sup>32</sup> 1971 Convention n.1, Art 9.1  
<sup>33</sup> 1971 Convention n.1, Art 9.3  
<sup>34</sup> 1971 Commentary n.26, p. 170  
<sup>35</sup> 1971 Commentary n.26, p. 179  
<sup>36</sup> 1971 Convention n.1, Art 3.2, 3.3  
<sup>37</sup> 1961 Convention, n.1, Art.3; 1971 Convention n.1, Art 2  
<sup>38</sup> 1961 Commentary, n.2 p. 90  
<sup>39</sup> 1971 Commentary n.26, p. 30-31  
<sup>40</sup> 1961 Commentary, n.2 p. 95  
<sup>41</sup> 1971 Commentary n.26, p. 138  
<sup>42</sup> 1971 Commentary n.26, pp. 31, 71  
<sup>43</sup> 1961 Convention, n.1, Art.2.4  
<sup>44</sup> 1971 Convention n.1, Art 3.2, 3.3  
<sup>45</sup> INCB Report 2001, available at [http://www.incb.org/e/ind\\_ar.htm](http://www.incb.org/e/ind_ar.htm), paras 158-9  
<sup>46</sup> Directive 2001/83/EEC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [Directive 2001/83/EEC], Official Journal L 311/67, Art. 3  
<sup>47</sup> Directive 2001/83/EEC n.46, Art. 1.2  
<sup>48</sup> Directive 2001/83/EEC n.46, Art. 3  
<sup>49</sup> “Accelerated evaluation of products indicated for serious diseases (Life threatening or heavily disabling diseases)” CPMP/495/96 rev.1, available at <http://www.emea.eu.int/pdfs/human/regaffair/049596en.pdf>  
<sup>50</sup> ICMC Report n.15, p. 30  
<sup>51</sup> ICMC Report n.15, p. 20  
<sup>52</sup> ICMC Report n.15, p. 31

- <sup>53</sup> ICMC Report n.15, p. 29  
<sup>54</sup> Communication with AFSSAPS  
<sup>55</sup> International Conference on Medicinal Cannabis, 22-23 November 2001, The Hague – Reader [ICMC Reader] p. 9  
<sup>56</sup> ICMC Reader n.55, p. 11  
<sup>57</sup> ICMC Reader n.55, p. 35  
<sup>58</sup> ICMC Reader n.55, p. 34-5  
<sup>59</sup> ICMC Reader n.55, p. 11-12  
<sup>60</sup> ICMC Report n.15, p. 20  
<sup>61</sup> ICMC Reader n.55, p. 13  
<sup>62</sup> ICMC Report n.15, p. 13  
<sup>63</sup> ICMC Report n.15, p. 31  
<sup>64</sup> ICMC Report n.15, p. 17  
<sup>65</sup> ICMC Report n.15, p. 32  
<sup>66</sup> Austrian National Focal Point report 2001  
<sup>67</sup> See section “Amendments”, above; 1971 Commentary n.26, pp. 31, 71  
<sup>68</sup> 1961 Commentary, n.2 pp. 90-97, cf 1971 Commentary n.26, p. 30 “under the Single Convention, the Commission has only the choice between acting in accordance with the recommendation of the World Health Organisation or not taking any action.”