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A Survey on the Medical Use of Cannabis in Europe: A Position Paper.

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1 **0. Abstract**

2 **Aim:** The aim of the current study is to investigate the status of availability and prescription of
3 different medicinal variants of cannabis and their status in European countries.

4 **Methods:** A web-based survey was sent to all member societies of the European Federation of
5 Addiction Societies (EUFAS) in two waves during the summer of 2017. All 34 member societies in 19
6 different European countries were invited to participate.

7 **Results:** We received 28 responses from 17 European countries. The cannabis extract nabiximol
8 (Sativex®) is the most prevalent cannabis based medicinal product marketed in Europe. Synthetic
9 cannabinoids and standardized cannabis is less prevalent and no countries allow for growing of
10 cannabis for personal medical use. The bringing of medical cannabis products across borders to
11 countries where the drug is not marketed is quite limited. The use of medical cannabis seems to be
12 restricted to some central medical conditions, but off-label use is prevalent in some countries.

13 **Conclusion:** The use of medical cannabis in Europe seems to be restricted mostly to the use of the
14 cannabis extract nabiximol. There is only limited use of the cannabis plant as such for medical
15 purposes possibly indicating a different scenario in Europe as compared to the USA.

16 **Positioning:** EUFAS as an umbrella association of European addiction societies stresses the need for
17 further studies on the efficacy of medical cannabis and warrants for the possible dangers associated
18 with increased popularity of medical cannabis. Regulations on a European level are needed
19 concerning registration and medical indications, the development of uniform compounds and
20 strength of the products, and rules concerning sales and marketing.

1. Introduction

Based on some evidence [1], albeit debated [2, 3] and a common belief in the medical benefits of the cannabis plant but also based on a public opinion wanting to change drug laws, [4], several US states have allowed the use of cannabis for medicinal purposes.

There is increasing research regarding the possible medical uses of cannabis. The most promising lines of research were into wasting syndrome as part of AIDS [4], spasm in relationship to multiple sclerosis (MS) [5], pain [6], nausea following chemotherapy for cancer [7] and also glaucoma [8]. There are also several reports on the use of cannabis for other maladies, such as post-traumatic stress disorder (PTSD), amyotrophic lateral sclerosis, Tourette's disease, epilepsy, Chron's disease, attention deficit and hyperactivity disorder (ADHD), fibromyalgia and others [9]. A meta-analysis performed and published in 2016 concluded that there was moderate evidence for the effect of cannabis on pain and spasm related to MS, but low evidence for the use in chemotherapy related nausea, AIDS related wasting, insomnia and Tourette's syndrome [1]. Others are much more skeptical, criticizing this meta-analysis for its methodology and claiming that the evidence for therapeutic use of cannabis is very low [10].

Possibly as a reflection of the political significance of medical cannabis in the US the product used has to a large degree been cannabis as such, most often in the form of marijuana. As highlighted by the Irish report of 2017 [11] other products are more often used in Europe. This could be marijuana with known content of Δ^9 -tetrahydrocannabinol (THC) and cannabidiol (CBN) (e.g. Bedrocan®), it could be synthetic cannabinoids such as nabilone or dronabinol, or it could be cannabis extracts (nabiximols; Sativex®).

Also in European countries there is an ongoing debate on the legislation of cannabis. Pressure groups working for decriminalization and legalization of cannabis are also quite active in the discussions on medical cannabis. Much of the online information on the legislation on medical cannabis is produced by such NGOs may in fact present a too optimistic view of the current legislation in the different countries.

The aim of the current study was to investigate the status, i.e. availability, legal, of different medicinal variants of cannabis and their use in real clinical practice in several European countries. In an online survey of member societies of European Federation of Addiction Societies (EUFAS) the two following questions were asked:

1. To what extent is cannabis and different types of derivatives allowed for medical use in your country? What products have a market authorization?
2. For what medical conditions is the drug used?

2. Materials and methods

2.1 Materials

This web-based survey was sent to all member societies of the EUFAS in two waves during the summer of 2017. EUFAS is an umbrella organization connecting National country addiction societies (www.eufas.net). All 34-member societies in 19 countries were asked to name up to 5 individual responders, i.e. national researchers or clinicians in the addiction field. If no answer was received up to 2 reminders were sent. The invitation was sent by personalized e-mails to avoid being caught in the e-mail-programs spam, filters. From the member societies where no response was received, the authors of this paper searched the personal files for country contacts. As a last resort, the web was searched for researchers on medical cannabis in the respective countries and e-mails were sent to these.

Twenty-eight responses from 17 European countries were received. Where more than one response was received from a country, the answers were aggregated to construct one answer per country.

2.2 Methods

The survey included questions on a) synthetic cannabis (nabilone, dronabinol), b) cannabis extract (nabiximol; Sativex®), c) standardized cannabis (Bedrocan®, Bedrolite®), d) growing cannabis for personal use and medical purposes and e) the use of wild type cannabis for medical purposes.

For all these, several questions were asked: if there was a market authorization and if the drug was in fact marketed. What the indications for use and possible off-label use were. We also asked about the possibility for so-called compassionate prescribing, i.e. import for personal use from countries where the drug is marketed after receiving a prescription from a doctor. Lastly we asked about the possibility to bring the drug from abroad when travelling, allowing for patients to go abroad to get a prescription and returning home with medical cannabis for personal use.

When asking about the medical conditions for which the drug was used we addressed both the official indications and the other conditions for which the drug was used off-label.

2.3 Ethics

This article does not contain any studies with human or animal subjects.

3. Results

The main results concerning the availability of the different kinds of medical cannabis products in different European countries are shown in tabel 1: Five countries (Austria, Germany, the Netherlands, Spain and UK) indicated that they had marketing authorization for synthetic cannabinoids. Nabiximol (Sativex®) was the drug with most wide spread authorization, marketed in 12 of the 17 responding countries and only 5 countries stating this cannabis drug does not hold marked authorization. Two countries (Germany and the Netherlands) allowed for the use of standardized cannabis. No countries allowed personal growing of cannabis for medical purposes or the use of wild type cannabis for medical purposes.

Judging from the not always identical answers from the countries with several responders there was a bit of uncertainty whether or not patients are allowed to bring cannabis based medicines for personal use travelling from one country to the next or if compassionate prescribing is allowed. These data are not shown. Compassionate prescribing of synthetic cannabinoids was allowed in Belgium, Norway and Romania, while bringing synthetic cannabinoids for personal use was allowed in Norway and Portugal. Compassionate prescribing of cannabis extracts was allowed in Lithuania and Portugal, while bringing cannabis extracts for personal use was allowed in Portugal. Norway and UK allowed bringing standardized medical cannabis for personal use.

Table 2 shows the different indications allowed for each type of cannabis drug. With regard to comprehensiveness, the data are not presented for each country, even if the indications and the off-label use varied substantially between the countries. The great variation between the responses of the countries and even responders within one country may reveal that there is some confusion regarding allowed indications and off-label use. However, the cannabis products were most often used for vomiting and nausea following chemo-therapy, but also in general, for glaucoma (only Denmark) and for spasticity and pain in MS. Some countries mentioned depression and sleeplessness (both standardized cannabis in the Netherlands) and Tourette's syndrome (Austria, Denmark and Norway) as allowed indications.

The conditions for which cannabis is used off-label are of course more varied. Table 2 only mentions those off-label uses not listed among the authorized indications, even if some countries responded that they only used cannabis for one of these indications off-label.

4. Discussion

The major finding of this web-based survey among member societies of EUFAS are 1) that nabiximol (Sativex®) is the most prevalent cannabis product for medical use in Europe. 2) Synthetic cannabinoids and standardized cannabis are less used and only one country allows for growing of cannabis for personal medical use. 3) The bringing of medical cannabis products across borders to countries where the drug is not marketed also seems to be quite limited. 4) The use of medical cannabis is limited to some central medical indications like vomiting and nausea following chemotherapy and spasticity and pain in MS. 5) Off-label use includes many other medical conditions in some countries.

The context of medical cannabis in Europe seems to be quite different to that of the USA [11]. In the US medical cannabis has been introduced largely to bypass international laws regulating cannabis use. In Europe medical cannabis has been introduced through more regular medicinal channels and is authorized through the medicinal agencies [12]. Even if debated, there has been an increasing knowledge on the medical possibilities of cannabis related drugs [11, 13], but still the introduction of medical cannabis has been slower in Europe wanting to lean more on medical evidence than what we have seen in the US. In the States the widespread use of medical marijuana paved the way for legalization and increasingly commercialization. It is difficult to speculate if the different development of medical use of cannabis in Europe will impact similarly on the attitude towards recreation use of cannabis and the legislation surrounding it [14].

This study has several limitations as it is a short web-based study with limited response. We know from other publications that e.g. Sativex® apparently is approved for marketing in 17 European countries [12]. The results of our survey seem to confirm the prominence of Sativex®, i.e. is reported in 12 countries by our responders. However, due to the limited response in our survey it cannot be concluded whether some of the countries having the drug on the market are non-responders in our survey or whether, although approved for marketing, the use (and knowledge of) in real life practice is limited. Indeed, data on the use in real life practices within the different countries are very scarce, and we do not have information on the level of prescribing or use of medical cannabis, thus in spite of our low response rate we think the present data provide an important indication of the medical cannabis context in Europe. Finally, we need to be aware that this is a rapidly changing field and regulations in any given country may change quickly [11].

Given the highly variability and diversity of the context of medical cannabis use and policies in Europe, the EUFAS has taken the results of this survey as a starting point to express its position towards the evolution of medical cannabis in Europe. Within the public opinion the popularity of medical cannabis use is growing. This trend is being enforced by both the commercial interests involved and the media attention. However, caution is needed while several critical elements are still in need of substantiation and generalization (and possible commercialization) might carry negative public health consequences. The following topics need to be addressed more thoroughly to provide a basis for future policy development:

1. There is as yet not enough critical mass of evidence to support the use of medical cannabis in the treatment of most medical conditions. More studies are needed exploring the effectivity and safety of cannabis use and identify its effect on specific disorders.

- 153 2. There is a need to develop more standardization in the different cannabis products. This relates
154 to administration form (smoking, vapor or oral) and standard dosing of active compounds.
155 Regulations (and registration) on a European level are warranted.
- 156 3. The increasing popularity of medical cannabis use and possible future regulation and
157 commercialization initiatives (with associated marketing efforts) carries a great danger of changing
158 the attitudes and perceptions, specifically in adolescents, towards favorable and positive attitudes
159 with respect to cannabis use in general. This can be expected to be associated with an increase in
160 cannabis use [15]. These risks call for well-balanced European level regulations concerning sales and
161 marketing of these products.

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166 This study did not involve any use of human material or research animals and thus did not need an
167 approval from the regional review board on medical research ethics.

168 JGB has no conflicts of interest to report. GD has received honoraria from Lundbeck for alcohol
169 research but has no conflicts of interest inflicting on this cannabis survey. AG has received honoraria
170 from Lundbeck and D&A Pharma for alcohol research but has no conflicts of interest inflicting on this
171 cannabis survey. KM has received honoraria from Lundbeck and Pfizer for alcohol research but has
172 no conflicts of interest inflicting on this cannabis survey. FW has no conflicts of interest to report.

173

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211 **Table 1.** The responses to the web-based survey among the EUFAS member societies on whether they have different cannabis-based product on the market
 212 for medical purposes

Country (number of responders)	Synthetic cannabis (Marinol®, dronabinol)	Cannabis extract (nabiximol; Sativex®)	Standardized cannabis (Bedrocan®, Bedrolite®)	Growing for personal use and medical purposes	Wild type cannabis for medical use
Austria (2)	Yes	Yes	No	No	No
Belgium (1)	No	Yes	No	No	No
Denmark (1)	No	Yes	No	No	No
Finland (2)	No	Yes	No	No	No
France (1)	No	Yes	No	No	No
Germany (2)	Yes	Yes	Yes	No	No
Italy (1)	No	No	No	No	No
Lithuania (2)	No	No	No	No	No
Netherlands (1)	Yes	Yes	Yes	No	No
Norway (5)	No	Yes	No	No	No
Poland (1)	No	Yes	No	No	No
Portugal (1)	No	No	No	No	No
Romania (1)	No	No	No	No	No
Russia (1)	No	No	No	No	No
Spain (3)	Yes	Yes	No	No	No
Sweden (1)	No	Yes	No	No	No
United Kingdom (1)	Yes	Yes	No	No	No

213 No response from member societies in: Croatia, the Check Republic, Greece, Hungary. Ireland and Luxembourg

214

215 **Table 2.** The different indications for which different cannabis products are marketed in different European countries

	Synthetic cannabis	Cannabis extract	Standardized cannabis	Growing personally	Wild type cannabis
Authorized indications	Glaucoma Vomiting and nausea (also following chemo-therapy) Pain (also MS) Spasticity (MS) Palliative medicine Tourette	Vomiting and nausea (also following chemo-therapy) Pain (neuropathic and MS) Spasticity (MS; some only treatment resistant) Spasticity in other neurological disorders HIV/AIDS Tourette	Spasticity (MS; some only treatment resistant) Pain (neuropathic and MS) Depression Sleeplessness		
Off-label use (other)	Cannabis use disorder	Mental disorders Cannabis use disorders Inflammatory bowel disorder Cancer glioma Treatment-resistant epilepsy	Many indications (more diffuse mentions)	Many indications (more diffuse mentions) Pain Sleeplessness Spasticity Stress Spain: cannabis clubs	Many indications (more diffuse mentions)