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for Drugs and Drug Addiction

Low-THC cannabis products in Europe

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Introduction and rationale

In recent years an increasing number of cannabis products, including herbal cannabis and cannabis oils, have been offered for open sale in Europe. These products claim to contain only low levels of tetrahydrocannabinol (THC), the chemical responsible for most of the psychoactive effects of cannabis, and therefore might not be controlled under drug laws in some countries. This development has given rise to concerns at the policy level with regard to both the legal status of these products and their potential to cause harm. A specific challenge, and one that is faced by both policymakers and those wishing to supply low-THC products, lies in establishing the legal status of low-THC products and which regulatory frameworks apply to their sale. In particular, there are uncertainties associated with those low-THC products that take forms similar to illicit cannabis products, such as smoking mixtures, oils and edibles. These products are the primary focus of this report.

With a view to mapping this phenomenon and beginning to address knowledge gaps, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) initiated an exploratory trendspotter study in the autumn of 2018.

It is important to note that the analysis provided here is intended as a purely descriptive exercise that describes, as far as it is possible, the current situation in an area that is complex, politically and commercially sensitive and highly dynamic. While this is helpful for informing discussion in this area, the reader should note that nothing in this report is intended as a recommendation or constitutes any form of legal or other opinion on how low-THC products should be regulated. Furthermore, the EMCDDA perspective is that of a drug monitoring agency. As low-THC products have appeared in areas that fall under the competencies of other EU agencies and bodies, while we have done our best to describe the situation as far as we understand it, this report does not necessarily represent the views of any other parties with responsibilities in this area. Finally, we have summarised various legal frameworks that may be relevant to low-THC products in this report. However, these descriptions are provided for the purposes of this report only and are not intended to be used or have meaning beyond this.

The study applied the trendspotter methodology, which involves the triangulation of data from a range of sources, in this case including a literature review, a web survey and an expert meeting (see box 'The trendspotter methodology', on page 5). In addition, information received during discussions with the EMCDDA's network of legal and policy correspondents was included.

This publication brings together the study's findings with regard to the overall aim of providing an initial overview of the situation in Europe with respect to the open sale of low-THC products. The specific objectives were to identify and further explore the types of product available and the range of sales outlets, user profiles, associated harms and responses taken in different EU countries.

A number of significant developments have taken place in selected European countries since the original data were collected and, where possible, updates have been included. Nevertheless, it is important to acknowledge that this is a rapidly evolving area and one with relatively limited information currently available. Thus, the findings presented here will necessarily be incomplete, and they need to be viewed as an introduction to the situation and pertinent issues, as well as providing a platform for further research and monitoring.

The following sections of this report summarise the study's findings and its analyses. Where results are based on the literature, references are cited; otherwise, the findings are based on EMCDDA and national monitoring and the qualitative sources mentioned above.

What are low-THC cannabis products?

There is some debate over what is included within the term low-THC cannabis products. The definition of low-THC cannabis products used in this publication is 'products being or containing cannabis herb, resin, extracts or oils that claim or appear to have a very low percentage of THC and which would be unlikely to cause intoxication'. They may be marketed for their low THC levels or for their high cannabidiol (CBD) levels. The definition excludes licensed medicines and products that use cannabis plant fibre only, such as textiles. It should be noted that some products containing extracts from the cannabis plant or its seeds have also appeared as cosmetics or foodstuffs; in this report we concentrate on those smoked or ingested products that are more likely to pose risks to public health. The classification of an individual product as a food, cosmetic or herbal smoking product is defined by EU and national provisions and is discussed in the section 'The regulatory context for low-THC products' (see page 10).

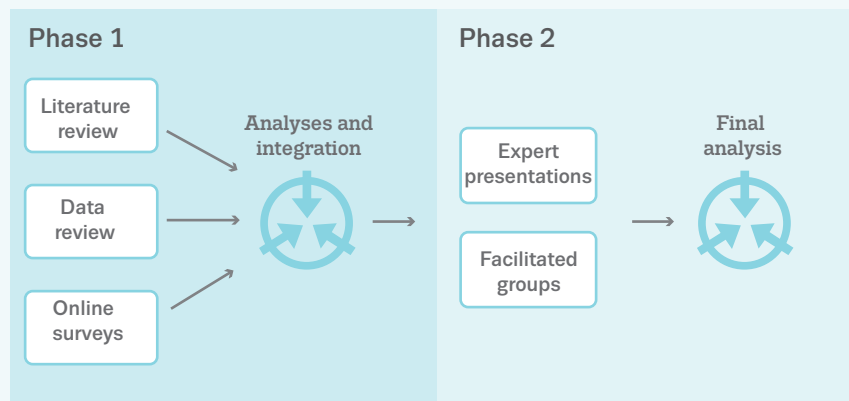
Cannabis flowers and extracts contain a wide variety of chemically related substances collectively known as cannabinoids. The percentage of each cannabinoid can vary greatly by plant variety and by growing technique. The two most extensively studied cannabinoids are THC and CBD. THC produces effects such as feeling 'high', relaxation and altered perception – the effects that people

The trendspotter methodology

This exploratory study used the EMCDDA's trendspotter methodology, which draws on a range of different investigative approaches and uses data from multiple sources (EMCDDA, 2018). The investigation was divided into two main phases, as illustrated below. The first phase included a survey of and meetings with the EMCDDA legal and policy correspondents' network, input from the EMCDDA reference group on drug supply indicators and a non-systematic review of routine sources and of scientific and grey literature (including desk research into sales websites). In addition, with a view to improving the geographical coverage, an online survey was sent to the EMCDDA Reitox network of national focal points (16

respondents). The second investigative phase centred on an expert meeting, held in Lisbon in November 2018. The event was attended by 12 experts from seven countries, who presented information on the situation in their country, participated in facilitated working groups and contributed to an in-depth analysis of the topic, providing insights from a range of perspectives, including industry, shopkeepers, law enforcement agencies, medicines regulation authorities and drug research organisations.

Analysis was based on triangulation of all the information sources, with a view to providing as complete and verified a picture as possible.



who use cannabis recreationally usually seek from the drug – while CBD does not result in the same intoxicating effects as THC.

This means that CBD is generally not considered to have the sort of psychoactive profile associated with drugs used recreationally or for their intoxicating properties. However, it should be noted that the action of CBD on the brain is a complicated topic and is not discussed in detail here.

Moreover, some commentators have noted an association between the use of CBD and some health benefits. However, the evidence for the effectiveness of CBD for most conditions that have been studied is limited, and many of the health benefits claimed remain topics requiring further research (EMCDDA, 2018). Again this is not an issue reviewed in any detail in this publication.

The situation in Europe regarding low-THC products

Types of low-THC products

A wide variety of low-THC cannabis products is now available in Europe. These include those that mirror established illicit cannabis products, such as herb, resin and oil, and other types of smoking products, such as e-liquids and crystals. Cannabis-infused edible products are also on sale, both as ready-to-eat products and beverages and as ingredients such as flour and pasta. Other cannabis products, such as balms, creams and pastes, are also available.

The study found that low-THC cannabis products were being offered for sale in the majority of EU countries (Table 1). As the low-THC phenomenon has expanded to more countries, so has the range and variety of types of low-THC cannabis products available across sales outlets, with oil and herbal products being the most commonly identified forms reported here. Resin products appear to

TABLE 1
Types of low-THC cannabis-based products advertised for sale in the EU and Norway, February 2019

Country	Herb	Resin	Oil	E-liquids	Edible products	Crystals
Austria	X	X	X	X	X	X
Belgium	X	X	X	X	X	–
Bulgaria	–	–	X	–	–	–
Croatia	X	–	X	X	X	X
Cyprus	X	–	–	X	–	–
Czechia	X	X	X	–	X	–
Denmark	–	–	X	–	–	–
Estonia	–	–	–	–	–	–
Finland	–	–	–	–	–	–
France	X	X	X	X	–	X
Germany	X	X	–	X	–	X
Greece	X	X	X	X	X	X
Hungary	–	–	X	–	X	–
Ireland	X	X	X	X	–	X
Italy	X	X	X	–	X	X
Latvia	–	–	–	–	–	–
Lithuania	X	–	X	X	–	–
Luxembourg	X	–	X	–	X	–
Malta	–	–	X	X	–	–
Netherlands	–	X	X	X	X	–
Poland	X	–	X	X	–	–
Portugal	–	–	X	–	–	–
Romania	X	–	X	X	–	–
Slovakia	–	–	–	–	X	–
Slovenia	X	X	X	X	X	–
Spain	X	X	X	–	–	–
Sweden	X	–	X	X	X	–
Norway	–	–	–	–	–	–
United Kingdom	X	–	X	X	X	–

Note: The reported advertising of a product in a country at the time of the survey is indicated by a cross (X).

be less common. Table 1 provides a snapshot of the situation, using limited sources, as at February 2019. The data presented are likely to be incomplete, and may not reflect the current situation in terms of the types of product available in individual countries. Nevertheless, the table illustrates both the widespread availability of these products across Europe and their diversity.

The sale of low-THC products in Europe

Some of the earliest developments in the low-THC market in Europe are reported to have taken place in Switzerland. In 2011 Switzerland increased the limit defining how a cannabis plant is classified under the Narcotics Control Act from 0.3 % to 1 % THC, in order to take into account

measurement uncertainty and biological variability in industrial hemp production. While some entrepreneurs started to market low-THC cannabis products based on this limit, there was no significant change in the market immediately following the introduction of the higher limit. However, the number of cannabis products on offer containing CBD has expanded since mid-2016 (Zobel et al., 2019), when one company marketed a large amount of ‘low-THC’ cannabis product, regulated as a ‘tobacco substitute product’ with associated health warnings and taxation levels. Once the information began to disseminate that products containing less than 1 % THC were not subject to cannabis legal controls in Switzerland, the marketing of these low-THC cannabis products increased.

Following the expansion in the sale of low-THC cannabis products in Switzerland, similar situations arose in

neighbouring countries. These new products were observed in Austria from March 2017 and Italy from May 2017, before spreading to Germany, Belgium and France by early 2018.

Informants in this study highlighted the fact that there may have been a widespread assumption that, in accordance with Regulation (EU) No 1307/2013, on granting payments to (hemp) farmers, any product containing less than 0.2 % THC was not restricted by law and could be advertised and sold to the public. The Regulation was not intended to imply that.

| Types of retailers

In the European context, the low-THC market is characterised by a wide variety of retailers. While cannabis-themed products can now be found in everyday retail outlets, such as health food chain stores, chemists and cafes, there are also dedicated shops selling low-THC cannabis products. Some of these specialised shops focus on health and well-being, while others are more closely associated with the recreational cannabis market, having more in common with tobacconists, 'vape shops' or Dutch cannabis 'coffeeshops'.

In this report, for the sake of simplicity, these two types of shop will be referred to as either 'health/lifestyle shops' or 'tobacco/coffeeshops'. However, in reality, the boundaries between the two types can be fluid and there may be overlap in the types of product sold and the method of selling. Either type of shop may sometimes offer literature about the health benefits of the products or accessories, such as lighters, pipes and grinders, or sometimes cannabis seeds and cultivation equipment such as plant pots and lighting.

The specific nature of the shops and sales mechanisms, whether they are bricks and mortar or primarily online, varies from country to country. In some countries, such as Austria, Greece and Luxembourg, there are vending machines selling low-THC cannabis products. Some shops and brands offer to deliver their products throughout the EU, others to a limited list of countries and some only within their base country. Following the introduction of Regulation (EU) 2018/302 in December 2018, online sellers are no longer permitted to block customers from other EU Member States, except in the case of countries with laws that prohibit the sale of these products. Nevertheless, some suppliers state that it is the responsibility of the buyer to check the laws and regulations of the destination country.

Herbal products appear to be more commonly sold by tobacco/coffeeshops, while health/lifestyle shops tend to stock CBD products such as creams and balms. Overall, it seems that there is not always a clear distinction in the type of products sold in different shops. What tends to differ is the marketing strategy used, with the same product being promoted or advertised differently depending on the focus of the retailer and the intended customer base.

In some countries, certain shops, both health/lifestyle shops and tobacco/coffeeshops, may act as wholesalers supplying low-THC products to other shops. For example, it was reported that in Belgium several new shops were offering such business-to-business connections, encouraging other shops to sell their stock and keeping a percentage of the profit.

| Origin of the products

Information on the source of the supply of low-THC cannabis products is not consistently provided by suppliers. In this study, the types of information reported on the origin of products included the specific location (e.g. the country); the manufacturer; whether produced domestically or imported; whether grown indoors or outdoors; and sometimes claims that they were sourced from certified producers. A brief review of retailers advertising low-THC products on the internet also found claims that their sources are 'EU-approved hemp varieties' and examples that indicated cultivation in a wide range of countries including Austria, Croatia, Czechia, France, Germany, Greece, Italy, Montenegro, Morocco, the Netherlands, Poland, Spain, Switzerland and Slovenia. However, it was also reported that declarations of origin may not always be accurate; experts reported cases in which import documents on postal packages had been mislabelled to hide their true origin.

| Product quality

Reports from the study indicate that there is wide variation in product quality and this gives rise to a number of concerns. These include whether the product matches what is claimed in terms of the actual content, particularly with respect to levels of CBD and THC, and whether there are contaminants, which may be a particular issue for substances that will be ingested but can also apply more generally.

Independent product testing was reported by several countries, including Austria, Czechia, Finland, Italy,

Slovenia and Sweden. In Austria, Italy and Luxembourg, analyses of confiscated products were reported to show generally low THC but high CBD levels, with Italy reporting some samples with levels of CBD in the 50-60 % range. In Austria, from a sample of around 200 products, 49 were found to be above the legal limit for THC, with several showing 0.4-1.1 % THC rather than the 0.3 % permitted (Federal Ministry of Social Affairs, Health, Care and Consumer Protection, personal communication), putting the sellers at risk of prosecution. In Czechia, tests of 29 CBD oils in 2017-2018 found that one third had discrepancies with the amount of CBD stated on the label (ICCI, 2018). THC was not mentioned on 60 % of labels, although one quarter of the samples may have resulted in a driver testing positive after taking the recommended dose of oil. Some products sold as 'high in CBD' therefore contained levels of THC that could potentially have resulted in noticeable intoxication if consumed in sufficient volumes (see box 'Challenges in defining appropriate levels of THC in legislation', on page 14).

Tests of CBD oils also found known carcinogens, including polycyclic aromatic hydrocarbons (PAHs) and benzo(a)pyrene, above the maximum levels set for oils and oil-containing food supplements in European Commission Regulations (EU) No 835/2011 and (EU) 2015/1933, respectively. In two batches tested, the maximum levels set for benzo(a)pyrene and the sum of four PAHs were exceeded in approximately half of the samples tested. The highest levels found were seven times the limit set for benzo(a)pyrene and almost 20 times the limit set for the sum of four PAHs. One batch of supposedly 'organic' product contained traces of a pesticide banned 20 years ago.

This variability in CBD content and the potential presence of significant levels of THC and potentially harmful contaminants have also been reported in other studies (Pavlovic et al., 2018; Gibbs et al., 2019).

Marketing of low-THC products

The marketing of low-THC cannabis products, including both promotion and advertising, varies between and within countries. Many low-THC cannabis products are marketed and sold online through dedicated websites. Prices may or may not be displayed and the option to make a purchase may or may not be provided. For example, in Luxembourg there were websites where the products were displayed without information on pricing, and the customer was directed to a physical location to make a purchase. Social media are also used for product promotion and advertising but seem to be rarely used as purchase platforms,

although in some cases purchase is possible through direct messaging.

Some retailers tend to focus on providing information on the inherent properties of the product, for example the variety of cannabis, content, flavour and aroma. Other retailers emphasise the product's lifestyle aspects, for example whether it is vegan, gluten free, organic or environmentally friendly.

Information on the perceived health benefits of the products, primarily CBD-related, may also be provided, either directly in relation to the product itself or indirectly by providing links to research and scientific papers. For CBD products, the typical dosage may be suggested, usually expressed in terms of drops or millilitres in a given period.

Health claims appear to be a significant contributor to the demand for CBD-related products. Although the evidence base in this area remains limited, there are claims that CBD improves well-being and helps to eliminate or alleviate a variety of health problems, including anxiety, insomnia, loss of appetite, digestive problems, migraines and breathing problems, and that it can act as an antidepressant and painkiller. These claims are often made on CBD sales websites or in promotional material. Examples also exist of claims that CBD may be used for the treatment of psoriasis and other skin problems, glaucoma and multiple sclerosis, and that it strengthens the immune system. However, health claims for foods should be authorised under Regulation (EC) No 1924/2006 on nutrition and health claims made on foods, and no such health claims have been authorised for cannabis products.

It is important in this context to note that CBD does have approved medical use for a limited number of medical conditions, and the scientific literature was summarised in recent EMCDDA reports (EMCDDA, 2018; Hall, 2018). A plant-derived CBD oral solution was approved by the US Food and Drug Administration in June 2018 (as Epidiolex), and by the European Medicines Agency in September 2019 (as Epidyolex), as an adjunctive therapy for seizures associated with Lennox-Gastaut syndrome or Dravet syndrome (intractable childhood epilepsy).

In summary, a number of regulatory challenges can be identified concerning the marketing and promotion of some CBD products. These include inadequate product labelling; inconsistent content; potentially poor product quality; a lack of acknowledgement of the limitations, or overstating, of the evidence concerning the effectiveness of CBD products for therapeutic use; and a lack of safety information or information on potential harms and possible

contraindications. However, it is also important to note that, while these issues may give rise to legitimate consumer protection and safety concerns, to date, there is very little evidence of any reported harms in Europe, either in the scientific literature or anecdotally associated with these products. At the same time, it should also be noted that this is not an area in which robust monitoring currently takes place, and rare or long-term problems associated with the use of these products may be difficult to detect.

Product labelling and disclaimers

Some items being marketed as CBD or low-THC products, particularly those being sold as health or well-being products, include label information on the levels of CBD and THC in the product, generally by weight (in milligrams) or as a percentage. In the case of THC, this may be presented as a percentage that will not be exceeded (e.g. less than 0.2 % THC), and in some cases claims may be made that the product is certified THC-free or that the content is below the level stated. The label may also provide some guidance on the dosage, including the maximum amounts to use.

Often the products are labelled by the seller as food supplements or as room scenting products, and sometimes the intended mode of use is given, such as for smoking or another form of consumption. However, products are not always presented in a consistent way; the same or a similar item may be presented in different ways in different shops or countries.

In some cases disclaimers suggest how the products should not be classified or used. While product disclaimers are not common, those identified tended to fall into three categories:

- health disclaimers: the product should not be used to treat diseases; the sellers state that they are not responsible if the product is misused;
- consumption disclaimers: the product is not intended for consumption, not recommended for smoking or not to be burned because of the risk of cancer; the product is for collectible purposes only;
- user-related disclaimers: the product is not for use by minors, not recommended for women who are pregnant or breastfeeding and not to be used while driving.

The use of product labelling and disclaimers may indicate how retailers of low-THC cannabis products are mindful of the legal frameworks that may permit or restrict the sale of such products. Examples include praising the taste, yet stating that the product is not for consumption or selling,

for example, herbal products with warnings that the products are only collectibles.

In addition, differences between countries in the use of disclaimers and marketing methods indicate that retailers are aware of the country-specific legal frameworks and the environment in which they are operating and seek to adapt to these.

It is interesting to note that some countries, such as Austria, have already responded to the phenomenon and classified various products. By classifying low-THC herbal cannabis products as 'herbal smoking products', it becomes necessary to display health warnings and sale to minors becomes restricted. To illustrate this, it was reported that one product with a picture of a unicorn on the label was considered illegal as a smoking product, as it might appeal to minors.

Characteristics and motivations of users of low-THC products

The information available on consumers and consumption of low-THC cannabis products, including the former's characteristics and motivations, is extremely limited. In Switzerland, a survey of over 1 500 CBD users was conducted by Addiction Switzerland in 2019. The respondents were recruited through Facebook and a community of interest, with around one third reporting use of CBD products on more than 20 days a month, about three quarters reporting using cannabis flowers and more than half also reporting using illicit cannabis (Zobel et al., 2019). In this survey, three main motivations for use were identified: (1) for well-being (to combat stress or insomnia); (2) for health (to treat pain, depression, nausea); and (3) to moderate their use of illicit cannabis (to reduce illegal use or the effects of THC).

The study also found that people with health-related motivations for use had an older age profile than those motivated by lifestyle or an interest in experimenting with products similar to the established illicit cannabis products. Consumers with health motivations were more likely to purchase products from health/lifestyle shops and included respondents reporting mistrust of big pharmaceutical companies and seeking natural products as self-medications or as food supplements. Finally, respondents reporting motivations for use associated with their use of illicit cannabis were younger than the other two groups and more likely to purchase from tobacco/coffeeshops.

An Austrian market survey, conducted in July 2019, explored CBD-containing product awareness and use

among a sample of internet users aged 16-69 years (sample size 1 009) ⁽¹⁾. Of the respondents, 14 % reported that they had experience of CBD-containing products, and almost a quarter (23 %) said that they had acquaintances who had tried such products. Three quarters of these said that they had a positive experience with the product, and 8 out of 10 suggested that they were likely to use CBD again in the future. Younger respondents (aged 16-29 years) were more likely to report having used CBD: 22 % reported that they had used CBD at some time, compared with 13 % of 30- to 49-year-olds and 10 % of 50- to 69-year-olds. While the survey method may have resulted in a sample that over-represents the type of people who might use CBD-containing products, it is interesting to note that the sample extended across all age groups in the population.

The regulatory context for low-THC products

The United Nations (UN) drug control conventions provide the basis for national drug control laws and state that unauthorised sale of 'cannabis flowers' and 'extracts and tinctures of cannabis' should be subject to criminal penalties. However, the conventions do not apply to the cultivation of cannabis plants for industrial purposes (e.g. fibre, seed). There is no explicit mention of CBD in the UN conventions, which has resulted in different interpretations of whether plant-derived CBD should be considered an 'extract of cannabis' or a substance unlikely to be abused and therefore not requiring control. It should also be noted that synthetic forms of CBD can be produced that are not derived from extracts of cannabis plants.

The EU has many directives and regulations that may be applicable to low-THC cannabis products in their different forms and components, and which provide standardised definitions of different types of products, such as foods, food supplements and medicines. Some of these may apply automatically and uniformly to all EU Member States; others will need to be transposed into national law (see box 'Main EU legislation to be considered in the context of regulating low-THC cannabis products', on page 12).

In addition, the assessment of the legislation applicable to individual products is a complex process and carried out on a case by case basis. Clarification may be requested from the relevant departments of the European Commission.

Criteria have been established within the EU to define different categories of cannabis plant varieties, and some may be cultivated and supplied for hemp fibre if they have low levels of THC. The granting of payments under the

common agricultural policy is conditional on the use of certified seed of specified hemp varieties; only varieties with a THC content not exceeding 0.2 % may be used (Regulation (EU) No 1307/2013). This limit applied to the agricultural production of cannabis varieties may have given rise to the belief that any finished product containing less than 0.2 % THC is not restricted by law and may be legally made available to consumers.

In fact the 0.2 % limit in EU law is intended only as a criterion for the granting of EU payments for agriculture; higher national limits may be established for other purposes.

The EU plant variety database lists varieties whose seed can be marketed throughout the EU, including approximately 70 varieties of the species 'hemp – *Cannabis sativa*' (European Commission, 2019b). Some EU Member States may explicitly exclude all derivatives of those varieties from their narcotic schedules. This includes all parts of the plant, seeds, extracts and tinctures, as well as the resin. Imports of hemp are also subject to certain conditions to ensure that the THC limit is respected (Regulation (EU) No 1308/2013). It should be stressed, however, that this legislative framework was developed for the hemp industry. Therefore, it cannot necessarily be assumed that it is appropriate to apply it to products intended for human consumption.

As there are many health claims around low-THC and primarily CBD products, it is also relevant to consider the EU legislation regarding medicines in this context. Directive 2001/83/EC establishes that a medicinal product is one that restores, corrects or modifies physiological functions by exerting a pharmacological action or is presented as having properties intended to treat or prevent disease. In this way the directive, which lays down the requirements and procedures for marketing authorisation of medicinal products for human use, applies to medicinal products containing cannabis derivatives, requiring a marketing authorisation for any sale. Marketing authorisation is granted for a specific product if the safety, quality and efficacy of that product to treat a disease is confirmed. Recently, EU-wide marketing authorisation has been granted to the medicinal product Epidyolex, a plant-derived CBD oral solution, indicated for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in children aged 2 years or older. While health claims appear to be a significant contributor to the demand for CBD products on open sale, there is, however, currently limited evidence available on the effectiveness of CBD products for many other conditions for which effectiveness has been claimed.

Furthermore, cannabis-infused edible products have been on sale in many EU Member States, whether ready-to-eat

⁽¹⁾ Web survey conducted for Magu-CBD.

products and beverages or ingredients such as flour and pasta. Various regulations may be relevant here: Regulation (EC) No 178/2002 lays down the general principles of and requirements for food law and states that the definition of 'food' does not include medicinal products, cosmetics or narcotic or psychotropic substances within the meaning of the 1961 and 1971 UN conventions, implying that substances regarded in the conventions as narcotic or psychotropic substances cannot be classified as foods. A special category exists for novel foods, which in simple terms can be defined as foods that had not been consumed to a significant degree by humans in the EU before 15 May 1997, when this regulation first came into force. The EU Novel food catalogue serves as orientation on whether a product will need an authorisation under the novel food Regulation. It is important to note that the catalogue is not formally part of EU food legislation, as it serves as only a guidance document and has no formal legal meaning.

The catalogue contains the following guidance under the heading '*Cannabis sativa* L.':

In the European Union, the cultivation of Cannabis sativa L. varieties is permitted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2 % (w/w). Some products derived from the Cannabis sativa plant or plant parts such as seeds, seed oil, hemp seed flour, defatted hemp seed have a history of consumption in the EU and therefore, are not novel. Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities. (European Commission, 2019c).

Under the headings 'Cannabidiol' and 'Cannabinoids', the EU Novel food catalogue has a note that reads:

There was a request whether this product requires authorisation under the Novel Food Regulation. According to the information available to Member States' competent authorities, this product was not used as a food or food ingredient before 15 May 1997. Therefore, before it may be placed on the market in the European Union as a food or food ingredient a safety assessment under the Novel Food Regulation is required. (European Commission, 2019c).

Food business operators can place a novel food on the EU market only after the Commission has processed an application for the authorisation of a novel food and has

adopted an implementing act authorising the placing on the market of a novel food.

Currently there appear to be some developments in this area of applying for authorisation of novel foods (Norwinski et al., 2019). Over 60 applications were made for the authorisation of CBD-containing products under Regulation (EU) 2015/2283 on novel foods. It is for the European Commission to verify whether individual applications fall within the scope of the Regulation. This includes a verification of whether the specific product falls within the definition of 'food' laid down in the General Food Law Regulation ((EC) No 178/2002). Doubts have been raised on whether CBD can be considered a 'food' as the General Food Law excludes from this definition substances considered as narcotic or psychotropic substances within the meaning of the UN drug conventions (²).

Furthermore, the cosmetics regulation (Regulation (EC) No 1223/2009) requires notification of new products on the EU market to the EU [Cosmetic product notification portal](#), and several cosmetic products containing CBD can be found there.

In accordance with the relevant EU provisions (such as the definition of a medicinal product under Directive 2001/83/EC and the definition of a cosmetic product in Regulation (EC) No 1223/2009), the Member States national competent authorities will determine the classification for any individual product, on a case-by-case basis, and in this way it would be possible for a 'borderline' product to be classified as a medicine in one country and a food in a second country. The introduction to the European Commission's Cosmetic ingredients (CosIng) database highlights this point:

If, due to such ingredients, a product restores, corrects, or modifies physiological functions by exerting a pharmacological, immunological or metabolic action, the product shall be qualified as a medicinal product. However, products that, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions, may be qualified as cosmetic products. The qualification of a product is to be decided by the national competent authorities, under the supervision of the courts, on a case-by-case basis, taking into account all the characteristics of the product. (European Commission, 2019a).

Finally, Directive 2014/40/EU on tobacco and related products (TPD) defines 'herbal products for smoking' as 'a product based on plants, herbs or fruits which contains no

tobacco and that can be consumed via a combustion process'. The Directive in itself does not exclude the possibility that cannabis or related products may be included in herbal products for smoking. On the contrary, if these can be used for smoking, they need to comply with the provisions of the TPD. The TPD in itself does not lay out provisions on whether a product or its ingredients are legal or not, but intends to regulate products which can be legally placed on the market.

These products are specifically regulated by Articles 21 and 22 of the TPD with specific provisions for product labelling and ingredients reporting. Prior to placing a new product on the market, manufacturers and importers need to submit to the national competent authorities a list of ingredients and respective quantities by brand name and type. Herbal products for smoking which contain or may be otherwise associated with cannabis were reported in more than 20 Member States to date with a notable increase in the number of products reported in the last two years (2019 and 2020).

Recent regulatory responses to the rise in low-THC products

As policymakers in different countries around Europe have noticed the sale of low-THC products gaining increasing visibility, so the regulatory environment has started to change to both acknowledge and in some cases restrict their availability. At the EU level, there have also been some developments in this area.

In January 2019 the EU Novel food catalogue (see above) updated the entry relevant to low-THC cannabis, deleting the specific entry for CBD and inserting an entry for 'Cannabinoids'. This now states that:

[...] extracts of Cannabis sativa L. and derived products containing cannabinoids are considered novel foods, as a history of consumption has not been demonstrated. This applies to both the extracts themselves and any products to which they are added as an ingredient (such as hemp seed oil). This also applies to extracts of other plants containing cannabinoids. Synthetically obtained cannabinoids are considered as novel. (European Commission, 2019c).

In addition, in the area of cosmetics, several cannabis extracts or products, including CBD, are listed in Commission Decision (EU) 2019/701 as common ingredient names for use in the labelling of cosmetic

Main EU legislation to be considered in the context of regulating low-THC cannabis products

- Medicinal products: Directive 2001/83/EC (medicinal products directive)
- Foods: Regulation (EC) No 178/2002
- Food supplements: Directive 2002/46/EC
- Novel foods: Regulation (EU) 2015/2283
- Cosmetics: Regulation (EC) No 1223/2009
- Tobacco products: Directive 2014/40/EU
- Nutrition and health claims on foods: Regulation (EC) No 1924/2006

products. Nevertheless, the European Commission has recently stated that cannabis extracts are banned in cosmetics, as they fall under the definition of 'cannabis', which is listed in Schedule 1 of the UN 1961 convention (European Parliament, 2019).

Regulating THC levels at national level

The interpretations and applications of the legal frameworks in individual European countries differ. In some countries plant-derived low-THC or CBD-containing products are considered to be cannabis extracts, and therefore unlicensed sale is subject to criminal penalties, while in others they can be traded without a licence, as they are viewed as having insignificant psychoactive properties and therefore at low risk of misuse and unlikely to pose a threat to public health. Some countries state (by law or guideline) that a product containing less than 0.3 % or 0.2 % THC is not controlled under drug laws. Although quantitative limits of permitted THC exist, this is not always the only factor in national laws. Other circumstances may need to be considered when assessing legal status, such as the type of plant source, the reason the plant was grown, whether it was licensed, how the product was extracted and how the product was presented for sale. For example, quantitative limits may also come with stated conditions, such as 'originating from an authorised variety of cannabis', 'if not viable for narcotic purposes' or 'if not misused'.

National variations in limits mean that products imported from a country with higher permitted THC levels, for example from Switzerland (where the national limit is 1 % THC), may breach another country's national limits.

However, as well as variations in the levels set by countries, there are also differences in how levels of THC are set in

different types of legislation, with laws applying to industrial uses, narcotics laws and assessments of food safety taking different approaches to establishing acceptable levels of THC (see box 'Challenges in defining appropriate levels of THC in legislation', on page 14). In 2018 Denmark changed its regulations and introduced a threshold limit that made it possible to produce and sell cannabis-based products containing up to 0.2 % THC without contravening national drug control legislation, while in 2019 Italy passed a decree defining the maximum levels of THC in food as 2 milligrams per kilogram for hemp seeds and hemp flour and 5 milligrams per kilogram for hemp seed oil.

Regulating CBD products

There are also national differences in the way CBD is regulated. If CBD is considered to have medicinal properties, it may be controlled and distributed under medicinal product regulations. Its access to the market will depend on the interest of companies to present applications for the marketing authorisation for a specific product. The EU framework for medicinal products does not allow for a broad recognition of a substance as a medicine. Each marketing authorisation request should be supported by data on safety, quality and efficacy, for a specific product.

While permitted THC levels are commonly stated in legislation at national level, this does not appear to be the case for CBD levels. Furthermore, there is a range of extracts marketed as CBD with no clear definition of their exact content and a lack of evidence for their effects in humans. Generally, there seem to be few quantitative limits for CBD content but more focus on the conditions attached to its sale. In Romania, for example, any consumable product originating from cannabis is controlled under criminal law. In Denmark, CBD products (e.g. oils) are considered likely to have a pharmacological effect (based on product type, strength and dosage), and so they are regarded as medicinal products. In Finland, CBD has been clearly classed as a medicinal product, so unlicensed sale is not permitted.

In Austria the Federal Ministry of Social Affairs, Health, Care and Consumer Protection issued guidance in December 2018, stating that cannabis flowers should be sold as herbal smoking products to adults only with a health warning and that CBD-infused edibles would be classed as novel foods, and therefore it was illegal to sell them before a risk assessment had taken place. CBD extracts could not be marketed as dietary supplements, and the sale of CBD-containing cosmetics would no longer be permitted. In July 2019 Belgium issued a list of herbal

products for smoking that could be marketed as long as the business operators are registered to pay excise tax – many product names are clearly cannabis related (e.g. 'kush', 'diesel') (SPF Santé Publique, 2019a). An article accompanying this list highlighted that smoking products containing CBD must contain less than 0.2 % THC and must not be presented as having therapeutic properties, or as herbal teas or potpourri (SPF Santé Publique, 2019b). In some countries, the legality of marketing the product may depend on the source of the CBD, the format of the product or how the product is presented. It is not clear how online sales and marketing affects this.

Both the target group and the use to be made of the product can be a factor in determining appropriate intake levels and their regulation. In 2017 the European Industrial Hemp Association proposed that, for the average adult, products providing a daily oral intake of over 200 milligrams of pure CBD should be regulated as medicinal products, those providing a daily oral intake of 20-160 milligrams should be regulated as over-the-counter medicines or as food supplements, and amounts leading to a daily intake for adults of under 20 milligrams should be permitted in food products (EIHA, 2018).

In January 2019 there was also a proposal to change the UN drug control legislation relating to CBD. Following a critical review of cannabis and associated products by the World Health Organization (WHO) Expert Committee on Drug Dependence, a letter from the Director-General of the WHO to the UN Secretary-General, dated 24 January 2019, put forward six recommendations, including that there should be a footnote to the entry for cannabis and cannabis resin in Schedule I of the 1961 convention that would read 'Preparations containing predominantly cannabidiol and not more than 0.2 % of delta-9-THC are not under international control'.

In March 2020 the UN Commission on Narcotic Drugs decided to vote at its reconvened 63rd session on the six WHO recommendations on the international control of cannabis and cannabis-related substances. The UN Commission on Narcotic Drugs decided on 2 December 2020 (by 27 votes to 25 and with one abstention) to delete cannabis and cannabis resin from Schedule IV of the 1961 Convention. These substances remain in Schedule I of the 1961 Convention and thus remain subject to all levels of control of the 1961 Convention. The Commission decided not to follow the other recommendations made by the WHO.

In 2018 a business in France imported low-THC cannabis oil from Czechia and began to sell it to the public in e-cigarette cartridges, promoting its CBD content. The oil was made from the whole cannabis plant, which is

legal in Czechia but not in France, where the commercial use of hemp is restricted to fibre and seeds. The business owner was convicted, and appealed. The case was referred to the European Court of Justice (C-663/18), which declared in November 2020 that while the CBD in the case was not a drug within the meaning of the 1961 Convention, the fundamental principle of free movement of goods between Member States could still be limited on grounds of the protection of the health and life of humans. However, such a limit should not go beyond what is necessary in order to achieve its objective, and should be applied in a consistent and

systematic manner. The Court stated that, while the evidence of CBD posing a risk to health was still limited but may justify precautionary restrictive measures, it was inconsistent to apply the marketing ban only to organic, and not synthetic, CBD.

The court's statement that CBD was not a drug within the meaning of the 1961 Convention has implications for interpretations of the EU laws discussed above: these may be addressed in the near future.

Challenges in defining appropriate levels of THC in legislation

The legislative framework originally intended for the hemp industry, which is based on the percentage of THC in hemp, is not appropriate for the many variants of cannabis product that have recently appeared on the market and should not be used as surrogate safety limits for human consumption without further checks.

The percentage of THC can be measured and referred to at a variety of levels.

- The level of THC that a certain variety of cannabis plant will usually produce. This serves to distinguish between legal hemp and illegal cannabis plantations.
- The levels found in the different parts of the plant. Levels are lowest in the roots, stalks and seeds, higher in the leaves and highest in flowers and resin. This serves to distinguish what parts of the plant may be used for industrial purposes without extensive testing, or what might be of value to divert to illegally extracting THC.
- The level found in the extracts. This may be used to indicate whether an extract (usually oil) has intoxicating properties or not.
- The level found in the final consumable product, for example an edible product.

The input (ingredient) is easier for the producer to control, but the output (product) is more relevant when considering the effect on the consumer. Nevertheless, it is possible to grow low-THC hemp and from it produce a high-THC extract, highlighting the importance of considering the final product and not just the input material.

Currently there may be inconsistency between laws applying to industrial uses and narcotics laws with

respect to whether percentage or weight is used to determine the amount of THC in a product. It may be possible for a product (e.g. oil) containing a low percentage of THC that is within the permitted industrial levels to exceed the total weight of THC permitted under narcotics laws. For example, 500 millilitres of 'CBD oil' containing 0.2 % THC will contain approximately 1 gram of THC, a threshold for narcotics possession or sale offences in some countries.

Canada and the US state of Colorado have set limits of 10 milligrams of THC in one 'unit' of a (recreational) edible product for intoxication, such as one (square of) a chocolate bar. In Canada, 10 milligrams of THC is sold in a 32-gram bar of chocolate, resulting in an intoxicating dose being sold at a concentration of barely 0.03 %.

In the case of food safety levels, the concept of a maximum safe daily dose is used. The European Food Safety Agency (EFSA) uses the acute reference dose of a substance when carrying out risk assessments of food products and contaminants; the acute reference dose is the maximum dose per kilogram of body weight per day that is deemed safe. The EFSA reference dose for THC of 1 microgram per kilogram was calculated using an uncertainty factor of 30. The European Industrial Hemp Association considers that, in comparison with the uncertainty factor of 3 for opium alkaloids in foods such as poppy seeds, this produces a limit for THC in food that is excessively cautious (EIHA, 2017). In Austria and Switzerland, the uncertainty factor has been reduced to 10. In New Zealand the maximum safe daily THC intake is 7 micrograms per kilogram body weight with no apparent problems reported, and Canada's industrial hemp regulations of 2019 exclude products from the Cannabis Act if they contain no more than 10 micrograms of THC per gram of product.

Quality control and law enforcement

A number of participants in this study, coming from a criminal justice background, highlighted the fact that the tasks of law enforcement and customs bodies have become more complicated now that low-THC cannabis products are appearing on open sale. One issue is lack of clarity over which regulatory framework should be applied in any particular situation. Customs officers, for example, may be seizing products that claim to have low THC levels and would thus fall outside drug control laws in some countries, but the products may in fact have illegal levels of THC. Currently the only way to determine whether a product is legal or not is to test its content, a process that can be both expensive and time consuming. The sale of low-THC cannabis herb and resin products therefore poses a new challenge for law enforcement, as distinguishing between low- and high-THC cannabis on the street, in shops or at the border is not simple, and it is impractical and costly to test all products. In Austria, Italy, and Switzerland, the police now have a rapid reagent test for use on the street; some portable tests can analyse whether a product contains THC or not and others analyse the amount of THC. Not all law enforcement agencies across Europe have these instruments available, however. It is also important that, even when tested in a laboratory, it can be difficult to achieve consistent results from the same product (Giese et al., 2015).

Looking to the future: what traction do low-THC products have?

The argument can be made that the change in the law in Switzerland helped to provide the foundation for the introduction of low-THC cannabis products on to the European market and that the perceived grey area around these products' legality and promotion has helped this market to expand rapidly, to the extent that the open sale of these products is now common across Europe. In contrast, it can be argued that producers wanting to manufacture products containing low amounts of extracts from the cannabis plant or products containing synthetic versions of CBD, to meet consumer demand, are hampered by the lack of a clear regulatory framework in this area. These developments have not occurred within a vacuum, however. The wider political and cultural environment, including recent legalisations in Canada and

some US states, may have contributed to the market's growth and arguably potentially added to the normalisation of sales of products containing cannabis extracts.

Understanding developments in this dynamic area is also handicapped by a lack of information. There is currently very limited information on the range of products available in Europe and who is using them, beyond the studies in Austria and Switzerland highlighted in this report. There is also no information available on the extent of use of these products. Given that many of these substances are traded across borders, it may be helpful to undertake cross-national studies and develop standard monitoring tools to collect information on the products available and the people using them to improve understanding of developments in this area.

From the information available it appears that for many users of CBD-containing products the motivation for use is linked to anticipated health and well-being benefits. However, while some cannabis-based products are currently being advertised as highly beneficial for certain medical conditions, such as insomnia, loss of appetite, depression and digestive problems, the evidence for the effects of CBD and THC on the body and in relation to most of these conditions is limited. Where self-reported findings or results from trials exist, because of the combinations of cannabinoids and compounds in cannabis and the difficulty in measuring dosage, claiming any consistent health benefit of openly sold CBD products is difficult.

A greater understanding of appropriate safety limits for THC and CBD is required to enable a more thorough assessment of the potential harms and benefits of low-THC cannabis products. When establishing such limits, different forms of the product will need to be taken into account, as the bioavailability of THC will differ; transdermal creams and ingested foods with similar THC contents will have different effects on the brain. It is also not yet known whether there may be other long-term risks associated with the use of such products. This is a rapidly changing market and developments are likely, which may change the risk/benefit profile over time. For example, some manufacturers are finding ways to make THC water soluble, which increases its bioavailability, so there is the potential for drinks containing THC to be more potent. This highlights a need to support more research into the benefits and harms to health as well as establishing a system for reporting adverse effects from consuming these products.

There appears to have been something of a ‘gold rush’ atmosphere among entrepreneurs selling low-THC products, with shops rapidly opening and closing, and the situation in flux. Keeping abreast of regulatory changes will be a challenge for small businesses, and increasing regulation is likely to favour bigger companies. Some businesses have reported problems when dealing with global payment providers such as Visa, Mastercard and PayPal; they are based in the United States, which at the federal level does not permit sales of cannabis products. The internet also appears to be playing a crucial role in the expansion of this phenomenon, and several mainstream marketplace platforms and social media applications offer these types of products. Regulation in the virtual environment can be challenging for many products, and these challenges are likely to be particularly pronounced in this area.

Another issue highlighted in this report concerns the labelling and marketing of low-THC products in ways that may make it difficult to identify the relevant legal framework that would apply to their sale (e.g. narcotics laws, smoking control, food quality control). This is not an entirely new phenomenon, as similar regulatory issues arose when new psychoactive substances started appearing for sale on the European drug market. One example is the use of disclaimers, such as ‘not for human consumption’, that attempt to shift responsibility for consumption to the user. Consumer protection requires the seller to ensure that products are clearly labelled, which would mean that products could be classified and covered by the relevant national legislation on safety, advertising, etc. Industry bodies have themselves called for greater clarity around the regulations that apply, and this may be an opportunity for policymakers and trade bodies to work together to design regulatory standards that may protect consumers from the most serious threats presented by the current unregulated industry. In labelling products, policymakers will need to address not only safety limits but also the confusing message given to the consumer by using different measurements of THC and CBD content and whether the percentage of THC, maximum dose per day or ratio of THC to CBD should be used.

The increased availability of low-THC cannabis products on the market also gives rise to broader questions about the possible impact on the public’s attitude to cannabis use. One line of argument suggests that the increase in accessibility can be considered a form of ‘soft legalisation’; another proposes that the phenomenon represents an increasing public nuisance; a third asks if the restrictions on the substance are disproportionate, as it does not appear to threaten public health. Public opinion aside, it is likely that European countries will experience a period

involving some balancing of low-THC product supply and demand on the one hand and challenges for regulators on the other, including managing the issues associated with varying product quality. In terms of the products sold, there are some indications that one of the products with the greatest potential for lasting demand is CBD oil. It remains to be seen if the demand for cosmetic products containing cannabis extracts grows in the future. There is also a debate on the extent to which low-THC cannabis products are likely to be attractive to consumers seeking a legal substitute for illicit cannabis, given that these products do not produce the intoxicating effects associated with illicit cannabis. There are therefore many unknowns in this area that complicate discussions on what should constitute a reasonable and proportionate policy response. One thing is clear, however: future consideration of what constitutes an appropriate response to developments in this area will benefit from a better understanding of this diverse and dynamic phenomenon, and public health and consumer protection concerns will require a greater knowledge base for both low-THC and CBD-containing products and their actual contents, forms and short- and long-term effects.

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- [Cannabis policy: status and recent developments](#) is the EMCDDA online hub for cannabis policy information and news.

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About this publication

The open sale of cannabis products in Europe has raised concerns among policymakers, both with regard to the legal status of these products and their potential for harm. The products are marketed for their low THC (tetrahydrocannabinol) content, which sellers claim exempt them from control by drug laws, or as sources of CBD (cannabidiol). This publication presents an initial overview of the situation, covering the types of low-THC products available, user profiles, associated harms and regulatory responses in Europe. Low-THC products that take forms similar to illicit cannabis products, such as smoking mixtures, oils and edibles are a primary focus of this study. The report highlights the challenges facing both policymakers and those wishing to supply low-THC products regarding establishing the legal status of the products and which regulatory frameworks apply to their sale.

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