

THE LEGAL FRAMEWORK FOR OFFERING AND MARKETING MEDICINAL CANNABIS PRODUCTS AND CANNABIS-BASED CONSUMER GOODS.

Cannabis-based consumer products are currently enjoying a huge surge in popularity across Europe. The best sellers are food items, food supplements and cosmetics. There has also been increased demand for medicinal cannabis since it was legalised in a number of EU countries in 2017, and particularly with it now being covered by health insurance policies in some cases. Finished medicinal products, and magistral as well as officinal formulas, are also a key part of this trend. There are, however, a number of issues relating to the marketing of cannabis products which still need to be clarified. One of the key issues is the extent to which foods containing cannabidiol should be classified as "novel food". This Client Briefing is designed to provide an overview of the legal framework and requirements for offering and marketing medicinal cannabis products and cannabis-based consumer goods.

CANNABIS: THE RENAISSANCE OF ONE OF THE WORLD'S OLDEST CULTIVATED PLANTS

The hemp plant *Cannabis sativa* L. is among the oldest cultivated plants in the world. Often used for medicinal purposes, it may be consumed in a number of forms or used for its narcotic properties. Cannabis contains a variety of substances including more than 100 different cannabinoids. The most well-known of these is probably tetrahydrocannabinol (THC) because of its psychoactive effect. The other main type of cannabinoid, cannabidiol (CBD), is not psychoactive.

Cannabis is still a controlled substance within the EU. The exception tends to be cannabis plant seeds where these are not intended for use in illegal cultivation. In order to make cannabis a viable raw material for industrial purposes, a number of member states make exceptions for cannabis plants grown in the European Union from certified seed or for those with a low THC content (Germany and several other member states apply a threshold of 0.2%). Cannabis intended for medicinal use, i.e. cannabis grown for medicinal

Key topics

This Client Briefing is designed to provide an overview of the legal framework and requirements for offering and marketing medicinal cannabis products and cannabis-based consumer goods. It looks at the following:

- Cannabis: The renaissance of one of the world's oldest cultivated plants
- Healthcare products
- Consumer goods
- Legal consequences of unlawfully marketing products or placing them on the market

purposes under government supervision, and preparations authorised for sale as medicinal products, are also not classified as narcotic products.

HEALTHCARE PRODUCTS

Cannabis is relevant in two types of healthcare products: Finished medicinal products manufactured by pharmaceutical companies and magistral as well as officinal formulas (i.e. medicinal products prepared on the basis of a general prescription).

Finished medicinal products

In those cases where medicinal products containing cannabis require EU authorisation there remains a major challenge to providing the proof of efficacy required for this authorisation under Article 6 of Directive (EC) No 83/2001. There are currently only two finished medicinal products containing cannabis on the market in the majority of EU states. One of these is approved for the treatment of multiple sclerosis (*Sativex*[®] mouth spray) and the other for treating the side effects of chemotherapy (*Canemes*[®] capsules). Another product containing the active ingredient CBD (*Epidyolex*[®]) was given EU authorisation in September 2019 for the treatment of rare but severe forms of epilepsy. Despite this, there is much to suggest that demand and market opportunities for cannabis-based products will continue to grow in the near term.

Prescription medication and officinal preparations

Another potential use for medicinal cannabis is in magistral as well as officinal formulas prepared in a pharmacy on the basis of a general prescription. These formulas do not require approval as a medicinal product. This could potentially include a number of cannabis-based medicinal preparations. The flowering/fruitley tops of the cannabis plant are particularly relevant in this respect since they can be used in inhalable and other similar products.

CONSUMER GOODS

The question of whether or not cannabis-based consumer products may be offered for commercial sale in the EU is decided by the provisions on controlled substances and the applicable regulatory framework.

Food and food supplements

Legal provisions relating to controlled substances and narcotics have yet to be harmonised under EU law. This means that there are no provisions which apply across the EU and any assessment has to be limited to individual member states. The greatest degree of conformity exists in terms of the seeds of the cannabis plant. These may be used in foods and food supplements in a number of member states as long as there is no potential for them to be further used for narcotic purposes or to cause intoxication. This is generally ensured if they are processed in a certain way which neutralises their ability to germinate (e.g. roasting). There are, however, major differences in terms of the requirements relating to other parts of the cannabis plant and the acceptable THC level. The main difference in terms of the latter is that some countries mostly measure the THC level of the final product, while others measure the THC level in the cannabis plants used. In Germany, for instance, it appears that it is currently the case that other parts of the plant may not be used in foods. This is because the exceptions agreed for cannabis are mostly intended to boost the market potential of hemp as a raw material and not to allow people to buy low-THC preparations and products, such as food, drink and tobacco items, or as a means of relaxing the ban on the sale of cannabis.

The aforementioned type of commercial use, precluding any further use as a narcotic or to cause intoxication, does not generally exist in respect of products intended for personal consumption. It can only exist where the hemp is processed into a "safe" product such as paper, rope or textiles. It therefore seems likely that cannabis-based products which are intended for personal consumption, particularly foods or beverages, are no longer included as exceptions and must therefore be classified as controlled substances.

Another relevant regulatory aspect for cannabis-based foods and food supplements is the fact that they may in some cases be classified as "novel food" within the meaning of Regulation (EU) No 2283/2015. Article 3 para 2 lit. a) thereof states that "novel food" means any food that was not available or used for human consumption to a significant degree within the European Union before 15 May 1997 and which may be classified under any of the categories set out in the regulation. Products will not be classified as novel food only if it can be shown that the specific product (and not any similar or comparable product) was "used for human consumption to a significant degree" prior to the above date. This requires that the existing scale of consumption of the product means that it no longer appears to be necessary to make the marketing of the product conditional on additional safety checks in order to protect public health. If this cannot be demonstrated, any novel food may only be offered for sale once authorisation for this has been issued and when it has been added to the "union list" of novel foods.

A particular distinction needs to be made in the case of cannabis. According to the EU novel food catalogue, which is neither exhaustive nor legally binding, any foods derived from the hemp plant and any parts thereof, including the seeds, seed oil or seed meal, are not classified as novel food. On the other hand, extracts derived from the hemp plant and any products manufactured from these containing cannabinoids such as CBD are currently regarded as novel foods under the EU catalogue. Despite the catalogue not being legally binding, it does have indicative value. It has also not yet been possible to show any significant degree of human consumption of these extracts to the satisfaction of the relevant public and judicial authorities.

If this level of previous consumption cannot be demonstrated, it will remain the case for the time being that extracts will be classified as novel food. With no approval having been issued for these extracts, including the cannabinoids, under Regulation (EU) No. 2283/2015, they cannot currently be offered for commercial sale in any case.

The conclusion from all this is that the only cannabis-based food stuffs, including food supplements, which may currently be marketed in most EU member states are those deriving from the seeds of the cannabis plant. This applies both from a regulatory perspective and in terms of any provisions relating to narcotics and controlled substances.

Advertising for those cannabis-based foods and food supplements which are already available tends to focus on the supposedly positive beneficial properties of the cannabis plant, particularly in terms of health and well-being. The key consideration in this respect, in addition to any generally applicable principles (such as the requirement that food information should not be misleading set out in Article 7 of Regulation (EU) No 1169/2011) is that it is not permissible to make any misleading claims for cannabis-based foods. The same applies to any health claims, since they are not included under the health claims approved under Regulation (EU) No 1924/2006. Another consideration is that any health claims made for foods and food supplements give risk to the potential for the product to be classified as a medicinal product by presentation, as defined in Article 1 no. 2 lit. a) of Directive (EC) 83/2001 and the national provisions derived therefrom. A product is considered to meet this classification requirement if the overall impression given by the product is

that it is suitable for treating or preventing disease. The result of a product being classified as such is that it could most likely no longer be marketed as a food or food supplement and would only be marketable subject to authorisation as a medicinal product under Article 6 para 1 of Directive (EC) 83/2001 and the national provisions derived therefrom.

Cosmetics

According to the applicable provisions on controlled substances, the seeds and the other parts of the cannabis plant may be used in cosmetics if the plant was grown from certified seed or if the relevant THC threshold is not exceeded.

From a regulatory perspective, there is a blanket ban on the use of any of the controlled substances referred to in Tables I and II of the United Nations Single Convention on Narcotic Drugs in any cosmetic products. This ban is based on Article 14 para 1 lit. a) of Regulation (EC) No. 1223/2009. Table I of the Single Convention on Narcotic Drugs specifies cannabis, cannabis resin, extracts and structures, with Article 1 lit. b) of the Convention stating that the seeds and leaves are excluded when not accompanied by the flowering/fruited tops. This means that cannabis-based cosmetic products should generally be permitted if they are made from cannabis leaves or seeds. While the stalks of the plant are not explicitly excluded under the Convention, there are legitimate reasons to assume that it does not cover them and that they may be used in cosmetic products. Firstly, it seems likely that the seeds and leaves are excluded due to their low cannabinoid content. The stalks also demonstrate low levels of cannabinoids and are therefore also likely to be excluded under the Convention. Secondly, cannabis is excluded from the Convention so that it can still be used for industrial and commercial purposes which take advantage of its fibrous nature. The stalks of the plant are particularly fibrous and are therefore likely to be excluded from the Convention as well.

The provisions of Regulation (EU) No 655/2013 are particularly important in terms of the advertising of cannabis-based cosmetic products. They state that any claims must be supported by adequate and verifiable evidence. Claims also need to be "honest" with presentations of a product's performance not going "beyond the available supporting evidence". With many aspects of the cannabis plant still not having been fully researched, it is best to take a conservative approach in any advertising for cannabis-based cosmetic products, particularly in terms of any potentially beneficial properties it may have as regards personal care. Another important consideration when making health claims about cosmetic products is that those products are not classified as medicinal products by presentation as a result.

LEGAL CONSEQUENCES OF UNLAWFULLY MARKETING PRODUCTS OR PLACING THEM ON THE MARKET

Any medicinal products, foods, food supplements or cosmetic products which do not meet the applicable regulatory requirements may be banned from commercial sale. Attempting to market these products or place them on the market may also constitute a regulatory or even a criminal offence under the national laws of individual EU member states.

EU law does not provide for any clear competition law sanctions which apply across the European Union. Member states are required to ensure that adequate and effective means exist to combat unfair commercial practices and that these are available to persons or organisations regarded as having a legitimate interest in combating those practices (Article 11 para 1 of Directive (EC) 29/2005). Competitors must be able to assert claims for the cessation or prohibition of unfair commercial practices in line with Article 11 para 2

subsection 1 of Directive (EC) 29/2005 and claims for damages in accordance with Article 13 of Directive (EC) 29/2005. According to no. 9 of Annex I to Directive (EC) 29/2005, for example, misleading commercial practices include stating or otherwise creating the impression that a product can legally be sold when it cannot

CONCLUSION

Medicinal cannabis products and cannabis-based consumer goods are becoming increasingly popular. Parties offering these products still face a considerable amount of legal uncertainty, particularly as regards the issue of foods and food supplements being classified as "novel food". Individual EU member states still often have their own provisions, which are frequently interpreted and applied in a restrictive way, particularly as regards enforcing any bans which may already exist. It remains to be seen how this situation will develop in terms of both individual member states and the EU as a whole.

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