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FDA and Life Sciences

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Europe – Towards a More Harmonized Market for CBD?

On 19 November 2020, the European Court of Justice (“ECJ”) ruled on the French ban of cannabidiol (“CBD”) extracted from whole hemp plants in a case relating to the marketing and distribution of hemp oil containing CBD (case C 663/18)¹. The legality of the ban and of other national restrictions on CBD and CBD products depend on whether such restrictions are adequate and proportionate to the effects of CBD on public health.

The French Public Health Code authorizes the cultivation, importation, exportation and industrial and commercial use of *Cannabis sativa L.* (hemp), provided that only the fibre and seeds of the plant are used and that the plant contains less than 0.2% delta-9-tetrahydrocannabinol (“THC”). The limitation to the use of fibre and seeds only *de facto* amounts to a ban on CBD since CBD is mainly produced from the leaves and flowers of the plant.

The Court was asked whether this ban on CBD infringes (1) EU Regulations No 1307/2013² and No 1308/2013³ relating to the common agricultural market or (2) the principle of free movement of goods set out in Articles 34 and 36 of the Treaty on the Functioning of the EU (TFEU).

The Court’s answer to the first question was “no.” The ECJ ruled that the CBD at issue did not qualify as an agricultural product and thus did not fall into the scope of application of Regulations 1307/2013 and 1308/2013 at all. The Court then turned to the second question, whether the French ban on CBD infringes on the principle of free movement of goods. A preliminary issue was whether CBD qualifies as a narcotic drug under the United Nations Single Convention on Narcotic Drugs⁴ (“Single Convention”) because this qualification would prevent a claim of free movement for CBD within the EU. The Court decided that, while CBD falls into the legal definition of narcotic drug, it would be contrary to the purpose and general spirit of the Single Convention to consider CBD as a



narcotic drug since, based on the available scientific evidence, CBD has no psychotropic effect or harmful effect on human health. Then, regarding the principle of free movement of goods, the Court decided that the French restriction was a quantitative restrictive measure on imports under Articles 34 and that, pursuant to Article 36 TFEU, the restriction could be justified by the protection of public health. The Court concluded that it was for the national referring court to make the determination of whether or not the restriction was justified by the protection of public health, but provided some guidance for the referring court.

This alert briefly explains the relevant legal background. It then examines the European decision and its potential impact on the CBD market in Europe.

The ruling is important because of the increasing use of CBD in different sectors of the market, such as pharmaceuticals, cosmetics, and food. Generally, the ruling should lead the EU Member States to review the current prohibitions and restrictions on marketing of CBD and to replace those that are not adequate and/or proportional with less restrictive ones, which in turn should lead to opening the EU market for CBD and CBD-derived products.

This alert focuses on CBD and addresses neither the use of cannabis for medical or experimental use, nor other hemp-derived products, compounds and cannabis.

A. LEGAL BACKGROUND

Cannabis is regulated at both the European and national level.

EU Regulation. — At the EU level, cannabis is regulated under the legislation on narcotics and on common agricultural market.

On the one hand, the EU Council Framework Decision 2004/757⁵ and the Convention implementing the Schengen Agreement⁶ refer to the Single Convention and the Convention on Psychotropic Substances 1971 that both classify cannabis as a narcotic and require the Member States to adopt all measures necessary to prevent and punish illicit trafficking in narcotic drugs and psychotropic substances.

On another hand, Article 38 of the TFEU authorizes the EU to define and implement a common agriculture policy. The agricultural products covered by the EU agricultural legislation are listed in Annex I of the TFEU. Part VIII of Annex I includes '*True hemp (Cannabis sativa L.) raw or processed but not spun; tow and waste of true hemp (including yarn waste and garnetted stock)*'. Two regulations adopted under the common agricultural framework are relevant for cannabis:

- Regulation 1307/2013, which establishes common rules on direct payments to farmers, authorizes the production of varieties of hemp the THC content of which does not exceed 0.2%;
- Regulation No 1308/2013, which establishes a common organization of markets for agricultural products, regulates imports of hemp into the EU but specifies that more restrictive provisions may be adopted by the MS.

National Regulations. — The EU's objective is to create a common market in which goods circulate freely by, among other means, harmonizing the national legislations in the areas under its exclusive and shared competences.



Harmonization is achieved by EU legislation. In the absence of EU harmonizing legislation, the Member States may adopt national measures, subject to the principle of free movement of goods. This principle prevents national restrictions on imports or measures having an equivalent effect that hinder intra-EU trade (Art. 34 TFEU) unless they are justified by grounds of public interest, including the protection of public health (Art.36 TFEU), and provided that they are adequate and proportionate to their objective.

Therefore, the aspects of the production, marketing, importation, etc. of cannabis and related products that are not covered by the EU common agricultural policy may be regulated by the Member States.

National rules on industrial hemp and CBD or CBD products vary significantly. Cultivation of industrial hemp with 0.2% or less THC is legal in most EU Member States (0.3% in Austria and Luxembourg), but domestic extraction/production of CBD is strictly regulated. For example, in the Netherlands, producing industrial hemp for the use of its fiber and seeds is allowed, but harvesting hemp leaves and flowers and producing hemp extracts (like CBD) is prohibited. Thus, plants are cultivated in the Netherlands, but CBD is extracted in other countries. In Sweden, the Supreme Court considers hemp-derived products/preparations containing THC to be narcotics, regardless of the THC level. In Slovakia, CBD and hemp extracts are illegal. In Bulgaria, CBD may not be produced, but CBD products may freely be imported and sold. Overall, this patchwork creates legal uncertainty as to the regulation of cannabis and related products in the EU.

French Regulation. -- The French Public Health Code regulates the production, manufacture, transportation, importation, exportation, possession, supply, transfer, acquisition and use of plants, substances or preparations classified as poisonous, i.e. narcotic or psychotropic. Cannabis is classified as a narcotic, and Article R. 5132 86 (1) of the Public Health Code specifically regulates the production, manufacture, transportation, importation, exportation, possession, supply, transfer, acquisition or use of cannabis, cannabis plants and resin, products containing or obtained from cannabis.

This article is implemented by the Order of 22 August 1990 that authorizes the cultivation, importation, exportation and industrial and commercial use (fibre and seeds) of varieties of *Cannabis sativa L.*, provided that the THC content of those varieties does not exceed 0.2%. A ministerial guideline of 23 July 2018 specifies that only the fibre and seeds of the plant may be used. Given that CBD is found mainly in the leaves and flowers of the plant rather than in its fibre and seeds, extracting CBD in compliance with the Public Health Code is very technically difficult and expensive.

B. COURT CASE – FACTS

The case concerns the marketing and distribution of Kanavape, an electronic cigarette marketed by Catlab, the cartridges of which contain CBD oil. The CBD was lawfully produced in the Czech Republic from whole hemp plants that had been grown locally. Catlab imported the CBD oil in France, packaged it in cartridges, and sold the cartridges.

Catlab's directors were prosecuted for, among other offenses, infringements of the law on poisonous substances. As part of the criminal investigation, the French Medicines Agency (the National Agency for the Safety of Health Products or 'the ANSM') tested the Kanavape cartridges and concluded that the level of THC was always below the legal threshold and that Kanavape did not qualify as a 'medicinal product'. Nevertheless, Catlab's directors were



found guilty by the Criminal Tribunal of Marseille because the CBD oil was produced from the whole hemp plant rather than its fibre and seeds.

They appealed against that judgment before the Aix-en-Provence Court of Appeals, claiming that the French restriction of CBD from the whole hemp plant was contrary to EU law. The Court of Appeals decided to refer a question to the European Court of Justice: whether Regulations No 1307/2013 and No 1308/2013 and the principle of free movement of goods (Art. 34 and 36 TFEU) must be interpreted as precluding national legislation that prohibits the marketing of CBD when it is extracted from the whole hemp plant instead of from its fibre and seeds.

C. COURT CASE – RULING

The Court had to examine, first, whether the French restriction infringed the regulations on common agricultural market and then, if it did not, whether it infringed the principle of free movement of goods within the EU.

Interpretation of Regulations 1307/2013 and 1308/2013. – The ECJ ruled that the CBD used in the Kanavape cartridges does not qualify as agricultural product. Annex I of the TFEU, which lists the agricultural products, includes “*true hemp (Cannabis sativa), raw or processed but not spun; tow and waste of true hemp (including pulled or garnetted rags or ropes)*”. The CBD oil at issue was extracted from the *Cannabis sativa* plant by carbon dioxide (CO₂) extraction so that it was neither raw hemp (it was not harvested, retted or scutched hemp) nor bast fibres (the extraction process did not involve separating the fibre from the rest of the plant). Therefore, Regulations 1307/2013 and 1308/2013 are not applicable.

Interpretation of Articles 34 and 36 TFEU. – The application of the principle of free movement of goods to the Kanavape CBD oils raised the following questions.

Is CBD a narcotic drug? Generally, the harmfulness of narcotic drugs is recognized and their marketing, importation, etc. are prohibited in all the Member States except for strictly controlled trade for medical and scientific uses. Insofar as narcotic drugs which are not distributed through such strictly controlled channels are prohibited from being released into the EU economic and commercial channels, companies that market cannabis may not rely on the principle of free of movement of goods. The Court therefore first had to determine whether CBD qualifies as a narcotic drug.

The ECJ noted that CBD is not covered by the Convention on Psychotropic Substances or by the EU Framework Decision 2004/757. It then decided that it is not included in Schedules I and II of the Single Convention (referred to in the EU Framework Decision 2004/757 and the Convention implementing the Schengen Agreement).

According to the Court, a literal interpretation of the Single Convention might lead to the conclusion that CBD extracted from the whole plant of *Cannabis* genus – including its flowering or fruiting tops – constitutes a cannabis extract and thus a ‘drug’ within the meaning of the Schedule I Single Convention. However, the objective of the Single Convention should be taken into account when interpreted, and one of its objectives is to protect human health and welfare. The definition of ‘drug’ thus is intrinsically linked to the state of scientific knowledge about the harmfulness of cannabis-derived products to human health. Given that, based on the available scientific evidence, CBD does not appear to have any psychotropic effect or harmful effect on human health and does not contain a



psychoactive ingredient, the ECJ decided that it would be contrary to the purpose and general spirit of the Single Convention to include it under the definition of 'drugs'.

To the extent that CBD does not qualify as a narcotic drug under the Single Convention, Articles 34 and 36 TFEU apply.

Does French law impose a restriction on import from other MS? -- The principle of free movement of goods prohibits quantitative restrictions on imports between Member States and all measures having equivalent effect. This prohibition covers any national measure that is capable of hindering, directly or indirectly, actually or potentially, intra-Union trade, i.e. of preventing products originating in a Member State from entering into another Member State.

The Court considered that the prohibition on marketing of CBD lawfully produced in another Member State – when it is extracted from the whole hemp plant and not solely from its fibre and seeds – constitutes a measure having equivalent effect to quantitative restrictions within the meaning of Article 34 TFEU.

Is the quantitative restriction on import justified by public health? – A measure having equivalent effect to quantitative restrictions may be justified on one of the grounds of public interest set out in Article 36 TFEU or by imperative requirements. In either case, the national measure must be appropriate for, and proportionate to, the objective pursued.

The ECJ first recalled its case law regarding Article 36:

- It is for the Member States to determine the level of protection that they wish to afford to public health and the way to achieve that level. This level may vary from one Member State to another; hence, some discretion is allowed, which is particularly wide where uncertainties persist in the current state of scientific research.
- Article 36 TFEU contains exceptions to free movement of goods with the EU and must be narrowly interpreted. It is therefore for the national authorities to demonstrate, taking the results of international scientific research into account, that their legislation is necessary to effectively protect the interests it refers to and, in particular, that the marketing of the products poses a genuine threat to public health. The real risk alleged for public health should appear sufficiently established based on the latest scientific data available. The risk assessment to be carried out by the Member States must appraise the degree of probability of harmful effects on human health and the seriousness of those potential effects.
- In exercising their discretion relating to the protection of public health, the Member States must comply with the principle of proportionality. The risk assessment may reveal a high degree of scientific and practical uncertainty, which influences the Member State's discretion. Under the precautionary principle, a Member State may take protective measures without having to wait for the reality and seriousness of those risks to be fully demonstrated, but the assessment of the risk cannot be based on purely hypothetical considerations. Where it proves impossible to determine with scientific certainty the existence or extent of the alleged risk, but where there is a likelihood of real harm to public health should the risk materialize, the precautionary principle justifies the adoption of restrictive measures, provided they are non-discriminatory and objective.



The Court then ruled that it is for the referring court to determine whether the restriction on the marketing CBD lawfully produced in another Member State – when it is extracted from the whole *Cannabis sativa* plant - is appropriate and proportionate to protect public health. It however provided guidance to the national court in order to make such a determination:

- Determination of whether the restriction is appropriate: the restriction would not affect the marketing of synthetic CBD that has the same properties as CBD extracted from the whole *Cannabis sativa* plant and could be used as a substitute. The referring court should verify that fact which, if proved, would indicate that the legislation was not appropriate for reaching the objective in a consistent and systematic manner.
- Necessity of a prohibition on the marketing of CBD where it is extracted from the whole *Cannabis sativa* plant: France is not required to demonstrate that the dangerous property of CBD is identical to that of narcotic drugs, but the referring court should assess the scientific data available to make sure that the risk to public health does not appear to be based on purely hypothetical considerations.

Overall, the ECJ ruled that (i) CBD does not qualify as a narcotic drug ; (ii) Articles 34 and 36 TFEU preclude a national legislation which prohibits the marketing of CBD lawfully produced in another Member State when it is extracted from the whole *Cannabis sativa* plant and not solely from its fibre and seeds, unless that legislation is appropriate and proportionate to secure the protection of public health; and (iii) it is for the national courts to make this determination. This ruling was consistent with the EU Commission's position.

D. IMPLICATIONS OF THE RULING

Less restrictive national legislations. — The ECJ ruling could have a significant impact not only for the French market but also for the EU market for CBD and CBD products. Current national regimes regulating hemp derived CBD products could be loosened, and more proportionate restrictions could be adopted, leading to a partial liberation of the CBD market. At minimum, further investigation and research on the effects and risks of hemp-derived CBD can be expected from the Member States that wish to keep general prohibitions and a strict framework on hemp derived CBD products, since only a risk to public health which is sufficiently established may justify a prohibition against market products imported from other Member States.

On 24 November, following the ECJ ruling, the French Inter-Ministries Mission for Combatting Drugs and Addictive Behaviors (MILDECA) published an alert on CBD. While they are already examining ways to take the ECJ's conclusions into consideration, the French authorities insisted on the importance of convincing scientific evidence. They also underlined the importance of developing a common European approach to CBD-based products.

The next question is the alternative restrictions that may be considered as proportionate. While the ECJ suggested that a general prohibition on the cultivation, industrialization and marketing of hemp solely to fibre and seeds and as result of hemp derived CBD is disproportionate and thus not compatible with EU law, it did not propose alternative measures. Those measures could be specific product characteristics (i.e. a maximum CBD content), restricted sale channels, or advertisement limitations. In each MS, it is for the national courts to assess the adequacy and proportionality of the existing and future restrictions.



In the long-term, the Court's ruling could trigger the adoption of more harmonized national legislations on hemp-derived CBD and thus a less fragmented European CBD market and thereby a more secure environment for both the CBD industry and the CBD consumers.

Food sector – CBD is not a narcotic drug. — The ruling could also have a significant impact on other market sectors that use CBD such as the food sector.

In most EU countries, CBD is not classified as controlled drug, and CBD products may fall under the scope of other EU sectorial frameworks. For example, under EU food legislation, hemp seeds and seed-derived products (i.e. seed oil, hemp seed flour, defatted hemp seed) are considered as foodstuffs, and the Member States may adopt specific national legislation restricting their placing on the market as food or food ingredients. The status of hemp leaves, hemp flowers and their derived products, however, remains a grey zone.

Since February 2019, extracts of *Cannabis sativa L.* plant and derived products containing cannabinoids (including CBD) are considered novel foods and, as such, must be authorized before being marketed in the EU (Regulation 2015/2283 on Novel Food). However, in July 2020, the EU Commission announced that it was considering placing CBD derived from the whole hemp plant and other hemp flower extracts under the Single Convention as narcotic substances. This announcement led to the suspension of the assessment of the applications for authorization of hemp-derived CBD products as novel foods, until further clarification.

On the other hand, the UK Food Standards Agency (FSA) announced that CBD and CBD-derived products should be regulated as novel food and that novel food applications will be accepted in the UK after Brexit.

The ECJ ruling, which clarifies that hemp-derived CBD does not qualify as narcotic drug, should lead the EU Commission to review its position on the legal status of those products.

What about other CBD products? The ECJ ruling concerned a product containing CBD extracted from whole hemp plants by a CO₂ extraction process. What about other CBD products? A distinction should be made depending on whether the CBD product does or not qualify as agricultural product under Annex I of the TFEU. If, like the Kanavape CBD, it does not qualify as such, the ECJ ruling in the *Kanavape* case applies. If, on the other hand, it qualifies as agricultural product, then Regulations 1307/2013 and 1308/2013 apply. The question becomes whether the application of Regulations 1307/2013 and 1308/2013 would lead to another outcome. First, Regulations 1307/2013 and 1308/2013 should not apply to national restrictions other than those relating to cultivation (subject-matter of Regulation 1307/2013) and imports from non-EU countries (subject-matter of Regulation 1308/2013). Second, even assuming that those regulations are applicable, the reasoning would be similar to this made by the Court in the *Kanavape* case. In a nutshell, Regulations 1307/2013 and 1308/2013 do not prevent the Member States from adopting restrictive measures on intra-EU trade of CBD in order to protect public health, provided that those measures are adequate to protect public health against the risks arising from CBD and are proportionate to that objective.



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¹ ECJ, 19 November 2020, *B S and C A*, Case C-663/18.

² Regulation (EU) 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009.

³ Regulation (EU) 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007.

⁴ United Nations Single Convention on Narcotic Drugs of 1954 as amended by the 1972 Protocol.

⁵ Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking.

⁶ The Schengen acquis - Convention implementing the Schengen Agreement of 14 June 1985 between the Governments of the States of the Benelux Economic Union, the Federal Republic of Germany and the French Republic on the gradual abolition of checks at their common borders.