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Medical Cannabis & Cannabinoid Regulation 2025

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France: Law and Practice

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FRANCE

Law and Practice

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Contents

NOOA Avocats is a boutique law firm based in Paris, France that is dedicated to the life sciences sector. Founded in 2020, NOOA Avocats advises and represents the interests of various types of companies in the life sciences sector on regulatory matters (market access, clinical trials, product advertising, vigilance, etc), assists them with drafting and negotiating transactions, and represents them in litigation. NOOA Avocats also has an extensive practice in the cannabis sector, advising clients on regulatory and strategic issues related to both the medical cannabis and wellness hemp markets in France, and representing them in commercial litigations against competitors. Always acting as a business partner, the firm participates in *"best friends"* network with other law firms and consulting companies who specialise in the life sciences and cannabis sectors, both in France and globally, to provide clients with worldwide expertise and to support them in their international projects and development.

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Marie Sanchez has over 15 years of prior legal experience, and founded NOOA Avocats to better serve clients in the life sciences sector (including clients in the pharmaceuticals, medical devices, nutraceuticals, cosmetics, food supplements and veterinary drugs sectors) by offering bespoke guidance on regulatory issues, litigation and contractual matters. She has also developed in-depth expertise on regulatory and legal issues related to the emerging cannabis industry. Her clients include companies of all sizes, both French and international. She is a member of the Paris and Quebec Bars, the International Bar Association (IBA) and the French Regulatory Affairs Association (AFAR). She is also a member of the governing board and co-chair of the International Committee of the International Cannabis Bar Association (INCBA).

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1. Regulatory Framework

1.1 Primary Laws & Regulations

In France, cannabis and cannabinoids are regulated by a complex set of rules composed notably of laws, decrees and ministerial orders setting forth a general prohibition of cannabis, which is classified as a narcotic substance.

General Prohibition of Cannabis Under French Law

According to the French public health code, the production, manufacturing, transportation, importation, exportation, possession, sale, purchase and use of plants, substances or preparations classified as poisonous, including narcotic substances and psychotropic substances, are governed by regulatory provisions defined by ministerial orders. For the sake of clarity, ministerial orders (*Arrêté* in French) are administrative acts published by ministers and set forth certain rules regulating (for instance) specific sectors, products or activities.

The French ministerial order of 22 February 1990 (Appendix I) classifies cannabis and cannabis resin as narcotic substances. More specifically, French law strictly prohibits the production, manufacturing, transportation, importation, exportation, storage, supply, distribution, purchase or use of:

- cannabis, and its plant and resin, as well as products that contain it or that are produced from cannabis, its plant or its resin; and
- tetrahydrocannabinols, their esters, ethers and salts, and the products containing them.

Exceptions to the General Prohibition Rule

Nevertheless, French law provides for several exceptions to the general prohibition.

The manufacturing, transportation, importation, exportation, possession, sale, purchase or use of medicines containing cannabis or one of the cannabis plant components is allowed if the product has been granted a marketing authorisation either from the French Medicines Agency (*Agence nationale de sécurité du médicament et des produits de santé* (ANSM)) or from the European Medicines Agency (EMA).

Other cannabis-based medicinal products that satisfy specific criteria (notably characteristics, composition, pharmaceutical forms, therapeutic indications) but do not hold a marketing authorisation are accessible as described below.

The ANSM can grant specific authorisations for the production, manufacturing, transportation, importation, exportation, storage, supply, distribution, purchase or use of cannabis and/or its components for research and development purposes.

Cultivation, importation, exportation, and industrial and commercial use of hemp plants that do not have any narcotic properties, or of products containing or made out of such hemp strains, can be allowed by ministerial order upon proposition from the General Director of the ANSM.

To date, cannabis regulation remains a work in progress, since there is no fully established legal framework in France. Adult-use cannabis is not legal, and legalisation thereof is unlikely to happen any time soon. Medical cannabis (other than medicines containing cannabis and holding a marketing authorisation) was authorised and therefore accessible to a very limited number of patients through a pilot programme until 25 March 2024, and is currently only accessible to patients that were enrolled in the pilot programme until the legalisation of medical canna-

bis becomes effective. Regulation on wellness hemp remains subject to grey areas that could benefit from numerous clarifications for the sake of a safe market, both for consumers and for operators.

Medical Cannabis

To date, medical cannabis is only allowed in France if:

- the product is a medicine holding a marketing authorisation or is accessible through early-access programmes (eg, Sativex, Epidyolex, Marinol) issued by the French or the European competent health authority (*"medicines containing cannabis"*) or
- the cannabis-based product is supplied, prescribed and administered to patients under the conditions of a pilot programme that started in March 2021, until the legalisation of medical cannabis (to be understood as cannabis-based medicinal products subject to a use authorisation) enters into force.

In other words, any activities related to the cultivation, production, manufacture, transportation, importation, exportation, detention, supply, transfer, acquisition or use of cannabis for exclusively therapeutic purposes outside one of the above-mentioned frameworks are considered criminal offences related to drug trafficking, and are therefore prohibited in France.

The pilot programme on therapeutic cannabis, which began in March 2021, was designed to enrol up to 3,000 patients over an initial two-year period to assess the feasibility of the supply, prescription and delivery of medical cannabis to patients for whom no other therapeutic alternative is available. Because there is no domestic production line in France yet, supply was performed exclusively by foreign companies who were selected through a tender, and who were initially required to supply the products free of charge and at their own costs for the entire duration of the pilot programme.

The requirements related to the products, the supply chain, physician training, prescription and delivery as part of the pilot programme were set out in a statement of work published on 19 October 2020, as summarised below.

- Medical cannabis is allowed for five therapeutic indications:
  - (a) neuropathic pain that cannot be treated with available therapies (medicines and non-medicines);
  - (b) certain serious and pharmaco-resistant forms of epilepsy;
  - (c) as part of supportive care in oncology (eg, nausea, vomiting, anorexia);
  - (d) palliative situations; and
  - (e) painful spasticity related to multiple sclerosis or other central-nervous-system-related diseases.
- The products must be supplied as finished products only in their final packaging, ready to be delivered to the patient.
- The authorised forms of medical cannabis were initially dried flowers for inhalation by vaporisation (smoking use was excluded from the allowed uses) and oil and capsules for oral use.
- The products use different ratios – the tetrahydrocannabinol (THC) dominant ratio, cannabidiol (CBD) dominant ratio, or balanced THC and CBD ratio.
- The production of medical cannabis must comply with a certain number of industry standards, such as good agricultural and collection practices (GACP) for starting materials of herbal origin (EMEA/HMPC/246816/2005) and good manufacturing practices (GMP)

set forth in the French public health code or any equivalent guidelines recognised at the international level, in addition to several other guidelines, including:
  (a) the Guidelines on Quality of HMPs/THMPs (CPMP/QWP/2819/00 Rev 2);
  (b) the Reflection Paper on Microbiological Aspects of HMPs and THMPs (EMA/HMPC/95714/2013); and
  (c) the ICH Q2 Guidelines for Validation.
- The plants used to make the products must meet the specifications of the monograph *"Plant Drugs"* (1433) of the European Pharmacopoeia.
- Suppliers need to obtain both an importation authorisation for narcotic substances from the ANSM and an exportation authorisation for narcotic substances from the country of origin.
- Selected suppliers were required to enter into a partnership agreement with a pharmaceutical establishment located in France for the distribution of medical cannabis to pharmacies and hospital pharmacies that participate in the pilot programme.
- The pharmaceutical establishment located in France in charge of the distribution of the medical cannabis on the territory must have the status of operator and importer, if applicable, and must hold a narcotics authorisation relating to medical cannabis in the context of the pilot programme.
- The initial prescription of the products was reserved to physicians working at multidisciplinary reference centres specialised in the five indications for which treatment with medical cannabis was allowed. However, once the patient was stabilised, general practitioners were allowed to prescribe medical cannabis to them, upon agreement of both the specialist and the general physician.
- All prescribers involved in the pilot programme must have followed mandatory training (e-learning).
- The dispensing of medical cannabis occurred initially in hospital pharmacies and could later be carried out by retail pharmacies once the stabilisation of the patient had been reached.

While legalisation of medical cannabis was initially expected at the end of the two-year programme, the French authorities decided to extend the pilot programme by one year (Decree No 2023-202 of 25 March 2023).

The pilot programme ended on 25 March 2024 and medical cannabis (*"cannabis-based medicinal products"*) was expected to be generalised on the French market by 1 January 2025 at the latest. However, the complex political situation in France in 2024 resulted in major delays in the setting-up of the legal and regulatory framework. While the legal framework was set out in December 2023 and transposed in the French public health code, the relevant regulatory decrees and orders whose publication is necessary for the generalisation of cannabis-based medicinal products to become effective remain a work in progress at this date.

More specifically, the legal framework regarding cannabis-based medicinal products was set out in French Law No 2023-1250 of 26 December 2023, on the financing of social security for 2024. The law refers to the term *"cannabis-based medicinal product"* and defines it as *"any medicinal product whose active substance is composed of a preparation based on Cannabis sativa L (extract), manufactured in accordance with the good manufacturing practices set out in Article L 5121-5 [of the French public health code] or any equivalent internationally recognised standard by establishments mentioned*

in Article L 5124-1 [of the French public health code] and meeting the specifications set by an order of the Minister for Health issued on the recommendation of the General Director of the French National Agency for the Safety of Medicines and Health Products".

The law also sets out the following conditions for cannabis-based medicinal products to be placed on the French market.

- The cannabis-based medicinal products can only be manufactured and distributed by duly authorised pharmaceutical establishments.
- The cannabis-based medicinal products must obtain a temporary authorisation for use from the ANSM. The use authorisation is delivered for an initial period of five years, renewable for subsequent periods of five years.
- Only companies established in a member state of the European Union (EU) or a country party to the Agreement on the European Economic Area can apply for a use authorisation.
- The use-authorisation holder must collect follow-up data of patients treated at its own costs and provide the ANSM with an annual report.
- The cannabis-based medicinal products can only be prescribed as last-line treatment.
- The information delivered by the use-authorisation holder to healthcare professionals in relation to the use authorisation regarding cannabis-based medicinal products must not be considered promotional. The ANSM is yet to set out the framework for such information (for sanctions in the case of breach of this obligation, please see **1.6 Enforcement & Penalties**).

However, the legalisation of medical cannabis can only become effective once the relevant decrees and orders setting out the specifications on cannabis cultivation, the specifications on products, prescription and delivery, as well as the criteria for price-fixing and reimbursement of the products, are published, which is yet to happen.

On 19 March 2025, the French government notified the drafts of a decree and two orders on the European Commission's Technical Regulation Information System (TRIS) database, in order for the Commission to assess their compliance with EU law.

These draft regulatory documents provide specifications notably on the production line, the products that can be authorised for use and the prescription and delivery requirements. According to these documents, the following applies.

- Only companies that are authorised as *"pharmaceutical establishments"* (as defined by the French public health code) can apply for a use authorisation for cannabis-based medicinal products.
- The cultivation of the cannabis plant for medical purposes can only be carried out by growers that have entered into an agreement for that specific purpose with a pharmaceutical establishment holding the use authorisation for cannabis-based medicinal products.
- Only indoor cultivation is allowed and the premises where the cannabis plant is to be cultivated must meet the strict requirements, notably in terms of security set out in the relevant order. Outdoor growing is strictly prohibited.
- The requirements for the use-authorisation dossier to be submitted to the ANSM are the same as those applicable to standard marketing authorisation dossiers for medicines, except for clinical study results that do not apply to cannabis-based medicinal products.

Likewise, the pharmacovigilance requirements are the same as those applicable to medicines holding a marketing authorisation.
- Prescription of cannabis-based medicinal products can only be done as a last line treatment – ie, when other available therapies have failed, and in cases where other existing medicines offer little relief or are not tolerated well by patients, or when no suitable pharmaceutical speciality is available.
- Initial prescription must be hospital prescription only.
- Physicians must complete a specific training prior to being able to prescribe cannabis-based medicinal products. However, specifications on this mandatory training are yet to be defined.
- The five therapeutic indications in which cannabis-based medicinal products can be prescribed are the same as those authorised under the pilot programme (as previously described).
- Cannabis-based medicinal products can only be placed on the market as finished products and in accordance with the following requirements:
  (a) dried or granulated flowering tops are not authorised unless they are presented in secure, tamper-proof primary packaging;
  (b) the pharmaceutical forms of authorised final products are oral or sublingual forms;
  (c) other pharmaceutical forms can be authorised provided that they are authorised by the ANSM;
  (d) smoking use of the cannabis-based medicinal products is prohibited; and
  (e) inhalation is permitted provided it is done by using a specific inhalation device that must hold a CE mark as a medical device.

The status quo period is to end on 20 June 2025, provided that no event will stop the clock in the meantime. If the European Commission does not issue a detailed opinion, one could reasonably expect the decree and orders to be finally published during the fourth quarter of 2025.

In the meantime, in order to ensure that the patients that were enrolled in the pilot programme can still have access to medical cannabis, the French Minister of Health has decided to extend the pilot programme until 31 March 2026. During that extension period:

- only patients who were enrolled in the pilot programme and were still in it on 25 March 2024 can access medical cannabis;
- the products accessible to those patients are the same as those authorised under the pilot programme (with the exception of dried flowers, which have been removed from the list of authorised products);
- only suppliers elected under the pilot programme can supply the products during the transition period; and
- the conditions of prescription and delivery remain the same as under the pilot programme.

In other words, the transition period does not allow access for new patients, nor does it extend the list of products or suppliers. Therefore, access to medical cannabis remains limited until its effective legalisation.

Industrial Hemp and Cannabinoid-Based Consumer Products

Industrial hemp and hemp extracts are governed by the French ministerial order of 30 December 2021, authorising the cultivation, importation, exportation, and industrial and commercial use of hemp plants that contain up to 0.3% of THC, and that are duly registered in the Common Catalogue of Varieties of Agricultural Plant Species

or the French Catalogue of Plant Varieties and Species.

Hemp extracts and hemp-derived finished products containing extracts can be legally marketed in France if they meet the following requirements:

- hemp extracts (including CBD) must be obtained by using the entire hemp plant, and finished products containing CBD must be extracted from the entire hemp plant; and
- the THC level contained in the hemp extracts and the products containing such extracts must not be more than 0.3%, without prejudice to the provisions of Articles 14 and 15 of Regulation (EC) 178/2002 as regards requirements on the general safety of goods, or to any other more restrictive regulation.

It should be noted that the ministerial order of 30 December 2021 initially set forth a prohibition on the retail sale to consumers, and the possession, use and/or consumption by consumers, of raw hemp flowers and leaves, regardless of their form (eg, smoking products, potpourri, tea), whether alone or mixed with other ingredients (such as tea preparations), hence limiting the authorised use of the entire hemp flower to industrial use only.

However, the French Council of State (*Conseil d'Etat*) repealed the litigious provision in a ruling of 29 December 2022, notably judging that the French government had failed to bring sufficient proof of an actual risk to public health or public order such as they were using as grounds for the prohibition. Consequently, the retail sale to consumers of raw flowers and leaves – whatever their form and including prepacked flowers – is now allowed in France.

In addition to the general rules mentioned above, specific rules apply depending on the category of the finished products concerned, as follows.

Rules for Specific Products

CBD smoking products

CBD smoking products (ie, plant-based products that do not contain tobacco and can be consumed by means of a combustion process) are subject to compliance with French rules under application of European Directive 2014/40 of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the member states concerning the manufacture, presentation and sale of tobacco and related products.

The products and their packaging are subject to strict conditions. Applicable law notably prohibits use on the packaging, the product itself and related commercial material of any mention, logo, image or promotional mark that:

- contributes to the promotion or incites the consumption of the product, by giving an erroneous impression of the product's characteristics, health effects, risks or emissions – the labels must not include any information on the product's nicotine, tar or carbon monoxide content, as the case may be;
- suggests that a product is less harmful than others, is intended to reduce the effect of certain harmful components of smoke or has vitalising, energising, healing, rejuvenating, natural, organic, or health or lifestyle benefits;
- indicates that the product is free of additives or flavourings; or
- creates confusion with a food or cosmetic product.

Packaging units and all outer packaging must also bear a health warning in the French language.

Manufacturers and importers are required to declare each product and its composition to the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) before placing it on the market.

CBD smoking products are not currently subject to excise duty in France. In the absence of a dedicated tax category, they are likely classified as other smoking or inhalation tobacco, and are subject to VAT at the standard rate of 20%.

In addition, in the absence of official specific regulation, the producers and distributors of these products are not currently subject to any approval being granted by the General Directorate of Customs and Excise.

CBD in foodstuffs

CBD is considered a novel food and must therefore be authorised prior to it being placed on the market as such or used in a food product as per Regulation (EU) 2015/2283 (the *"Novel Food Regulation"*). This point is explained in more detail in **3.2 Non-Controlled Cannabinoids in Food**.

Animal food products

CBD used as an isolated substance or enriched extracts obtained from extraction processes are considered food additives, and as such must be authorised prior to being placed on the market. To date, CBD, regardless of its processing method, has not been authorised at the EU level as a pet food additive.

CBD-based cosmetic products

CBD-based cosmetic products can be legally placed on the market if they comply with the provisions of Regulation (EC) 1223/2009 on cosmetic products (the *"Cosmetics Regulation"*), and assuming they do not make any health claim. The use of hemp extracts in cosmetic products is strictly regulated. CBD alone or other hemp extracts must not fall under one of the prohibitions set out in Annex II of the Cosmetics Regulation, notably entry No 30 *"Narcotics, natural and synthetic: All substances listed in Tables I and II of the Single Convention on Narcotic Drugs signed in New York on 30 March 1961"*.

Cannabis extracts that can be used in the manufacturing of cosmetic products without restrictions are listed in the European Commission's database for information on cosmetic substances and ingredients (CosIng). Even though CosIng is not legally binding, it is used as a reference by competent authorities, notably in the control of cosmetic products.

E-liquids and vaping products

E-liquids and vaping products can be marketed on the French market, provided that:

- the maximum THC level they contain remains below 0.3%;
- they comply with Regulation (EC) 1272/2008 (the *"CLP Regulation"*) and Regulation (EC) 1907/2006 (REACH) requiring registration with the European Chemicals Agency (ECHA) of chemical substances that are manufactured or imported in quantities above one ton per year;
- vaping products containing nicotine are declared to the French competent authority for the safety of food, environment and work (ANSES) by the manufacturer or the

importer six months prior to being placed on the market – the declaration must be made on the EU's common electronic entry gate, and the information and all related documents submitted as part of the declaration must be in French; and
- they are not sold to minors.

The regulation of CBD-based consumer products has been subject to many changes over the past few years. Case law has notably played a major role in the evolution of the applicable regulation.

However, there is still some lack of clarity on many aspects related to CBD-based consumer products. The need for clarification in regulation remains critical, to ensure both legal security for operators and consumer safety.

Most recently, the ANSES has proposed that CBD be classified as *"presumed human reproductive toxicant"*. On 17 March 2025, the dossier associated with such proposal was submitted for public consultation on the ECHA's website The consultation should last until 16 May 2025. The aim of this consultation is to give all stakeholders the opportunity to comment on this proposal, by providing any additional scientific arguments and information they may have on the substance's hazard properties. Following this consultation, the initial proposal, comments received and ANSES's responses to them will be analysed by the ECHA's Committee for Risk Assessment, which is to then issue an opinion on the harmonised classification of CBD.

Synthetic Cannabinoids

Lately, new cannabinoids (synthetic cannabinoids and phytocannabinoid derivatives) have emerged on the French market. Alerted by an increase in consumer intoxications, the French authorities have taken measures to classify these new narcotic substances.

Hence, in a decision dated 13 June 2023, the ANSM classified hexahydrocannabinol (HHC) and two derivatives thereof – ie, HHC-acetate (HHCO) and hexahydroxycannabiphorol (HHCP) – as narcotics.

Subsequently, by a decision dated 22 May 2024 and published on 24 May 2024, the ANSM classified several new substances as narcotics:

- 5F-CUMYL-PEGACLONE (5F-SGT-151);
- CUMYL-CH-MEGACLONE (SGT-270);
- 7APAICA;
- 5F-7APAICA;
- CUMYL-P7AICA;
- 5F-CUMYL-P7AICA;
- BZO-HEXOXIZID (MDA-19);
- BZO-POXIZID (5C-MDA-19);
- certain cannabinoid derivatives formed from the benzo[c]chromen nucleus, except CBN (cannabinol);
- HHCPO;
- THCA;
- H4-CBD; and
- H2-CBD.

However, the ANSM modified its decision by a new decision of 3 June 2024, by which it excluded from classification substances that may be contained in very low concentrations in products derived from industrial, textile or agricultural hemp – ie:

- CBNA (cannabinolic acid), a precursor of CBN which is already excluded from classification;
- THCVA (tetrahydrocannabivaric acid) and THCV (tetrahydrocannabivarin), provided that

their content does not exceed 0.3% respectively; and
- THCA (tetrahydrocannabinolic acid), provided that their THC content complies with the 0.3% threshold.

1.2 Regulatory Bodies

The cannabis sector is controlled by several competent authorities, each charged with specific missions.

The ANSM is charged with the control of health products governed by the French public health code. It is the control authority for:

- medicines containing cannabis and holding a marketing authorisation;
- medical cannabis (under the pilot programme and the transition period); and
- cannabis-based medicinal products that will hold a use authorisation after the legalisation of medical cannabis.

Among its powers, the ANSM can:

- provide marketing authorisations;
- authorise pharmaceutical establishments;
- issue importation/exportation authorisations;
- control regulatory compliance of products; and
- allow clinical trials.

It must be noted that since January 2024 the control of cosmetic products that the ANSM used to share with the *Direction générale de la concurrence, de la consommation et de la répression des fraudes* (DGCCRF) has been fully transferred to the DGCCRF.

The DGCCRF is charged with the control of several types of products – in particular, consumer products such as food and cosmetics. It ensures that these products are compliant in terms of quality, composition and labelling, and that they are not associated with misleading commercial practices related to their origin or quality. The DGCCRF also controls claims that may be made by distributors on their products.

The *Direction générale de l'alimentation* (DGAL) is charged with the control of food safety. It is competent to control supply chains of vegetal and animal food stuffs.

The *Agence nationale du médicament vétérinaire* (ANMV) is the competent authority for veterinary drugs, and is competent to:

- assess marketing authorisation applications;
- control the risk of side effects;
- control the quality of veterinary medicines and advertising thereof; and
- authorise veterinary medicines, clinical trials and pharmaceutical establishments, and the importation/exportation of products.

1.3 Self-Regulatory Authorities

In France, several trade bodies and organisations are in charge of medical cannabis or industrial hemp-related activities, including but not limited to:

- *Santé France Cannabis*
- *L'Union des industriels pour la valorisation des extraits de chanvre* (UIVEC);
- *Le syndicat du chanvre* (SPC); and
- *La Fédération nationale des producteurs de chanvre* (FNPC).

These organisations represent players in the industry, and participate in the setting of legal frameworks related to medical cannabis or industrial hemp.

1.4 Challenges for Market Participants

Medical Cannabis

Until the generalisation of medical cannabis (cannabis-based medicinal products) becomes effective – ie, once all the relevant application decrees and orders are published and have entered into force – market opportunities in France are limited to foreign suppliers and their French distributors who were selected for the implementation of the pilot programme, or to the marketing-authorisation holders of medicines containing cannabis, as the case may be.

While the legal framework is still being developed, and until actual publication of the relevant decrees and orders in the Official Journal, there is and will be a lack of visibility on certain fundamental questions, notably regarding the determination of applicable criteria for price-fixing and reimbursement of cannabis-based medicinal products.

Likewise, uncertainty remains as to the exact requirements applicable to the cultivation and production of cannabis for medical purposes as well as product specifications until the official publication of the relevant decree and orders.

The clock is ticking, and it goes without saying that market players are eagerly waiting for these regulations to be published.

Wellness Hemp

Companies producing and distributing cannabinoid-based consumer products, including CBD products, also face a number of challenges.

While the decision of the Council of State in December 2022 allowed the resumption of distribution and sale to consumers in France of raw hemp flowers and leaves, it should be noted that the French government is still expected to bring much-needed clarification. However, it remains unclear what modifications will be made, whether any new restrictions will be set out and when this will occur.

Another major challenge for operators in the French market relates to novel food. The absence of a clarified position being taken by the French competent authorities creates uncertainty and generates risk for market players, who are still likely to face controls and sanctions.

Finally, litigation has also arisen between economic players, with some companies engaging in lawsuits against competitors on the grounds of unfair competition.

1.5 Legal Risks

Conducting business in an emerging sector, for which the legal and regulatory framework is not entirely developed, necessarily involves risks.

The most common identified risk is that related to THC levels contained in products. Any product containing more than 0.3% of THC is considered a narcotic if:

- it is not a medicine containing cannabis and holding a marketing authorisation;
- it is not a cannabis product supplied as part of the pilot programme on therapeutic cannabis during said programme and currently the transition period, or a cannabis-based medicinal product duly authorised for use by the ANSM after the entry into force of the legalisation; or
- it has not been authorised for research and development purposes.

Any activity related to such product is therefore considered a drug trafficking offence.

In addition, companies distributing hemp-derived products including CBD products to consumers must be aware of the following risks.

Prohibition of Therapeutic Claims and the Risk of Qualification of Foodstuffs/Food Supplements as Medicinal Products

Therapeutic claims are strictly prohibited for food/dietary supplements, as set out in Regulation (EU) 1169/2011 of 25 October 2011 on the provision of food information to consumers. As the line between some product categories (ie, medicinal products, food supplements and foodstuffs) is very thin, making unauthorised health and therapeutic claims in relation to foodstuffs is likely to result in the requalification of the products as medicinal products and to entail criminal sanctions.

Prohibition of Sale of a Medicinal Product Without a Prior Marketing Authorisation

A medicinal product (including a medicine by presentation and a functional medicine) can only be placed on the market if it has been granted a marketing authorisation from the French competent health authority (the ANSM or EMA for human medicines, and the ANMV for veterinary medicines). If a food product may be requalified as a medicinal product due to the prohibited therapeutic claims that were made in relation thereto, the selling of a medicinal product without a prior marketing authorisation would constitute an offence.

Prohibition of Activities Without Mandatory-Use Authorisation From the ANSM

Regarding prohibition of manufacturing, placing on the market, brokering or distribution of cannabis-based medicinal products without having obtained the mandatory-use authorisation from the ANSM, see the definitions in **1.1 Primary Laws & Regulations**.

The Illegal Practice of Pharmacy

Under French law, only pharmacists are allowed to sell medicines. Consequently, operators using therapeutic claims to sell consumer products may face charges for illegal practice of pharmacy should their products be requalified as medicinal products.

Incitement to Use Narcotics

CBD products must not be presented or advertised in a way that could be interpreted as an incitement to use narcotics. In other words, any presentation and/or advertising of a CBD product that is likely to create confusion with recreational cannabis and hence to be considered as inciting the consumer to use recreational cannabis is strictly prohibited.

Breach of the Novel Food Regulation

Applicable enforcement and sanctions are discussed in **3.2 Non-Controlled Cannabinoids in Food**.

1.6 Enforcement & Penalties

Various authorities oversee compliance depending on the category of products concerned. Controls and administrative sanctions are applied by the ANSM for medicines and other health products, while the ANMV is the enforcement authority for veterinary products.

For consumer products, the DGCCRF runs frequent controls to verify compliance with the requirements for claims, presentation and labelling of products, as well as to identify any misleading commercial practices in relation to food products, food supplements and cosmetic products. The DGAL oversees enforcement in the case of any breaches of food safety requirements.

The competent authorities can apply administrative sanctions, such as by:

- issuing warnings;
- requiring corrective actions; and
- ordering the withdrawal of non-compliant products from the market.

They can also apply administrative fines to infringing companies.

In addition, several types of criminal penalties can apply. For criminal offences, enforcement is the responsibility of the public prosecutor, who can decide to prosecute either following police investigation or upon transfer of a report from the competent authorities mentioned above.

Key Criminal Sanctions

Of the common criminal sanctions that can apply in relation to the cannabis industry, the following are worth noting.

Drug trafficking

Drug trafficking can result in sanctions of between five years and life in prison (generally subject to a determined period of unconditional imprisonment) and a fine of between EUR75,000 and EUR7.5 million.

Placing on the market without prior authorisation

The placing on the market of a medicinal product without having obtained the requested prior marketing authorisation is a criminal offence punishable by up to five years' imprisonment and a fine of up to EUR375,000.

Activities without use authorisation from the ANSM

Manufacturing, marketing, brokering or distributing, free of charge or against payment, wholesale or retail, a cannabis-based medicinal product (as defined in **1.1 Primary Laws & Regulations**) without having obtained the required use authorisation from the ANSM is punishable by up to five years' imprisonment and a fine of up to EUR375,000. Moreover, this criminal offence is punishable by up to seven years' imprisonment and a fine of up to EUR750,000 when such offence is likely to:

- entail a serious risk to human health;
- have been committed as part of an organised gang;
- have been committed on a telecommunications network intended for a non-specified public; or
- have been committed by pharmaceutical establishments, brokers, dispensing pharmacists or hospital pharmacies.

These same sanctions also apply to the offence of advertising cannabis-based medicinal products subject to a use authorisation to healthcare professionals, in breach of the framework set out by the ANSM.

The illegal practice of pharmacy

The illegal practice of pharmacy is punishable by up to two years in prison and a fine of up to EUR30,000.

Incitement to use narcotics

Incitement to use narcotics is punishable by up to five years in prison and a fine of up to EUR75,000, even if the incitement does not result in actual use of recreational cannabis by a consumer.

Placing on the market and distribution of non-compliant products

The placing on the market and the distribution of non-compliant products (eg, in breach of

requirements relating to product composition, labelling and safety) can result in a fine of up to EUR1,500 multiplied by the number of non-compliant products.

Under French law, the amount of the fine applied to an individual is multiplied by five when applied to a legal person.

2. Cross-Jurisdictional Matters

2.1 Cross-Jurisdictional Issues

The main cross-border issues concern THC levels. The maximum THC level allowed in France is 0.3%.

Consequently, any product containing THC above this maximum level is considered a narcotic and falls under drug trafficking regulation, except where the product is:

- a medicine containing cannabis and holding a marketing authorisation;
- a medical cannabis product duly authorised as part of the pilot programme and after the entry into force of the legalisation, or a cannabis-based medicinal product duly authorised for use by the ANSM after the entry into force of the legalisation; or
- a product holding an importation authorisation from the ANSM.

Issues are likely to arise in the case of importation of products manufactured in other EU member states where allowed THC levels are higher than in France (eg, Italy, the Czech Republic), or of those manufactured in non-EU countries, such as Switzerland, where consumer products can contain up to 1% of THC.

Other issues may arise in relation to importation of finished products manufactured in non-EU countries where the applicable regulation is different from French and/or EU regulation. In practice, issues have been observed in the market in relation to the composition of some products (eg, cosmetic products containing unauthorised ingredients or ingredients subject to limitations on levels above the maximum authorised levels) or in relation to the labelling of products (eg, those missing mandatory information).

Finally, the use of the wrong tariff codes as part of importation/exportation activities would likely constitute tax fraud.

Operators should therefore be extremely cautious when engaging in importation/exportation activities (particularly between EU and non-EU countries) and pay close attention to the type of products they are marketing, in order to ensure compliance with the relevant applicable laws and regulations.

3. Legal and Regulatory Developments

3.1 Access to Medical Cannabis

To date, and until the entry into force of the legalisation of cannabis-based medicinal products in France (expected to occur in the coming months or early 2026 at the latest), access to medical cannabis remains very limited in the country. Indeed, very few medicines containing cannabis and holding marketing authorisations are available on the market, and they are only prescribed to a limited number of patients for very specific therapeutic indications.

Until the end of the extended transition period, now scheduled for 31 March 2026, medical can-

nabis (ie, cannabis-based medicinal product) is only accessible to patients who were enrolled in the pilot programme and who were still in it on the date the programme ended in March 2024 (please see **1.1 Primary Laws & Regulations**).

The regulatory framework is still being set up. In particular, decrees and orders setting out the following aspects are yet to be published:

- the requirements related to medical cannabis cultivation and processing;
- the definition of cannabis-based medicinal products' specifications;
- the definition of the criteria for the fixing of product-pricing and reimbursement; and
- conditions and modalities of prescription and dispensing to patients.

Time is of the essence, and France is being watched closely by market players anxious to enter the market once medical cannabis is legalised. In the meantime, most players are trying to navigate the practical and legal uncertainties around the legalisation.

A major challenge will be for the relevant players and the French government to find agreement on market access conditions and prices that satisfies all the parties concerned, especially considering the major investments required from industry players to meet the legal requirements regarding cannabis-based medicinal products and production thereof. Otherwise, this may discourage new players from venturing into the French market, and may eventually frustrate the purpose of facilitating access to these new medicines for patients in need.

3.2 Non-Controlled Cannabinoids in Food

Broadly speaking, food products can be placed on the market provided they meet the general safety requirements set out by applicable laws and regulations, notably Articles 14 and 15 of Regulation (EC) 178/2002.

The Novel Food Regulation

However, as in other EU member states, cannabinoids (including CBD) and food products containing cannabinoids are considered a novel food as per the Novel Food Regulation (see also **1.1 Primary Laws & Regulations**) and are registered as such in the Novel Food Catalogue.

Novel foods are products for which the history of safe consumption before 1997 has not been demonstrated. These products must therefore obtain an authorisation from the EFSA prior to being placed on the market. The prior authorisation requirement applies both to cannabinoid extracts and to finished products containing cannabinoid extracts as an ingredient, regardless of whether the extract is natural or synthetic.

Consequently, some food products that are derived from the hemp plant (eg, hemp seed oils, hemp seed flour and hemp seeds) are not considered novel food and can legally be placed on the market.

However, hemp extracts and any products to which hemp extracts have been added as an ingredient (eg, hemp seed oil, drinks, waters and chewing gum enriched with CBD) are considered novel food, and as such may not be placed on the market until a risk assessment has proved that they are safe for consumption and a novel food authorisation has been granted for CBD or another cannabinoid, as the case may be.

In addition, it should be noted that French Decree No 2006-352 of 20 March 2006 on food supplements expressly prohibits the use of novel food in the manufacturing of food supplements. Consequently, according to this regulation, only hemp seeds can be used in the manufacturing of food supplements (eg, cold-pressed hemp seed oil, grounded hemp seeds).

Enforcement of the Novel Food Regulation in France

In recent years, the enforcement of the Novel Food Regulation regarding CBD has apparently been handled very differently from one member state to another.

More specifically, while some countries' competent authorities have adopted a clear position on the implementation of the Novel Food Regulation and are taking restrictive measures accordingly, it appears that enforcement in France has been quite different. Indeed, it remained quite limited until 2023, with frequency of controls varying depending on region.

This has resulted in a very large number of CBD food products being placed on the French market. These products can be found at CBD stores, pharmacies, supermarkets and online.

Although it appears that the number of controls has increased since 2023, the French competent authorities have not taken any official position.

The apparent tolerance of French controlling authorities, combined with the lack of a clear and official position regarding the placing on the market of CBD food products and dietary supplements, creates an insecure environment where operators distribute their products while still being exposed to controls and potential sanctions, notably including:

- products' withdrawal from the market and prohibition from selling the products;
- destruction of products at the cost of a non-compliant company; and
- a fine of up to EUR1,500 per non-compliant product.

Several novel food authorisations have been applied for before the EFSA. However, to date no authorisation has been given for CBD.

Another issue resulting from the lack of regulatory clarity relates to the CBD levels contained in products. While some medicinal products containing high doses of CBD have obtained marketing authorisation, other consumer products available on the French market (and, in particular, at pharmacies) are also marketed with a very high CBD content, often along with therapeutic claims, and are largely used by consumers for self-medication, which is not without risk for the consumers.

To date, while observations in the field may lead one to think that products containing high levels of CBD may be removed from the market in the case of controls, there is no legal provision or official position from the competent authorities establishing a maximum level of CBD permitted to be used in consumer products – this, again, causes confusion and puts operators that venture to place their products on the French market at risk.

3.3 Decriminalisation

While France is often described as Europe's largest consumer of cannabis, it also has some of the toughest laws against drugs. Although the conversation regarding whether cannabis should be legalised has arisen several times over the past few years, with lobbying actions being

engaged or public consultation being launched, cannabis remains a major stigma in France.

To date, and despite the change in position of some neighbouring EU member states, there has been no discussion as to whether or not cannabis for recreational purposes should be legalised in France. Based on the current government's firm position on narcotics (particularly cannabis) which suggests even more enforcement of narcotic laws, and its decision to prohibit the use of dried raw flowers as cannabis-based medicines in order to (according to the French Ministry of Health) avoid any risk of confusion with recreational cannabis, it is very unlikely that any change will occur until at least the next Presidential elections, which will take place in 2027.

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