ENGLAND

I. Introduction

1. Identify the geographic scope and limits of your answers to the questions below.

The answers below are given specifically in relation to England (but either the same or equivalent or almost identical provisions apply in respect of the devolved jurisdictions).

II. Legislation

2. Please provide links to applicable statutes and regulations.[1]

1. Cannabis: Controlled Drug Status

- Misuse of Drugs Act 1971 c. 38 (as amended)
- Misuse of Drugs Regulations 2001 (as amended) ("MDR 2001")
- The Hemp (Third Country Imports) Regulations 2002 No. 787
- The Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015

2. Cannabis-based products for medicinal use in humans

- Medicines Act 1968
- Human Medicines Regulations 2012
- MDR 2001

3. CBD (as isolated substance in its pure form)

Food Products

- Food Safety Act 1990
- Regulation (EU) 2015/2283 (novel foods)
- The Food Supplements (England) Regulations 2003

Other Products (e.g.)

- General Product Safety Regulations 2005
- Regulation (EC) 1223/2009 (Cosmetics Regulation)

4. Other legislation

- Proceeds of Crime Act 2002 ("POCA")
- The Proceeds of Crime Act 2002 (Money Laundering: Exceptions to Overseas Conduct Defence) Order 2006
- UN Single Convention on Narcotic Drugs, 1961

A. Is there any pending legislation that could materially alter applicable statutes or regulations?

Not at the present time.

[1]We have focused on the key applicable domestic law.

B. Is there any proposed legislation that could materially alter applicable statutes or regulations?

Not at the present time.

3. Are cannabis laws in your jurisdiction pretty well settled or are they constantly changing in material ways?

The laws on cannabis and its status as a controlled substance (**"Controlled Drug"**) are pretty well settled. Cannabis is a Class B controlled substance and restrictions apply to its possession, cultivation, supply, import and export. In brief, these activities are subject to a licensing regime and licenses will not be granted with regard to cannabis for recreational use.

The laws relating to 'cannabis-based medicinal products for human use' (or cannabis-based products for medicinal use – **"CBPMs"**) are more recent (November 2018). The UK government has commissioned an assessment of the impact of the legislative change in this area. The report from this review is scheduled to be complete by November 2020.

CBD (in its pure form) is not (and has never been) a controlled substance under the 'misuse of drugs' legislation. The applicable law is well-settled in this respect. However, the use of CBD in certain products (including in particular food products) has raised a number of legal issues which are not, as yet, settled.

III. General information (e.g., governing bodies, licenses, import/export)

4. What governing body regulates/licenses or enforces activities that are allowed in your jurisdiction?

Controlled Drug

In general, it is unlawful to possess, supply, produce, import or export cannabis or to cultivate any plant of the genus cannabis other than under and in accordance with a license granted by the Home Office (a central government department).

CBPMs

The Medicines and Healthcare Products Regulatory Agency (the **"MHRA"**), an executive agency of the Department of Health and Social Care, regulates, among other things, medicinal products. It regulates the supply, manufacture, importation and distribution of medicinal products for human use.

The general rule is that a medicinal product needs to be the subject of a marketing authorization (i.e., license) but there is also a regulatory framework which applies in relation to unlicensed medicines (known as 'specials').

CBD Food Products

The Food Standards Agency (**"FSA"**) is an independent government department which has responsibilities in relation to food and food safety matters. It works closely with local authorities who also have regulatory responsibilities in relation to food law.

Other CBD Products

Local authorities have certain regulatory and enforcement responsibilities for other products that may contain CBD (e.g., cosmetics).

POCA

In addition, the Financial Conduct Authority will consider matters relating to proceeds of crime and the application of POCA.

5. What cannabis functions are allowed in your jurisdiction? E.g., growing, processing, retailing.

Controlled Drug

As above, it is unlawful to possess, supply, produce, import or export cannabis or to cultivate any plant of the genus cannabis other than under and in accordance with a license granted by the Home Office (a central government department).

Recreational use of cannabis is prohibited.

CBPMs

Since November 2018, CBPMs can be prescribed by clinicians that are listed on the Specialist Register of the General Medical Council. This can be a licensed medicine (to date there are two such licensed medicinal products) or an unlicensed medicine (subject to compliance with the applicable rules and guidance for prescribing unlicensed medicines).

CBD Food Products

CBD extracts were confirmed as having novel food status under applicable EU law in January 2019. Novel foods need authorization before they can be placed on the market, however, there are currently no CBD extracts or isolates which have received such an authorization. The FSA has confirmed that businesses need to have submitted fully validated novel food authorization applications by March 31, 2021. After this date only products for which a valid application has been received by the FSA will be allowed to remain on the market. Until then businesses can continue to sell their existing CBD food products provided that they are not incorrectly labeled, are not unsafe and do not contain substances that are subject to the 'misuse of drugs' legislation.

Other CBD Products

The use of CBD in other products is subject to either the relevant product sector (e.g., cosmetic products) or to general product safety laws.

6. What sales or use is allowed in your jurisdiction? E.g., edibles, vaping, tinctures, food additives, etc.

See above.

A. Are the rules different for medical vs. adult recreational use?

Yes – different rules apply.

Cannabis for recreational use is prohibited outright.

CBPMs may be prescribed by specialist clinicians (i.e., those listed as being authorized for this purpose on the Specialist Register of the General Medical Council). The specialist clinician does not need a Home Office license for this purpose. However, companies that wish to possess, produce, manufacture, supply, import or export such products will require a Home Office license in order to undertake these activities lawfully.

CBD products are subject to the rules applicable to the relevant product sector (e.g., food sector, cosmetics, etc.)

B. Are retail sales of any cannabis products restricted to specific retail channels? E.g., medical dispensaries, government-owned stores, etc.

Retail sales of cannabis are not permitted in the UK.

CBPMs are available by prescription only and accordingly only available for supply from registered pharmacies.

CBD products (where lawful) are not restricted to specific retail channels.

C. Are there zoning restrictions on where medical, wellness, or adult-use (recreational) outlets can be located? Applicable to all cannabis products?

Not applicable.

7. What import and export is allowed in your jurisdiction?

As above, a Home Office license is required to import/export cannabis and both a Home Office license and either a wholesale dealer's license or a manufacturer's license will be required for a CBPM.

CBD products can only be imported (placed on the market) if they are lawful in accordance with the relevant product rules/regulations.

A. Are there restrictions in relation to the countries of origin, i.e. which countries of origin are permitted?

There are no specific restrictions in relation to countries of origin, but certain import licenses are required (see above) and any importation will need to comply with the conditions and requirements of the license. Also, for unlicensed CBPMs notification of each intended import must also be given to the MHRA.

B. Please describe restrictions on the import of cannabis seeds.

The importation of hemp seeds from a non-EU country requires a license or an authorization from an appropriate authority (and the appropriate authority differs depending on which part of the UK the hemp seeds are imported into). A license is required in relation to 'hemp seeds for sowing' (namely seeds of particular varieties) - and such hemp seeds cannot have a THC content of more than 0.2%. An authorization is required in relation to 'hemp seeds other than for sowing'.

It is not yet clear whether these requirements will extend to EU countries following the end of the transitional period currently applicable in respect to the UK's exit from the EU.

8. Does your region distinguish between different types of cannabis products? (E.g., high or low concentrations of THC.)

A. If so, what distinctions exist?

B. If so, briefly describe the differences.

C. Identify any related laws that should be considered when answering this question.

Yes. The key distinctions are:

- Cannabis, cannabis resin, cannabinol and cannabinol derivatives – are controlled substances/drugs under the misuse of drugs legislation.
- CBPMs – a defined category of cannabis, cannabis resin, cannabinol and cannibal derivatives which is produced for medicinal use in humans and is a medicinal product or a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product.

With regard to different concentrations of THC, it is Home Office policy to permit cultivation of low-THC cannabis plants for the production of hemp fiber for industrial purposes or the obtaining of seeds which are then pressed for their oil, i.e., to enable use of the non-controlled parts of the plant and where the seeds are of an approved type with a THC content of not more than 0.2%. Accordingly, most licenses which authorize cultivation of cannabis prohibit the use of the leaves and flowers of the plant and include a requirement for them to be destroyed on site.

9. Are there legal requirements on Cannabidiol (CBD) products (without THC)?

CBD (in its pure form, so with zero THC) is not a controlled substance.

See also paragraph 5 "CBD Food Products" above.

IV. Patients and prescriptions

10. What specific medical conditions, if any, are recognized for treatment with cannabis?

Marketing authorizations have been granted for:

- Epidyolex - A cannabidiol-based orphan medicine indicated for use as adjunctive therapy of seizures associated with LennoxGastaut syndrome or Dravet syndrome.
- Sativex - a delta-9 tetrahydrocannibinol combined with cannabidiol as a treatment for spasticity in adults with multiple sclerosis.

However, as noted above, specialist clinicians are able to prescribe unlicensed medicines ('specials') and, as is the case with the prescribing of any unlicensed medicine, it is a clinical decision to determine the appropriate medication for the patient taking into account various relevant factors.

11. Is there a licensed practitioner requirement in order to prescribe cannabis for medical purposes?

Yes – as highlighted above only those clinicians that are on the General Medical Council's specialist register can prescribe CBPMs.

12. Are there patient registration or cardholder requirements?

No.

V. Special requirements

13. Does your jurisdiction require any recordkeeping from seed planting to the time of end user sale? For all cannabis products?

Yes. There are specific record-keeping requirements for the (lawful) supply of cannabis (including CBPMs) whereby the person supplying it must keep a register detailing the particulars of every quantity of cannabis obtained by them, and of every quantity of it being supplied by them, in chronological order. With regard to CBPMs, the register must also include details of the person who collected the drug and whether it was the patient, the patient's representative or a healthcare professional acting on behalf of the patient and whether proof of identity was requested and obtained.

There are also specific record keeping requirements in relation to the import of hemp and hemp seeds from a third country.

In addition, the Home Office license authorizing possession, supply, cultivation, etc. may also include conditions which require certain records to be maintained.

14. Are special taxes imposed? On what and when?

No.

15. Are there any special rules or limitations that apply to the industry? E.g., banking, patent or trademark protection, labeling requirements.

The usual rules apply to patent or trademark protection and labeling requirements. For example, in relation to the latter, labeling requirements are informed by the requirements which apply to the relevant product which contains the cannabis/CBD.

There are currently no specific provisions in financial services legislation or anti-money laundering legislation relating to cannabis. However, given the uncertainties relating to the legality of financing arrangements in the cannabis sector under POCA, our experience is that banks and other financial institutions are cautious about their involvement.

16. What is the legal status of access to financial services, including banking, merchant services, and cash handling?

Criminal liability may attach under the money laundering offenses under POCA (sections 327-329) in relation to the raising of finance for a cannabis business in the UK. This would certainly be the case where the finance is raised in relation to recreational cannabis (unlawful, as it is not licensed by the Home Office), but the position is less certain where the finance is raised for medicinal cannabis purposes, which is capable of being licensed by the Home Office. Advice will be required on a case-by-case basis, depending on the licensing arrangements, and the nature of the financing.

17. Is data collected to determine the social or health impact of the rules in your jurisdictions? E.g.,

A. Impact on use by under age/minors.
B. Impact on beer, wine and spirit sales.
C. Tax revenue.
D. Impact on crime, including drug and alcohol addiction.

Not at the present time – recreational use of cannabis is prohibited.

VI. Risks and enforcement

18. What are the most critical issues currently facing the industry in your jurisdiction?

The CBPMs regime is still in its infancy and the anecdotal evidence suggests that the lack of good quality randomized control trial data which demonstrates adequate safety and clinical effectiveness of CBPMs is a major hurdle to NHS prescribing. This is particularly the case for THC-containing products.

There is also uncertainty on the status and classification of CBD food products – which is heightened in light of the UK's exit from the EU as it is not yet clear whether the UK's regulatory framework will stay aligned to that of the EU.

19. What is the current enforcement landscape with respect to cannabis? E.g., strict enforcement, low-enforcement, decriminalization, legalization.

The possession, supply, etc. of cannabis without license (and licenses are not given for recreational use of cannabis) constitutes a criminal offense for which the penalty can be up to 14 years in prison and an unlimited fine (or both). Anecdotal evidence indicates that there may be low levels of enforcement for possession for individual use but high levels of enforcement in relation to cultivation, supply, imports, etc.

With regard to CBD, for existing food products there is effectively an 'enforcement amnesty' until March 2021 while businesses are given the opportunity to submit novel food applications for such products.

The position in relation to potential liability for money laundering offenses under POCA associated with raising finance is unclear. Many firms in the regulated financial sector (e.g., financial institutions, law firms) will file pre-emptive suspicious activity reports ('SARs') with the National Crime Agency, to confirm that the National Crime Agency has no objection to proposed transactions proceeding, to reduce the risk of criminal prosecution. However many regard the lack of guidance in this area as unsatisfactory, and it would be helpful for the Home Office to provide guidance to clarify the law and/or the prosecution policy in this area.

A. Does enforcement differ based on quantity?

Yes, the quantity may for instance determine whether the offense is merely possession of a Controlled Drug, or possession with intent to supply to another, the latter of which is likely to carry a more severe punishment than the former.

For example, the possession of cannabis can, on summary conviction, lead to a punishment of imprisonment for up to three months or a fine of GBP 2,500, or both, and on indictment, to imprisonment for up to five years or a fine of an unlimited amount, or both. The possession of cannabis with intent to supply to another can, on summary conviction, lead to a punishment of imprisonment for up to six months or a fine of a

prescribed sum, or both, and on indictment, to imprisonment for up to 14 years or a fine of an unlimited amount, or both.

B. Does enforcement differ based on product type?

Not with respect to the type of product but whether or not the product is or contains the controlled substance/drug that is cannabis.

VII. Your practice and useful links

20. Tell us a little about your cannabis practice and how it interacts with other practices at your firm. Remember to include any recognition awards your firm has received in this practice area. How much experience does your firm have providing services to cannabis companies and how much interest does your firm have to grow its cannabis practice?

Gowling WLG has a fast-growing cannabis practice in the UK and Europe, having worked closely with a number of leading cannabis companies and other companies supporting the cannabis industry over the past several years. We advise on everything from initial public offerings to real estate and product regulatory matters. Our professionals have a rich insight into the unique issues and opportunities the sector faces, as well as a nuanced understanding of the emerging regulations that will govern it. We have extensive experience in corporate finance, equity capital markets, M&A, product liability, money laundering liability and consumer protection issues, licensing, distribution, and packaging and labeling.

Our clients range from start-ups to those with multi-million dollar market capitalizations involved in pharma, healthcare, wellness and food and beverage, as well as importers, exporters, investment banks, financial advisors and investors.

In addition, Gowling WLG has a comprehensive life sciences and healthcare practice that combines in-depth sector expertise with full-service capability. At a time when healthcare is becoming increasingly international, our lawyers are working across jurisdictions to bring best-practice and innovation to clients across a range of areas: from pharmaceutical and the bio-industry, to integrated health, social care/care homes and digital health.

In life sciences, our strong reputation has seen the firm described as having a "sterling commercial life sciences practice for complex license, research and collaboration agreements" by Chambers 2020, where it is ranked in Band 2 UK-Wide. Similarly, Gowling WLG is ranked in Tier 2 for Healthcare in Legal 500 UK (London), referencing the firm's active role in the sector and highlighting its advice to Guy's and St Thomas' NHS Foundation Trust on its ground-breaking public-private partnership to become an international orthopaedic center of excellence.

Our diverse practice "brings impressive scientific backgrounds" (Legal 500 UK), with many of our lawyers having previously worked in the industry as scientists and who hold relevant degrees and PhDs in areas such as biochemistry, chemistry, molecular biology, microbiology and genetics. Their reputation for innovation is illustrated through, for example, work on Arrow declarations, where the team led on and won the only two cases where such a declaration has been awarded (FKB v AbbVie and in GSK v Vectura). This is simply new law and our experts have been instrumental in creating and shaping it.

Similarly, on transaction work this 'innovative thinking' is seen in the team's approach to some of the past year's most high-profile deals in the sector: for example, a multi-billion dollar cancer drug collaboration agreement for AstraZeneca and Daiichi Sankyo; Sosei Heptares' new collaboration with AbbVie to target inflammatory diseases; AstraZeneca's landmark agreement for the development and distribution of Oxford University's potential COVID-19 vaccine; and Montreux Healthcare Fund's acquisition of neuro rehabilitation business Christchurch Group.

The achievements of our experts have seen the practice gain industry-wide recognition through awards such as Patrick Duxbury's recent win at the LMG European Life Sciences Awards and his *Who's Who* Legal Awards win in the category of 'Life Sciences – Transactional Lawyer of the Year 2019'. Gowling WLG is also short-listed for 'TMT Team of the Year' in this year's Legal Business Awards, and for 'Legal Advisors of the Year – Private' in the Health Investor Awards 2020.

21. Please provide links to any firm website, blogs, reputable trade publications, or attorneys that would help others understand the state of the law in your jurisdictions.

A. Are there any relevant trade organizations?

Yes, for example:
The Cannabis Trades Association (CTA)

B. Are there any relevant lobbying organizations?

Yes, for example:
Volteface
CLEAR Cannabis Law Reform

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