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A mellow form of cannabis regulation is now emerging

Cannabis and its derivatives are inching their way towards wider acceptance in medical and personal usage, as **Gary Grant** and **Michael Brett** explain

Since the last issue of the *Journal* went to press, there have been significant further developments in the way in which cannabis and cannabis derivatives are treated and regulated in the UK. The direction of travel is clear, towards greater openness to their presence in both formal and medical settings, and also to personal consumption, albeit with careful regulatory controls.

Scientific interest in the medicinal effects of cannabis is rampant. Several trials are taking place worldwide, including in Canada, Israel and the UK investigating whether medicinal cannabis could be used as a treatment for Covid-19. The trials are at a very early stage and it is too soon to draw any conclusions about whether cannabis will prove an effective treatment. One US study, for example, is investigating whether cannabinoids can be added to anti-viral therapies to reduce lung inflammation in those suffering from the pandemic.¹ From a less academic standpoint, an article in *The Times* of 9 May 2020 suggests that recreational interest in the drug has not waned either, with its headline reading, “Record high: Britons stock up on cannabis to cope with lockdown”.²

A diversifying cannabis marketplace

The UK leads the world in the production of legal cannabis, particularly for pharmaceutical purposes. The UN International Narcotics Control Board estimated in 2016 that the UK produced approximately 44% of the global production of cannabis for medical and scientific research. Although some time has passed, and more up-to-date statistics are hard to come by, the UK cannabis market is a leader in the legalised cannabis-growing industry.

There is considerable corporate interest in consolidating and accelerating this strong market position and UK companies are presenting attractive offerings to aid growth. A good example is the launch of CROP17, a collaboration between land consultants, farming experts, and the pharmaceutical industry aimed at facilitating increased

cannabis production, including assisting with compliance with the UK’s strict regulatory framework.

In addition, plans for Scotland’s first official cannabis farming operation obtained a boost with the recent grant by Dumfries and Galloway Council of planning permission for its greenhouse infrastructure.³ The future of the project is dependent now on the acquisition of the relevant licences to grow cannabis plants issued by the UK Home Office under regulation 12 of the Misuse of Drugs Regulations 2001.

The cannabis market is expanding beyond mere production and manufacture of cannabis or cannabis-derived products, though, into more sophisticated commercial instruments. The Medical Cannabis and Wellness UCITS ETF launched on London Stock Exchange in January 2020, offering investors the opportunities to acquire legal cannabis, hemp and CBD-related securities.⁴

CBD and novel foods

That said, the primary emerging cannabinoid market in the UK is centred around cannabidiol (CBD), a non-psychoactive compound produced by plants of the cannabis genus, which, as a pure compound, is not a controlled drug. Products containing CBD are readily available on the high street in food supplements, cosmetics, and vaping products. Proponents of the consumption of CBD argue in favour of a number of benefits, from better skincare, through increased relaxation and well-being, to therapeutic effects. Consumer research indicates that this positive messaging is catching on, with approximately 28% of Britons who have never tried CBD indicating that they would be willing to do so.⁵

1 <https://www.sciencedirect.com/science/article/pii/S0889159120307078>

2 <https://www.thetimes.co.uk/article/record-high-britons-stock-up-on-cannabis-to-cope-with-lockdown-65lpzd83j?shareToken=2061396df95d8d1fea1be14138acd0ec>

3 <https://www.thetimes.co.uk/article/plans-for-scotland-s-first-cannabis-farm-approved-nf9k2r2m0> . The planning decision notice (ref: 19/1682) can be found here: https://eaccess.dumgal.gov.uk/online-applications/files/0ED8666B41EBBB057C33F33FC9B4943B/pdf/19_1682_FUL-Decision_Notice-949607.pdf.

4 <https://www.lseg.com/markets-products-and-services/our-markets/london-stock-exchange/equities-markets/raising-equity-finance/market-open-ceremony/london-stock-exchange-group-welcomes-hanetf-and-purpose-investments-celebrating-launch-medical-cannabis-and-wellness-ucits-etf-0>.

5 <https://yougov.co.uk/topics/health/articles-reports/2019/10/18/quarter-britons-tempted-cannabis-extract-products>.

Mellower form of cannabis regulation

A recent study from the UK cannabis industry has however raised concerns about variations in quality of CBD products.⁶ It highlights a lack of consistency in chemical composition and a high incidence of controlled substances, both tetrahydrocannabinol (THC), the chemical which underlies the “high” experienced by cannabis users, and cannabidiol (CBD). The presence of CBD in notable quantities in CBD products may be a source of particular alarm for regulators: this compound is formed by the oxidation of THC and thus its presence in CBD products is likely to indicate that they have contained significantly higher THC levels earlier in their lifecycle.

The continuing rapid expansion of the market, problems identified in the safety of products and concerns about their legality are behind moves towards greater regulation in recent months. Most significantly, in February this year, the UK’s Food Standards Agency (FSA) issued Guidance confirming that it would introduce a staggered enforcement scheme in relation to businesses supplying CBD food products in the UK. This followed the FSA’s confirmation, back in January 2019, that it considers CBD to be a “novel food” within the EU food regulatory framework when contained in products intended for human consumption (such as CBD infused oils, tea and food supplements).⁷

The EU Novel Foods Regulation 2015/2283 prohibits the sale of products containing novel foods without authorisation. Novel foods are foodstuffs of which there is no evidence of consumption to a significant degree in EU countries prior to 1997. If the food was widely used in the EU before 1997, then it is not considered to be “novel” and may continue to be lawfully sold to the public (Article 7 of the regulation). The purpose of the regulation is, of course, to ensure that a relatively untried and untested new food is safe for the public to consume. If its safety cannot be assessed, and scientific uncertainty persists, the precautionary principle may be applied and authorisation refused.

Currently, the necessary authorisation can be obtained from the European Commission in one of two ways. Foods that can be shown to have 25 years’ continued use by a significant number of people in a non-EU country have a streamlined authorisation procedure (Articles 14-20 of the regulation). Foods that cannot claim such use must submit a full application under Article 10 of the regulation to the EC, which determines whether or not to authorise the food, taking advice from the European Food Standards Agency.

The recent FSA intervention reflects this crystallisation of the position at European level, which made clear that CBD

in its pure form is a novel food. The EC maintains a novel food catalogue, a non-binding list of products which are likely to be novel foods based on information received from EU member states through its Novel Foods Working Group.⁸ The catalogue’s primary function is to help food business operators comply with their duty, outlined in Article 4 (1) of the regulation, to identify whether their products are novel foods. The entry entitled “Cannabidiol” indicates that it constitutes a novel food, referring to the separate entry entitled “Cannabinoid”. The Cannabinoid entry includes the following text:

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

The FSA has given manufacturers of CBD-containing products until 31 March 2021 to submit authorisation applications, after which time products without authorisation, or a fully validated application pending, will be subject to enforcement. Subsequently, in late April 2020, the FSA clarified to industry that this deadline will not be extended.⁹

In order for authorisation to be granted by the EC, it must be shown that (Article 7 of the regulation):

- a. the food does not, on the basis of the scientific evidence available, pose a safety risk to human health;
- b. the food’s intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value;
- c. where the food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

The requirements for a valid application for authorisation are set out in Commission Implementing Regulation (EU) 2017/2469. The key message is that the EC requires a high

6 <https://www.liebertpub.com/doi/full/10.1089/can.2019.0078>.

7 <https://www.food.gov.uk/business-guidance/cannabidiol-cbd>.

8 https://ec.europa.eu/food/safety/novel_food/catalogue_en.

9 <https://www.theaci.co.uk/fsa-no-plans-to-extend-31-march-2021-deadline/>.

quality and quantity of technical and scientific evidence to demonstrate that the conditions for authorisation are met. The process from application to authorisation can be long and onerous. In 2015, the average length of time that it took for an application to result in a positive authorisation decision was three and a half years.¹⁰

A final complication to the authorisation procedure is the scope of the authorisation. Under changes introduced in 2015 (and implemented in 2018) under the regulation, inclusion in the list of authorised novel foods is intended to be generic: that is, it is a foodstuff that is authorised, rather than a particular product. On a basic level therefore, the authorisation of the isolated CBD compound could permit the whole industry to carry on. However, Article 26 of the regulation allows manufacturers to invoke a euphemistically-named “data protection” provision where their application contains proprietary information. This has the effect that only the specific applicant manufacturer can market the authorised food for a period of five years from authorisation.

Brexit adds its own novel dimension to this mix, as the FSA’s deadline for the validation of authorisation applications sits beyond the expected date of the end of the Brexit transition period on 31 December 2020. On that date, the regulation and implementing regulations made under it will become retained EU law, subject to alteration by the Novel Food (Amendment) (EU Exit) Regulations 2019/702. These regulations provide that the competency for deciding authorisation applications will pass from the EC to the devolved administrations, food safety being a devolved matter. This fact lies behind the request by the FSA for manufacturers to submit their authorisation applications to them as well as to the EC even before the end of the transition period.

Amidst all this regulatory fanfare, it appears that the industry is moving quickly to keep its products on the shelves. While the EC has four pending authorisation applications for CBD (one from an Irish undertaking,¹¹ one from a Swiss undertaking,¹² and two from Czech undertakings¹³), the FSA has indicated to industry that it has already started receiving applications.¹⁴ All four of the pending EC applications

have invoked Article 26, but it remains to be seen whether a UK industry-wide body will be able to submit a generic application to bypass the monopolistic tendencies of the system.

Although the FSA’s move this spring may appear on the face of it highly restrictive, it can be considered beneficial to the CBD industry: it provides regulatory clarity and certainty to business; the FSA’s enforcement holiday gives a clear, if temporary, basis for the lawful sale of CBD products; and the FSA’s stance offers producers a route to permanent lawful production and sale. Moreover, authorisation offers the prospect of great quality and safety assurance for consumer products, which, beyond their inherent benefits, helps create consumer confidence. Finally, while the application for authorisation procedure is onerous, the actual statutory requirements in Article 7 are not that challenging – or should not be for an industry that repeatedly claims that its products are safe.

However, many smaller, independent producers of cannabis-based products will be deeply concerned by the FSA’s novel food designation. Unlike the larger companies, they may be unable to afford the costly exercise of demonstrating their product is safe for human consumption. They fear the FSA’s move will extinguish their role in the increasingly lucrative market and serve to restrict consumer choice.

It seems most likely even after the Brexit transition period has ended that the UK will continue on the “novel food” path for cannabis products which its own domestic FSA has now more fully embraced.

Criminal enforcement

The prohibition on the manufacture, importation, supply and consumption of cannabis and controlled cannabinoids is of course enforced through the criminal law. There is a clear trend against strict application of criminal sanctions in this space, both on the part of the police and also in public opinion. Although criminal prosecutions are still brought for simple possession of cannabis in the UK, they are less likely to be subject to criminal sanction, and this is highly unlikely where the possession is said to be for medicinal purposes.

First, police forces are recording fewer offences of possession of cannabis each year, and in particular since cannabis was re-categorised as a Class B drug in 2009, reversing Labour’s earlier downgrading of it in 2001. Recorded crime levels are down to 2005 levels. One suggestion for this fall may be a decreasing allocation of police resources to address cannabis possession - another factor may be that regular cannabis use has fallen across that period, although

10 https://ec.europa.eu/commission/presscorner/detail/en/MEMO_15_5875.

11 https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_sum_ongoing-app_2020-1670.pdf.

12 https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_sum_ongoing-app_2019-0935.pdf.

13 https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_sum_ongoing-app_2019-1371.pdf;
https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_sum_ongoing-app_2018-0349.pdf.

14 <https://www.theaci.co.uk/fsa-no-plans-to-extend-31-march-2021-deadline/>.

Mellower form of cannabis regulation

this latter does not fit well with a peak in punishment in 2008-9.¹⁵ Secondly, recent crime statistics show that the police are increasingly preferring to use informal out-of-court methods, including “community resolutions”, to deal with cannabis-related crime, in preference to prosecutions or lower-level formal procedures.¹⁶

These informal measures, which in some police areas are used to deal with more than half of all recorded cannabis possession crimes, do not show up on a criminal record (although they may on an enhanced DBS certificate) and consist of an agreement between the police and offender. The latter may agree to undertake some form of restorative justice or rehabilitation activity.¹⁷

Both of these features of police response reflect a de-prioritisation of cannabis possession crimes. Some of this may be explained by tighter police resources being focussed on higher-level offences, but some must be attributable to an increasingly permissive stance to possession crimes, exemplified by the Chief Constable of Durham Constabulary’s much-publicised stance on personal consumption, namely:

If you have a small amount [of cannabis] for personal use you will not be prosecuted, you go into [a rehabilitation programme]. It frees up time to investigate more serious crime – that’s why we have a good detection rate.¹⁸

Even where prosecution is in fact brought, it may be that shifts in public opinion are making convictions more difficult to obtain, especially in sympathetic cases. In January 2020, a woman suffering MS and her husband were acquitted of possession and cultivation offences. Lesley Gibson had apparently turned to cultivation after her Sativex prescription had been withdrawn. The prosecution’s decision not to offer evidence on public interest grounds, despite Ms Gibson’s numerous previous convictions for unlawful possession and supply (including a seven-month prison sentence in 2007),

is perhaps reflective of wider social trends. Very few people in polls show support for prosecution of medical cannabis users: instead, a YouGov survey in 2019 indicated that a clear majority of people opposed such prosecutions.¹⁹

Conclusion

The discernible presence of cannabinoids on the high street and a greater public awareness of health claims made about such products cannot help but continue to shift public opinion in favour of the liberalisation of cannabis laws. The FSA’s recent move to regulate the CBD market could perhaps be seen as a forerunner for a regulatory approach to recreational products which contain controlled cannabinoids such as THC (despite public denials by the current Government). Although novel food status may, merely by imposing a new layer of bureaucracy and a real possibility of enforcement, have a short-term dampening effect on the CBD market in 2021, the benefits of a clear legal framework for the manufacture and sale of these products should not be underestimated. The engagement of regulators and government with the legal cannabinoid industry, combined with increased permissiveness as to use of cannabis on the part of the police and public, mean that considerable further shifts in the field of cannabis law can be expected, and very soon.

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NB: We are grateful to Hanway Associates for their helpful suggestions during the preparation of article.

15 <https://www.bbc.co.uk/news/uk-47950785>.

16 <https://www.telegraph.co.uk/politics/2020/01/15/cannabis-risk-decriminalised-police-let-users-community-resolutions/>; <https://www.gov.uk/government/statistics/police-recorded-crime-open-data-tables>.

17 <http://library.college.police.uk/docs/appref/Community-Resolutions-Incorporating-RJ-Final-Aug-2012-2.pdf>.

18 <https://www.theguardian.com/society/2018/jun/24/durham-police-chief-mike-barton-for-legalisation-cannabis-uk>.

19 https://d25d2506sfb94s.cloudfront.net/cumulus_uploads/document/jebv23n429/CDPRG_190617_190619_Combined.pdf.