CRN UK Paper on the Status of Cannabidiol (CBD)-Containing Products in the UK

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Status as a Food

The EU novel foods catalogue[1] includes an entry for Cannabidiol (CBD) and Cannabinoids in addition to the entry for *Cannabis sativa* L.

The entry for *Cannabis sativa* L states:

> *In the European Union, the cultivation of Cannabis sativa L. varieties is permitted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2 % (w/w). Some products derived from the Cannabis sativa plant or plant parts such as seeds, seed oil, hemp seed flour, defatted hemp seed have a history of consumption in the EU and therefore, are not novel. Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities.*

The entry for CBD refers the reader to the entry for Cannabinoids, which states:

> *The hemp plant (Cannabis sativa L.) contains a number of cannabinoids and the most common ones are as follows: delta-9-tetrahydrocannabinol (Δ9-THC), its precursor in hemp, delta-9-tetrahydrocannabinolic acid A (Δ9-THCA-A), delta-9-tetrahydrocannabinolic acid B (Δ9-THCA-B), delta-8-tetrahydrocannabinol (Δ8-THC), cannabidiol (CBD), its precursor in hemp cannabidiolic acid (CBDA), cannabigerol (CBG), cannabinol (CBN), cannabichromene (CBC), and delta-9-tetrahydrocannabivarin (Δ9-THCV). Without prejudice to the information provided in the novel food catalogue for the entry relating to Cannabis sativa L., extracts 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.*

It is very clear from the above entry that any products containing extracts of *Cannabis sativa* L. and derived products containing cannabinoids (including CBD) are not permitted as foods in the UK/EU.

Status as a Medicine

The UK Medicines and Healthcare Products Regulatory Agency (MHRA) is still investigating the status of CBD-containing products under medicines law.

The definition of a medicine[2] is as follows:

> *"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings (Limb 1).*

> *Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis (Limb 2)".*

Medicinal claims on or about any food product are prohibited. Therefore, CBD-containing foods presented with medicinal claims, either through labelling or associated marketing material, will most likely be considered to be unlicensed medicines under the first limb of the definition of a medicinal product.

There is emerging evidence of the clinical efficacy of CBD. It is therefore possible that, as this evidence increases, the MHRA could at any time determine that CBD products are a medicine under the second limb of the definition, at which point any such food products may be at risk of having to be removed from the market.

A current lack of objection by the MHRA to a CBD-containing product on the UK market:

i. does not mean that the product is legal;
ii. does not mean that the MHRA has endorsed any non-medical purposes for which the product might be used; and
iii. does not mean that the product may not have to be removed at some point in the future if the situation regarding its status changes.

It is recommended that companies review Appendix 10 of the MHRA Guidance Note 8 'A guide to what is a medicinal product'[3]. This appendix clearly sets out MHRA's position respect of the sale of CBD products.

Status as a Veterinary Medicine

The Veterinary Medicines Directorate has declared that they consider that veterinary products containing CBD are veterinary medicines and should be regulated as such. This decision was made on the basis that products containing CBD fulfil the following definition of a veterinary medicine in the Veterinary Medicines Regulations (VMR) by virtue of the effects they have:

> *"any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."*

CBD products for use in animals therefore now require a marketing authorisation before they can be sold or supplied in the UK.

There are currently no CBD based products that have been granted a UK veterinary marketing authorisation.

Status as an Unlicensed Controlled Drug

The UK Home Office has produced a Drug Licensing Factsheet on Cannabis, CBD and other cannabinoids[4].

The reference to THC content 'not exceeding 0.2% of the plant' in this fact sheet and the EU

novel food catalogue entry for *Cannabis sativa* L has led some companies to believe that their product is legal provided it contains less than 0.2% THC. This is not the case. The 0.2% THC content refers only to the THC content in the entire plant, NOT to the content of THC in any food products based on the plant.

> *If a CBD 'product' contained any controlled cannabinoids, unintentionally or otherwise (e.g., THC or CBD-V), then it is highly likely that the product would be controlled. It is our understanding that it is very difficult to isolate pure CBD, and in our experience many products in fact do not fully disclose their contents or provide a full spectrum analysis at an appropriate level of sensitivity to accurately and consistently determine their true content or control status.*
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> *Against this background, the presumption has to be one of caution - that is, that a CBD containing product would be controlled under the MDA 1971 / MDR 2001* as a result of its other cannabinoid content.*[4]
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> *Misuse of Drugs Act 1971 / Misuse of Drugs Regulations 2001

However, according to the Misuse of Drugs Regulations 2001, a product may be exempt if it meets the following definition:

> ***"exempt product" means a preparation or other product consisting of one or more component parts, any of which contains a controlled drug, where—***
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> *(a) the preparation or other product is not designed for administration of the controlled drug to a human being or animal;*
>
> *(b) the controlled drug in any component part is packaged in such a form, or in combination with other active or inert substances in such a manner, that it cannot be recovered by readily applicable means or in a yield which constitutes a risk to health; an*
>
> *(c)* ***no one component part of the product or preparation contains more than one milligram of the controlled drug*** *or one microgram in the case of lysergide or any other N-alkyl derivative of lysergamide;*[5]

Thus, a CBD-containing product might potentially be classed as an 'exempt product' if no more than 1 mg THC can be detected in the entire product (i.e. not per individual dose), but a greater quantity of THC would definitely place the product in contravention of the Misuse of Drugs Act 1971 / the Misuse of Drugs Regulations 2001.

Less refined and concentrated CBD oils may contain larger quantities of THC, and apparently police authorities in certain regions of the UK have become interested in CBD-containing products and their potential THC content[6].

The NHS has issued guidance to clinicians on medicinal cannabis[7] and, within this guidance, states the following:

> *There is also a wide range of other cannabis products available on the internet and in some commercial outlets such as health food outlets and from cannabis 'dispensaries' internationally. These products are of unknown quality and contain CBD and THC in varying quantities and proportions. In the opinion of the Home Office (see its guidance note here), any CBD product that contains any amount of THC will be a controlled drug within the meaning of the 1971 Misuse of Drugs Act, except under very specific circumstances.*

References

1. EU Novel food catalogue: http://ec.europa.eu/food/safety/novel_food/catalogue/search/public/index.cfm
2. Article 1 of Directive 2001/83/EC, implemented by Regulation 2 of The Human Medicines Regulations 2012 (S.I. 2012/1916).
3. MHRA Guidance Note 8: *A guide to what is a medicinal product*. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/759581/012__GN8_-_final_2018_combined_doc_Oct.pdf
4. Home Office Drug Licensing Factsheet- Cannabis, CBD and other cannabinoids. https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns
5. The Misuse of Drugs Regulations 2001: http://www.legislation.gov.uk/uksi/2001/3998/made
6. Personal communication.
7. NHS England Guidance to clinicians: Cannabis-based products for medicinal use. https://www.england.nhs.uk/publication/cannabis-based-products-for-medicinal-use-guidance-to-clinicians/