CONSERVATIVE
DRUG POLICY
REFORM GROUP

THE CONSERVATIVE DRUG POLICY REFORM GROUP'S RECOMMENDATIONS

On The Motion Concerning Limits on the Content of Controlled Cannabinoids in Cannabidiol Products

At the 63rd United Nations Session of the Commission on Narcotic Drugs on 02 December

20 NOVEMBER 2020

Contents

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1. Introduction

This briefing paper concerns the upcoming United Nations vote on removing cannabidiol (CBD) preparations with less than 0.2 percent THC from international control. We, the Conservative Drug Policy Reform Group, strongly **recommend that the UK votes in favour of this motion** at the 63rd United Nations Session of the Commission on Narcotic Drugs (CND) on December 2nd 2020, thereby safeguarding the burgeoning cannabidiol (CBD) industry in the UK, and stimulating the biosciences sector.

To vote in line with this recommendation does not mean following the herd of European Union member states in terms of the regulation and trade of CBD products overall within the United Kingdom. Indeed, our classification of CBD-containing products as novel foods to be regulated by the Food Standards Agency as introduced in 2019 with licensing applications due on 31 March 2021 sees us already carving our own path in this regard.

However, to subject UK CBD-producers and retailers to more stringent restrictions than in force in neighbouring countries in regard to CBD content and derivatives in domestically retailed products will set a nascent industry at an insurmountable disadvantage against nearby competitor industries. At present the UK has the potential to be a market leader and exporter in this sector, with the industry enjoying a projected value of £1 billion by 2025, provided its growth is safeguarded by appropriately careful decision making (rather than recklessly jettisoned by the adoption of overly stringent and unenforceable curbs).

2. Establishing a practical definition of zero percent THC, which is scientifically measurable

CBD products are generally assumed to be lawful to supply and possess by both vendors and consumers. However, it is difficult to isolate pure CBD without some trace contamination of controlled cannabinoids such as THC, and many of the available products are therefore presumed to contain controlled drugs; though the presence of THC in the product in question may be in practice be too little to warrant this, equivalent to zero percent THC. The current legislation on controlled cannabinoids is covered by the MDA 1971, however in practice current analytic technologies are not able to absolutely exclude the presence of any compound in a cannabis based preparation. In other words, there are certain threshold levels of sensitivity that we cannot see below, therefore we need a practical definition of zero in order for this policy to be enforceable by regulators and manufactures alike. At present the Home Office has not made any formal assessment of the zero limit and as such the CDPRG, the Center for Medical Cannabis (CMC) and the ACI are separately working on a robust evidence based paper to help the UK Home Office in determining the metrics of these limits. The CBD industry has been projected to grow to £1 billion by 2025, if properly regulated.

By voting in line with the WHO recommendations, and taking heed, the current barriers to growth of the sector in the UK would be dramatically reduced. This would not tie the UK into adhering to this upper limit later on nor stop us from establishing our own domestic policies, but would not preclude the predicted growth of the industry as it currently stands, and could lead to more value to the UK by facilitating the establishment of further business operations around the growing and processing of CDB on shore. The UK is already home to the successful GW Pharmaceuticals, a business involved in this very line of work.

A strategy that takes heed of the WHO recommendations at the upcoming UN vote has the potential to create more global producers and processors of based medicinal products and CBD based wellness products within the UK and would stimulate the growth of a wellness sector clearly and properly regulated with the minimum of doubt with regards to the law. If engaged with this will ultimately lead to introducing a realistically measurable and attainable limit that ensures current policy is coherent, supports public health by protecting the consumer and also stimulates the bioscience industry in the UK.

3. Thus the correct course of action for the UK is to support the WHO recommendation in the UN vote

The World Health Organisation's (WHO) Expert Committee on Drug Dependence (ECDD) plays a central role in the international drug control system. Its main task is to carry out medical and scientific evaluations of the abuse liability of dependence-producing drugs falling within the terms of the 1961 Single Convention on Narcotic Drugs and 1971 Convention on Psychotropic Substances. It then makes recommendations to the United Nations Commission on Narcotic Drugs (CND), who assist in supervising the application of international drug control treaties, whether or not these substances should be placed under international control or if their level of control should be changed.

The 40th meeting of the WHO Expert Committee on Drug Dependence (ECDD), held in Geneva, Switzerland in June 2018 was a specially convened session dedicated to carrying out pre-reviews of cannabis and cannabis-related substances. In addition to these pre-reviews, the committee discussed a critical review report on CBD. The subsequent 41st ECDD meeting in November 2018 carried out critical reviews to determine the most relevant level of international control for cannabis and cannabis-related substances and to determine whether the WHO should recommend changes in their level of control. Part of the rationale for the ECDD review was because cannabis has never been subject to a formal review by the ECDD since its original placement within the international drug control conventions and because more robust scientific research has been conducted in recent years into the harms and therapeutic use of cannabis and cannabis preparations - sufficient enough for a formal review. Furthermore, a number of countries have requested WHO to collect and analyse scientific evidence on harms and therapeutic use for review by WHO's ECDD, as more countries are embarking on regulated access to cannabis products and preparations for medical use.

4. Background

4.1 What is CBD?

Cannabidiol (CBD) is one of over 540 phytochemicals (plant-based compounds, including 144 known cannabinoids, 200 terpenes and 20 flavonoids) contained within cannabis, most of which are not controlled substances in the UK. A 2016 report from the ACMD reviewed the legal controls on 97 of the cannabinoids found in cannabis and identified 12 compounds controlled under the Misuse of Drugs Act 1971 (MDA 1971) and the Misuse of Drugs Regulations 2001 (MDR 2001). In their pure form, the other cannabinoids are not controlled by the MDA, including CBD-type compounds such as CBD, CBDA, CBDV and CBDVA. It is the issue of purity that is at issue.

Barriers to access to medicinal cannabis, as outlined in our report, *UK Review of Medical Cannabis Part A: The Needs of a Nation,* has led to the emergence of a burgeoning demand and thus large market for CBD consumer products. According to a recent report by the Centre for Medicinal Cannabis, people who had used a CBD product in the past year were also six times more likely to report using cannabis for medicinal reasons in the past year. This indicates a strong crossover between the non-prescription 'wellness' markets and the consumer base for cannabis-based medicinal products, both demographics pursuing legal access and quality control and wishing to avoid the vagaries in product quality associated with the illicit market. The CMC estimated that between 4 – 8 million adults in the UK had tried a CBD product in 2019, of whom approximately 1.3 – 1.7 million were regular users. The most common reasons for use were for overall health and well-being (54%), sleep (54%) and pain-management (42%).

There is a growing demand for CBD containing products as they are perceived to be non-psychoactive, legal, safe, natural health and wellness supplements, legally available in the absence of access to medicinal cannabis. In the CMC's 2019 report the size of the UK CBD market was an estimated £300M per year; larger than the combined Vitamin C (£119M) and Vitamin D (£145M) markets for that year. This market is expected to grow to around £1B by 2025, equivalent to the entire UK herbal supplement market in 2016.

There are widespread claims that many of the compounds in cannabis contribute to its purported medicinal and wellness benefits, reflective of its increasingly recognised therapeutic potential for

different conditions. CBD, in particular, has been the focus of substantial interest among researchers and consumers alike. It is available on the UK market in high street stores, pharmacies and online and comes in a wide variety of forms (such as oils, tinctures, capsules, creams, food products, supplements, and e-liquids) but these consumer products are not prepared for medicinal use, do not have medicinal product market authorisation, and cannot be advertised as having medicinal value. Still, allusions are made to the antipsychotic, analgesic, neuroprotective, anticonvulsant, antiemetic, antioxidant, anti-inflammatory, antiarthritic, and antineoplastic properties of CBD that have been demonstrated to varying degrees of reliability in clinical and preclinical studies.

4.2 Prior regulation of cannabidiol (CBD)-containing products in the UK

In October 2016, the MHRA announced that CBD-containing products that meet the definition of a medicinal product must have market authorisation before being supplied or advertised, unless ordered in accordance with 'specials' regulations under the conditions laid out under the Human Medicines Regulations 2012. A deadline of 31 December 2016 was set for CBD-containing medicinal products to have either achieved market authorisation or be removed from the market.

The next development around the regulation of CBD-containing products came apropos of Brexit, in the form of their reconceptualisation as novel foods in 2019. CBD products for oral use in humans, but which are not for medicinal use, are already regulated as novel food products. Novel foods are food products for which no significant history of consumption within the EU can be shown prior to May, 1997. In January 2019, the European Union's catalogue of novel foods was updated to clarify that extracts of cannabis and derived products containing cannabis were considered novel. The UK foods regulator, the Food Standards Agency (FSA), subsequently accepted the EU recommendation, taking over the responsibility for the assessment and sanctioning of CBD-containing products in the UK.

4.3 Current regulatory standpoint of CBD-containing products in the UK: Clarity needed around chemical composition

Taking charge of the UK's CBD industry, in February 2020 the FSA announced a deadline of 31 March 2021, for suppliers of CBD food products and food ingredients to have either submitted fully-validated novel food applications or to have removed their products from the market. It is not

permitted for new CBD food products to be brought to market until they are authorised by the FSA as novel foods, unless they had already been on the market prior to February, 2020. The FSA will accept formal applications for novel food authorisation when the Brexit transition period comes to an end in January, 2021.

Under the new regulations, law abiding producers and suppliers of non-medicinally-intended CBD products may market their CBD as non-psychoactive wellness products after having supplied evidence to the Home Office that their products comply with the regulatory limits on controlled substances. The current UK law *in theory* does well to protect the consumer, but in practice current quality control standards vary greatly between products. Numerous laboratory analyses of products allegedly containing pure CBD have identified concentrations of cannabinoids that differ from the amounts advertised.

4.4 Reviews by the World Health Organisation (WHO) that have led to the 02 December 2020 proposition to be voted on

Following the critical review stage WHO subsequently made recommendations to the Secretary General of the UN. In regard to cannabidiol preparations the recommendation is that that pure CBD should not be scheduled within the UN Drug Control Conventions by adding a footnote to the 1961 Single Convention on Narcotic Drugs to read:

"*Preparations containing predominantly cannabidiol and not more than 0.2 percent of delta-9-tetrahydrocannabinol are not under international control.”*

As previously mentioned, the WHO’s expert committee is tasked with evaluating the abuse potential of dependence-producing drugs and their assessment of the abuse potential of CBD products that contain traces of THC concluded that a 0.2 percent THC limit would be sufficient to protect against potential risk of abuse. The WHO's expert committee is there to play the UN role of the ACMD, but the ACMD itself concluded in January 2020 that Epidyolex, where delta-9-tetrahydrocannabinol (THC) is present (no greater than 0.15%) has a low risk of abuse potential, low risk of dependency and low risk of diversion.

At the 63rd reconvened UN session of the Commission on Narcotic Drugs (CND), which will be held on the **2nd December 2020**, the 53 member States of the UN Commission on Narcotic Drugs (CND), of which the UK is a signatory, will vote on the WHO recommendations. This is the usual process for making amendments to the Conventions. The CND may elect to implement the recommendations of the WHO with a 2/3 majority and any such decision would subsequently be communicated to all member States by the Secretary General of the UN.

The WHO's recommendation to withdraw cannabidiol preparations which do not exceed 0.2 percent of delta-9-tetrahydrocannabinol from international control would provide much needed clarity in a fledgling market that desperately needs it. Without it, this leaves the entirety of this sector in the UK technically illegal but also largely unenforceable. This is therefore an important moment to remedy this present regulatory failure. 0.2 percent THC is also the limit already enacted by the majority of other European states to date. Setting a lower tolerable limit than 0.2 percent on end products for consumer sale would jeopardise the ability of the UK CBD market to compete with international markets, with a substantial associated economic loss to the UK.

It should be kept in mind that any changes enacted at the UN level are not binding in the UK and voting in favour of this motion will not force the UK to adopt any particular domestic control strategy, nonetheless, there would be an advantage to following it, based on the economic arguments of competition with international markets and would this avoid a significant disadvantage to the UK market if followed.

5. Conclusion

We, the Conservative Drug Policy Reform Group, strongly **recommend that the UK votes in favour of this motion** at the 63rd United Nations Session of the Commission on Narcotic Drugs (CND) on December 2nd 2020, thereby safeguarding the burgeoning cannabidiol (CBD) industry in the UK, and stimulating the biosciences sector.