THE MECHANICS OF CHANGING ANY POLICY CONCERNING PROHIBITED SUBSTANCES IN THE UNITED KINGDOM

There is a prescribed process which must be followed prior to any change in laws which relate to controlled substances in the United Kingdom:

1. Firstly, the relevant Minister, in this case the Home Secretary, must identify the potential change in policy and the manner in which that potential change might manifest itself in respect of the misuse of drugs;

2. Secondly, the Minister must commission the Advisory Committee on the Misuse of Drugs (ACMD) to assess the available evidence which impacts on the potential change;

3. Thirdly, the ACMD collates such evidence as is immediately available and, if it believes that it is advantageous, invite the submission of further evidence from relevant parties;

4. Fourthly, the ACMD reports back to the Minister and makes recommendations in respect of the proposed change. Such recommendations are not fettered by the initial question posed and can be:

    - to make the proposed changes;

    - to make the changes, but to do so within different parameters;

    - not to make the proposed changes, but to make different changes; and,

    - not to make any changes at all.

On 21st January 2021 the letter from Kit Malthouse (dated 11th January 2021) to the Chair of the ACMD was published. Without betraying any confidences we had, on 12th January 2021, made it clear that the Home Office were not only willing to review the impact of current Drugs laws on Cannabidiol products, but that they intended to take positive action in that regard - you can read our comments here.

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Therefore, it can now be appreciated that the "Kit Malthouse letter" of 11th January 2021 is actually the fulfillment of Stages 1 and 2 above – when the Home Office, acting through their subordinates the Minister of State in the Home Office and Ministry of Justice (Kit Malthouse) invited the Advisory Committee on the Misuse of Drugs to receive evidence on the specified issue:

> *As you are aware, tackling drug misuse and the harms that it causes remains a top priority for this Government. The Home Office is keen to draw on ACMD advice on the issue of CBD products which are not medicines. There has been a proliferation of such products available online and on the high street in recent years. While as an isolated substance, CBD is not a controlled drug, there is recent evidence that many of the products available contain controlled cannabinoids and that it is difficult to isolate pure CBD. The Government currently has no plans to look at the status of CBD itself under drug legislation.*
>
> *There is currently not a legal framework in place specifically exempting CBD products from control under the Misuse of Drugs Act 1971, and with this in mind, the Government wishes to explore the possibility of creating a specific exemption in the Misuse of Drugs Regulations 2001 ('the 2001 Regulations') for CBD products which contain no more than a defined trace percentage of controlled cannabinoids. Primarily THCV, Δ^9-THC and CBN and the cannabinoid Δ^9THCA-A. We are interested to hear if you believe other controlled cannabinoids require consideration too.*
>
> *The Government is minded to amend the 2001 Regulations to permit CBD products that contain no more than a defined trace percentage of certain controlled cannabinoids as an impurity. Additionally, we are minded to amend the definition of an "exempt product" under the 2001 Regulations to give effect to the intent surrounding its introduction, being to only exempt products used for scientific or diagnostic purposes which contain an extremely small amount and proportion of controlled drugs, but unambiguously excludes consumer products and any products intended for human consumption, other than in scientific research. We request the ACMD to provide advice on how the exempt product definition in the Misuse of Drugs Regulations may be amended to apply only to diagnostic equipment or for scientific research, as originally intended.*
>
> *In terms of this trace amount, we propose that the defined trace percentage in CBD products be set at a level which will be between 0.01% and 0.0001% by weight per controlled cannabinoid. The precise level will be determined following further scientific testing advice. Given the current limited availability of reference chemicals, we consider that analytical capability is likely to be best focused on the quantification of THCV, Δ^9-THC, CBN and Δ^9THCA-A rather than all controlled cannabinoids that could be permitted*

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to be present in trace amounts. The Government intends to work further with the forensic science sector to assist in determination of the method of testing and precise definition of the trace amount. The 0.01-0.0001% per named controlled cannabinoid level (or lower) is proposed on the basis of evidence and will be subject to further confirmation on our part that responsible producers are able to produce CBD to this level of purity, and it is within the capabilities of the forensic science sector to quantify consistently and affordably.

In order to keep the level of controlled cannabinoids in CBD products down to an unavoidable trace level, we would ask that the ACMD considers the maximum dose for any non-negligible effect for THCV, Δ^9-THC and CBN and the cannabinoid Δ^9THCA-A. We are seeking further scientific testing advice on analytical capability to test for a cannabinoid content of 0.01-0.0001% by weight or lower per specified cannabinoid. In particular, we would ask that the ACMD considers whether such products would be liable to be abused or have ill effects, and whether the controlled substances could, in practice, be recovered from such products.

In furtherance of their statutory obligations, the ACMD have recently effected Stage 3 above and called for evidence to address seven specific questions.

We have recently seen some commentary which suggested that the actions of the ACMD is a result of the "kickback from the industry after Malthouse's letter in January". In fact nothing could be further from reality because, for the requirements of the process outlined above, the request by the ACMD is consequent upon the "Malthouse letter", not in opposition to it.

WHAT ARE THE ACMD SEEKING?

The Committee's remit is precisely defined and the seven questions which they have posed are targeted at that remit – they are not seeking generalised opinions on Cannabinoids, but specific data which pertains directly to the remit set for them.

Therefore, while market participants are obviously free to provide such information as they wish to the Committee, we would advise that the following aspects are borne in mind if you wish to have your contributions considered, rather than sidelined as failing to address the questions posed.

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We would observe that, if submissions are structured in the appropriate manner, then most market participants will be able to say everything that they want to in respect of each question – but to do so the structure of the answer must address the question and make all of the information imparted referable to that question. As a high-level overview, our observations would be:

1. *The commission refers to the cannabinoids Δ9-THC, CBN, THCV and Δ9THCA-A. Are there any further phytocannabinoids which should be considered? If so, which cannabinoids and please provide evidence.*

    - **The ACMD's remit in this regard relates to Controlled Cannabinoids and therefore it is only additional Controlled Cannabinoids which are relevant to their considerations. It is perhaps worth noting that the Laboratory of Government Chemists identified 12 psychoactive compounds in their Report in January 2021 (see Table 1) (here).**

2. *At what dose would each of these cannabinoids cause a psychoactive effect in humans? Are there any potential harmful effects at these dosages?*

3. *What are the conditions that precursors of cannabinoids such as Δ9-THCA-A might be transformed into controlled cannabinoids?*

4. *What is the combined level of the psychoactive cannabinoids that would not produce a psychoactive effect (in other words maximum combined dose of active ingredients) given the standard use of consumer CBD products?*

5. *Are you aware of any evidence of CBD products causing adverse reactions or harms which might be attributable to cannabinoid impurities? If so, please attach such evidence.*

    - **Any answer to these question should be referable to published scientific data, which should be included within the submission to the ACMD.**

6. *For producers of CBD-containing products for supply to consumers, what certification of quality of CBD extracts from raw materials do you require or expect.*

7. *For which controlled phytocannabinoids are there reference standards available or likely to become available in the near future for their use in testing?*

    - **These questions are much wider in scope and permit the responder to provide their opinion, which does not need to be supported by factual evidence.**

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THE CANNA CONSULTANTS

At The Canna Consultants we have always been at pains to remind market participants that:

- we are not a Trade Association;
- we are not a Trade Association which asserts itself as acting on behalf of the industry as a whole; and,
- we do not produce "Reports" which purport to engage with Government on behalf of the industry as a whole and define "acceptable" limits by reference to the requirements of Members.

What we are is an independent Consultancy which advises market participants and governments throughout the world on Cannabinoids, Cannabinoid Medicines and Cannabinoid Policy:

- it is inherent that in so doing, when we engage directly with market participants, we impart to them the insight which we have in respect of government policy as it impacts upon them presently, and as it will do so in the future, given our understanding of the "direction of travel" of government policy;
- it is inherent that in so doing, when we engage directly with governments, we impart to them the insight that we possess from those market participants whom we represent.

Thus, we are not a mouthpiece **for** defined elements of the market and nor are we a mouthpiece **for** government – what we are able to do is speak **to** the market and speak **to** government, seeking to ensure a sensible and progressive dialogue to benefit the interests of those whom we represent.

What is unique about The Canna Consultants is the assistance that we provide to both "sides" of the regulatory equation – the regulators and the regulated – to establish outcomes that are acceptable to all. If you want to be close to that equation, our doors are always open.

Remember what we always say: Be Careful Who You Listen To.

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