**Additional Notes to Cannabidiol 2 paper:**

* The UK Medicines & Healthcare products Regulatory Agency (MHRA) have sent letters to cannabidiol (CBD) suppliers that their products are medicines and must be licensed. It is not clear whether this is a revised opinion of the regulatory status. They had previously advised that CBD was not considered to be a controlled drug. In a press release published on 13 October 2016, they state *“We have come to the opinion that products containing cannabidiol (CBD) used for medical purposes are a medicine. Medicinal products must have a product licence (marketing authorisation) before they can be legally sold, supplied or advertised in the UK, unless exempt. Licensed medicinal products have to meet safety, quality and efficacy standards to protect public health.” –* MHRA statement on products containing Cannabidiol (CBD). URL: <https://www.gov.uk/government/news/mhra-statement-on-products-containing-cannabidiol-cbd> (accessed 17 October 2016).
* GW Pharmaceuticals have confirmed that the CBD [redacted under section 9(2)(ba)(i)] product contains 100 mg/ml CBD.
* There are several options that the Ministry is currently considering for reclassifying CBD, if this is the Committee’s recommendation, including amending the Misuse of Drug Act 1975 (MoDA). Removing/down-scheduling anything from MoDA is a longer and more involved process than an Order in Council (which can be used to up-schedule something). However, this should not change the Committee’s recommendation as your technical advice should not be affected by the legislative process associated with decisions made.
* We have received confirmation that Australia’s scheduling of [cannabidiol] CBD applies to the **active ingredient [cannabidiol]** only. This means that in a 100 mg/mL [cannabidiol] product there will be only a maximum of 2 mg/mL (0.2%) of [total] other cannabinoids found in [the] cannabis [plant] in the product. A product could still be made that was 100% active ingredient i.e. the product contains 98% CBD, 2% [total] other cannabinoids found in cannabis and nothing else.[[1]](#footnote-1)
* Cannabidiol and tetrahydrocannabinol (THC) are already prescription medicines, so any changes made by the Committee would be practically applied to medicines being classed as controlled drugs or medicines. The Committee are asked to provide advice on the classification of CBD under MoDA and, in addition, whether a limit should be allowed of other cannabinoids found in cannabis. It should be noted however, that the Ministry will also need to consider:
	+ whether the limit would apply to the active ingredient or final product for the practicality of product assessments
	+ whether that limit would be applied as a percentage or another unit such as parts per million (ppm, which is equivalent to mg/kg) in order to align with the Medicines Act 1981 (Note: 2% is equivalent to 20,000 mg/kg = 20,000 ppm).

If the Committee has recommendations on these points we ask you to include them in a statement of the intention of your decision in order to guide the drafting of the legislative changes.

1. Words in square brackets have been added in for clarification. [↑](#footnote-ref-1)