Expert Committee on Drug Dependence

Thirty-ninth Meeting

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World Health Organization

Expert Peer Review for Cannabidiol (CBD)

1. Comments based on the review report

a. Evidence on dependence and abuse potential

There are few studies regarding dependence, however, the Pre-Review describes in an animal study that no tolerance developed to CBD at any of the dosages, unlike with THC that was also studied. With regards abuse potential, in an animal administration study there was no indication of self-stimulation and reward activity for CBD. In discrimination studies, CBD did not substitute for THC. In humans, the Pre-Review reports that while the number of studies is limited, the evidence from controlled experimental research indicates that CBD is not associated with abuse potential. CBD was equivalent to placebo and unlike THC in the studies, did not exhibit features of abuse potential. Furthermore, the Pre-Review states study findings suggest that oral CBD does not reduce the reinforcing, physiological, or positive subjective effects of smoked cannabis. There are no case reports of abuse or dependence relating to the use of pure CBD.

b. Risks to individual and society because of misuse

There do not appear to be any instances of misuse by individuals. The PreReview Report states that across a number of controlled and open label trials of the potential therapeutic effects of CBD, it is generally well tolerated, with a good safety profile. No instances of non-fatal or fatal toxicity have been reported, indeed there is no evidence that CBD would produce acute toxic effects.

c. Magnitude of the problem in countries (misuse, illicit production, smuggling etc)

There do not appear to be any instances of misuse, illicit production or smuggling, etc of pure CBD. The Pre-Review describes that there is unsanctioned medical use of CBD based products. These are produced from high CBD content plants and distributed in a variety of forms, including oils and capsules. These products are sold online as unapproved treatments for a variety of disorders including epilepsy, cancer, AIDS/HIV, anxiety, arthritis, pain, and post-traumatic stress disorder (PTSD).

d. Need of the substance for medical (including veterinary) practice

The Pre-Review states that the clinical use of CBD is most advanced in the treatment of epilepsy. In clinical trials, CBD has been demonstrated as an effective treatment for at least some forms of epilepsy, with one pure CBD product currently in Phase III trials. There is also evidence that CBD may be a useful treatment for a number of other medical conditions. However, this research is considerably less advanced than for treatment of epilepsy. For most indications, there is only pre-clinical evidence, while for some there is a combination of pre-clinical and limited clinical evidence. The range of conditions for which CBD has been assessed is diverse, consistent with its various properties. Whilst CBD is present in some nabiximols products, there are no currently authorized pure CBD products but the Review states there are several in development.

e. Need of the substance for other purposes (e.g. industrial)

CBD has no industrial or other use.

f. Measures taken by countries to curb misuse

The Pre-Review Report stated that CBD is controlled (through national legislation either as a named substance or within a product or cannabis) in Australia, Canada, New Zealand, Switzerland, United Kingdom and the USA.

g. Impact if this substance is scheduled

No specific information but it may affect current or future therapeutic applications. CBD is not listed on the WHO Model List of Essential Medicines.

2. Are there absent data that would be determinative for scheduling?

None.

3. Other comments or opinions

None.

4. Expert reviewer's view on scheduling with rationale

CBD is not listed in the schedules of the 1961, 1971 or 1988 United Nations International Drug Control Conventions but CBD is being produced for pharmaceutical purposes as an extract of cannabis. There is no evidence that CBD as a substance is liable to similar abuse

and similar ill-effects as substances in the 1961 or 1971 Conventions (including cannabis and dronabinol (THC)). Nevertheless, the purpose of the pre-review is to determine whether current information justifies an Expert Committee critical review whereby the Committee finds that information may justify the scheduling or a change in the scheduling of the substance in the 1961 or 1971 Conventions. As such, as CBD is not currently a scheduled substance in its own right (only as a component of cannabis extracts), in my view the information presented in the Review Report does not justify a change in this scheduling position and does not justify scheduling of the substance. However, a critical review may be warranted within any review of cannabis extracts and tinctures.