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Global CBD Study Calls For Tighter Regulation And Clinical Trials

by David Ridley

A wide-ranging study of low-dose cannabidiol supplementation, its regulation, efficacy and safety calls for improved legislation, guidelines and quality control together with clinical trials exploring the increasingly popular ingredient's therapeutic benefits.

A study comparing cannabidiol availability across in nine countries – Australia, Canada, Germany, Ireland, Japan, New Zealand, Switzerland, UK and US – shows a wide variety of approaches in how access to CBD products is regulated.

A range of CBD products, including oils, gel capsules, purified crystal and topical products, were accessible without prescription in seven of the countries reviewed, found the study published this month in the *International Journal of Drug Policy* (see Figure 1, below).

Daily recommended doses with orally administered non-prescription CBD products were typically well below 150mg and substantially lower than the doses reported to have therapeutic effects in published clinical trials (e.g. 300-1500mg – see Figure 2, below).

CBD regulations in several of the countries studied were often unclear, the researchers discovered, with marketed products sometimes failing to meet legal requirements for sale.

“Many countries appear to permit OTC and online availability of CBD products but often without legislative clarity,” concluded the authors of the academic study.

“As consumer demand for CBD escalates, improved legislation, guidelines and quality control of CBD products would seem prudent together with clinical trials exploring the therapeutic benefits of lower-dose CBD formulations,” they recommended.

Free For All

One of the authors of the study, international Rx-to-OTC switch expert Natalie Gauld, said the researchers wanted to understand how CBD legislation differed around the world. "I thought it would be quite straight-forward, but found the opposite," she told HBW Insight.

Generally, medicines are usually prescription-only, or one of the various non-prescription classifications, Gauld pointed out. "The odd thing differs, but it is generally binary. CBD is not like that."

"And then the labelling of products is a bit of a free for all – they sometimes state the overall dose in the container rather than the strength, which we are not used to," she continued. "They don't always contain what they say they do, and there is the potential for products containing other substances not advertised on the pack."

"I think there is an opportunity for a country to take a pragmatic approach where CBD in low doses is licensed in some way – not necessarily as a medicine – so we can ensure there is not THC in excessive quantities, provide some assurance as to what the consumer is getting, and to reduce the potential for inappropriate claims," Gauld argued.

"Right now, all over the world people are accessing CBD that does not have a quality assurance, and without any health professional involvement," she added. "We need to better understand the potential for interactions at low doses, and what dose and for what indication it actually works. There is a lot of hype out there."

Efficacy

An interesting finding of the study was that all the "maximum dose" CBD products yielded daily doses well below those shown to be effective in clinical trials.

While effective doses in clinical trials range from 300-1,500mg/day or 14-23mg/kg/day, the authors noted, the recommended daily doses provided by OTC CBD products were, with one exception, below 150mg.

"As access to these predominantly low-dose CBD products increases internationally, high quality evidence supporting their therapeutic benefits in conditions such as pain, anxiety and sleep is scarce at best," they said.

However, the authors were keen to point out that this is not to say that OTC CBD products are ineffective, merely that high-quality scientific studies around the potential benefits of low CBD doses are yet to be conducted, and so efficacy at these doses remains to be demonstrated.

This represents a "significant opportunity" for industry, in collaboration with scientists and clinicians, to "backfill" the evidence, they argued, so that that they may "validate a global

consumer phenomenon, or alternatively, illustrate the magnificent folly of the entire enterprise."

Safety

Meanwhile, reviewing the scientific literature, the authors concluded that CBD has a "favorable safety profile" in humans and is generally well-tolerated at doses up to 6000mg in single doses or 1,500mg in multiple doses – 40- and 10-times the 150mg low-dose threshold in the markets studied.

"Outside of clinical trials involving epilepsy, the only adverse event more prominent with CBD over placebo is diarrhea," the researchers said. "Pharmacokinetic interactions between CBD and prescription medications remain possible but the likelihood of such interactions at the low CBD doses obtained from non-prescription products remains to be established."

"With regards to long-term use, there is little information available on the effects of CBD consumption beyond the 14-week time interval involved in recent clinical trials, and the occasional pre-clinical study where rodents have been dosed long-term without any obvious adverse consequences," the authors conceded.

"Obviously, then, there remains the possibility that hitherto unrecognized and problematic side effects may emerge in the future when patients using CBD over many months or years are studied," they added.

Up until now, safety concerns have been related to the inaccuracy of the labelling of OTC CBD products on the market, with the authors pointing to high profile exposes such as the Centre for Medicinal Cannabis' "CBD in the UK" report, published earlier this year. (Also see "*No Plans To Remove CBD Products From Shelves, Says UK Food Regulator*" - HBW Insight, 23 Jan, 2020.)

"Both over-labelling (the product provides lower cannabinoid content than stated on the pack) and under-labelling (the product provides higher cannabinoid content than started on the pack) were detected, with many products in breach of strict THC limits," McGregor and colleagues explained. "This would suggest that regulatory oversight in these jurisdictions is inconsistent at best."

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Source: McGregor, I. S, Elizabeth A. Cairns, E. A, Abelev, S., Cohen, R., Henderson, M., Couche, D, Arnold J. C. and Gauld, N. (2020). Access to cannabidiol without a prescription: A cross-country comparison and analysis. International Journal of Drug Policy, 85 1-14. *https://doi.org/10.1016/j.drugpo.2020.102935*