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Don't Cross the Streams!

We need a clearer distinction between medicinal, medical, and pharmaceutical cannabis products

Miguel Fagundes | 04/06/2021 | Opinion

People have been busy writing a great deal about cannabis and cannabis-derived products for the last few years. As you hack your way through the jungle of information, you will not only find medicines intended for prescription by doctors (for example, Epidiolex and Sativex) but also so-called "self-medication" products, including edibles, cosmetics, and dietary supplements. Such products can be directly sold to a consumer without a requirement for a prescription from a healthcare professional. Notably, the amount of CBD in these products is typically far lower than the concentrations found in clinical trials. Patients and consumers should also be aware that these widely available CBD products may not meet strict quality assurance guidelines as they are not regulated as medicines (regardless of their claimed wellness benefits) – and sometimes there is no specific legislation for products containing CBD...

Though there are major differences in the developmental and regulatory paths for cannabis-based prescription drugs and cannabis products developed for self medication, I think it is important to emphasize how little clarification has been provided to the public, patients, and even to the wider medical community.

Non-medical or "self medication" products are legally required to have a THC or psychoactive content below around 0.2 percent in the EU or between 0–5 percent in the USA, depending on the state. As with other herbal remedies, the declared contents of non-medicinal CBD preparations are variable, and often inaccurate.

Let's clear up some definitions. In my view, medicinal cannabis refers to both "medical" and "pharmaceutical" cannabis products. Medical cannabis is taken to mean plant-based or plant-derived cannabis or cannabinoid-containing products/preparations – either prescribed by a medical practitioner for the treatment of a specific condition or disease (for example, epilepsy, pain, multiple sclerosis) or purchased by consumers without prescriptions for medical purposes. By contrast, pharmaceutical cannabis refers to products that are formulated or processed using cannabinoids (natural or synthetic) that have been through full clinical trials and licensed as a medicine with marketing authorization; such drugs typically require medical prescriptions (for example, Sativex, Marinol, Syndros, and Cesamet).

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> *Some of us have a clear understanding of the difference, so why do patients and consumers find themselves in such confusing times?*

Some of us have a clear understanding of the difference, so why do patients and consumers find themselves in such confusing times? Well, given increasing signs of therapeutic usefulness and with relatively undefined regulatory pathways, a number of companies raced to become leaders in the medical/medicinal cannabis market, happily blurring (or brushing out) the lines along the way. This "green rush" has left us with two big questions: to what extent was this early race won at the expense of quality, safety, and efficacy issues? And have these trailblazers damaged the reputation and credibility of the cannabis industry as a whole?

I think it is high time the cannabis community made a clear and unbiased distinction between very different types of cannabis products – cannabis is not one thing. Once we've made the distinction, we need to agree on regulatory frameworks that protect patient safety in all cases. But what would that regulatory framework look like at a global level?

Despite centuries of widespread cannabis and cannabis-derived product use, we have a long way to go in terms of harmonizing the legal and regulatory framework across the globe. For example, understanding the regulations that must be applied to a specific primary processing stage (or even drying of the cannabis plant) is of paramount importance, yet interpretations of such regulations can differ significantly between countries.

> *The future facing among us agree that more and better testing at all steps in the cannabis product supply chain is optimal for patient safety – again, whatever the product type.*

And yet, complaints and confusion aside, the future facing among us agree that more and better testing at all steps in the cannabis product supply chain is optimal for patient safety – again, whatever the product type. Therefore, it is unfortunate that a dearth of reliable testing companies compounds the problem!

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We need more accredited laboratories with staff experienced in GLP, ISO, or GMP. Also, implementing a proper quality management system is key to efficiently address all the tasks related to documentations, testing, calibration, training, and so on. ISO/IEC 17025 is written to give an overview for testing and calibration labs; however, it lacks specifics. Figuring how the standards apply on a day-to-day process is something that can only be achieved by staff with the right training and background.

At the same time, we should not allow manufacturers to lead the show; health agencies must be the drivers of regulation and offer appropriate technical oversight. If they do not, we will end up with ambiguous standards and a lack of uniformity, which promote unsubstantiated, non-scientific and often blatantly false claims on product safety and efficacy. Cannabis is medicine so it should be tested like medicine with the right validated methods.

If we want the cannabis industry to be successful, we must all strive for uniformity and alignment – and that demands a joint effort between the different organizations and agencies around the world. We must work together to develop a comprehensive regulatory framework and then standardize manufacturing, testing, and, last but not least, labeling of cannabis products for both medical and medicinal markets.

And if companies can't get on board for the benefits of patient safety, then consider that regulations and testing also drive quality. Consider this: consumers and patients alike ultimately vote with their loyalty and money – and unmet expectations (medical or otherwise) caused by quality issues are very likely to put your profit margin at risk!

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About the Author

Miguel Fagundes

Chief Technical Officer (CTO), Botanical Holdings, London, UK