Preamble

The legal use of cannabis is increasing across the world. In particular, the medicine derived from cannabis is increasingly available on a global level.

The regulatory situation differs by country. Some countries allow cannabis to be used only for medical purposes. Others allow both medical use and adult-consumer use. While others have no legislation in place for either.

The adult-consumer use of cannabis and the aligned industry, by necessity, must be separated from medical. This is because the two markets and industries provide very different capabilities, growth agendas, products, dose formats and cannabinoid content, packaging and labelling, and user information alongside regulatory oversight controlling the quality, distribution, and the end use.

Defining these two markets through applicable standards, practices, and regulations means to:

- apply appropriate controls over materials and products and services that are intended for adult-consumer use or for medical use,
- reduce or eliminate access to substandard and poor quality cannabis-derived materials and products and services, and
- improve and maintain confidence among adult-consumers and all patients.

This article describes the dichotomous nature of adult-consumer use and medical use markets. And is a call to action for the collaborative development of much needed standards and practices.

1The medical market describes medicines (therapeutic products) intended to be used in or on human beings for a therapeutic purpose. Within the context of cannabis-based medicines, pharmaceutical-quality (minimum quality standard) products are either registered medicines or un-registered medicines.

Whereas cannabis intended for adult-consumer use is that which is typically taken for enjoyment, or leisure purposes, rather than for medical reasons. An adult-consumer purchases goods and services for personal use, and makes an active decision about consumption.
ADULT-CONSUMER USE VS. MEDICAL USE

Not a confrontation, rather a clarification and separation

Adult-consumer use vs. medical use is NOT intended to create a confrontation between industries or markets. Rather, addressing this topic is intended to find a balance, a better understanding of adult-consumer use and medical use.

Terminology leading discourse

Consistency of language used in discourse on this topic is necessary.

This article concerns cannabis-derived materials and products, principally derived from the plant Cannabis sativa L., and semi-synthetic cannabinoids, intended specifically for adult-consumers and patients.

Adult-consumer products describe the diverse group of cannabis-derived adult consumer products, chiefly intended for “enjoyment” or “wellness” purposes. An adult-consumer purchases goods and services for personal use, and makes an active decision about consumption.

Patients are prescribed cannabis-based medicines, containing a defined and standard cannabinoid content, which may include fully-standardised cannabis herbal material in standard dosages. Medicines refer to medicinal substances, or their preparation and use for the treatment or prevention of disease. Within the ‘Traditional Medicine’ context, the compounding and dispensing of a medicine similarly expects a patient interaction with a learned expert, medicine quality, and the prevention of harm.

A long history of cannabis use

Cannabis is the most commonly used (illicit and licit) drug substance worldwide [4, 5]. People have used cannabis for a very long time and for a variety of reasons, including for enjoyment and wellness. THC may induce feelings of relaxation and a mild euphoria [6, 8]. A smaller, generally non-overlapping group report ‘pain avoidance’ as a very important motivation. The use of cannabis for wellness purposes is also growing.

In the 2000’s, following the regulatory change to cannabis for medical use, cannabis products intended for adult-consumer use became available alongside the illegal market. The legal market, in various jurisdictions across North America in particular, is now taking total market position. This trend is exemplified in Canada. [1, 9]

It is important to recognize that cannabis products will be misused and, or diverted for misuse by adolescents. This is because many cannabis products contain psychoactive, intoxicating substances. The long-term heavy use of cannabis containing THC is known to cause harm to the developing brain (until humans reach mid-20’s), reducing cognitive performance. In particular, the heavy use of cannabis at young ages is associated with an increased risk of educational under-achievement [10-12]. Regular, heavy, and abusive use of cannabis, particularly high THC potency cannabis, may increase the risks of symptoms of poor mental health. [12-17] Adult use of cannabis products is associated to the use of drug combinations, or ‘poly-drug’ use, including alcohol [7, 18-21], which influences the harm associated with misuse.

The adult-consumer market

The use of cannabis has increased over the last decade, with the number of weekly and daily users also increasing over this period. [5] Historically, many more males constituted the majority of cannabis consumers. Today, females make up a lot of the new customers in the market – a result of normalisation and legality.

Cannabis adult-consumer products, are defined, in part, by consumer demand for aesthetic qualities and aroma. Perhaps similar to consumers of fine wine or craft beer. In ‘legal’ markets, consumers are wanting for better product information including about quality, the cannabinoid and terpene content (labeling like standard nutrition fact panel), its point of origin, information on prior product recalls, the designation of registeredandexmccannabis.org
Cannabis, in its various forms, has been used for medicinal purposes [24, 25]. Cannabis is one of the oldest known medicinal plants. For thousands of years, cannabis-based medicines were derived from plants and have lineage to our prescription medicines that were derived from plants and have lineage to cultural knowledge was formally adopted by modern medical practice. Many laboratories issuing certificates. And, more and more, the desire for products sourced from facilities certified organic.

Consumer demand currently reflects changing behaviors and consumer age, including the desire for discreet and easy-to-consume products for consumers ‘on-the-go’. Convenient products, like vapes, edibles, and infused beverages are increasing in market share.

Smoked cannabis flower remains an important part of the market (constituting 58% of total sales in Canada, for example). [9] With a desire to reduce or eliminate the harmful impact of smoking cannabis, consumers are increasingly seeking safer modes of intake. There is increasing demand for other products, including high potency vaporized cannabis concentrates, edibles (solids and liquids), and beverages (alcoholic and non-alcoholic). Over time, the product landscape may continue to diversify. [9, 22, 23] Indeed, there is planned and concerted diversification into cannabis beauty and skin care products, beverage sector, and even products intended for animals.

The intersection of adult-consumer cannabis products with the wellness industry enlarges the industry reach to consumers interested in the claimed therapeutic benefits of cannabis – without ever having to engage with doctors or pharmacists. Partly because of the media buzz piquing an interest in potential therapeutic applications – adult-consumers now seek cannabis products to relieve anxiety, enhance sleep, and self-manage pain. While, adults might use cannabis-derived products as an alternative to medicine prescriptions, that does not mean pharmaceutical-quality is not warranted, requested, or required. [1-3]

Consumption facilities, often described as ‘lounges’, much like the Dutch ‘coffee shops’, are similar to bars serving alcohol. These venues provide adult-consumers a venue to use products containing cannabis and to socialise. The proliferation of such venues may increase the opportunities for partnerships with existing beverage and food venues and cannabis retail outlets, affecting consumer trends into the future.

**MEDICAL USE**

In the parts of the world that allow cannabis-based medicines, most have implemented a typical pharmaceutical-medicine framework and prescriber-pharmacy model of care. Patients have a meaningful interaction with prescribers and pharmacists, where the care pathway is not disrupted by patients accessing medicines via a separate system such as ‘dispensaries’ and ‘cannabis clinics’. While pharmaceutical-quality cannabis-based medicines are increasingly being made available, among the health profession there are uncertainties and debate on the medicines’ role and appropriate use. Indeed, the clinical evidence for their use is incomplete, and cannabis-based medicine is still rarely included in national medicine guidelines.

**Cannabis-based medicines by popular demand**

Cannabis is one of the oldest known medicinal plants. For thousands of years, cannabis, in its various forms, has been used for medicinal purposes [24, 25]. In some jurisdictions, the legal use of cannabis was permitted for medical purposes since the 1960s. However, in the 2000s, cannabis became more mainstream and incorporated into modern medicine by popular demand, on a compassionate basis, rather than by typical medicine development. Currently, vast numbers of patients across the globe use cannabis in its crude form, while a smaller number have access pharmaceutical-quality products via health professionals including their doctors and pharmacists. Presently, pharmaceutical-quality cannabis preparations are used to treat chronic pain, cancer symptoms, neurological disorders, and hard-to-treat epilepsy [8, 25-30].

Despite the availability of pharmaceutical-quality preparations, there is a paucity of reliable clinical data. Reflecting this situation, cannabis-based medicines are currently not a first line treatment. Health professionals are concerned about the quality of the medicines, the correct dosing regimens for the condition being treated, and accountability for treatment-related decisions. [31, 32]

The rapidity of the developing regulatory situation often means retrofitting industry activities and clinical use to pharmaceutical medicine requirements.

**The medical market**

Since the 2000s, cannabis materials and products for medical and scientific use are increasingly being made available on a global level. Demand has increased significantly in the past decade.

The cultivation of cannabis for medical purposes is still in its early stages, with many industry players learning to control quality and consistency. Manufacturing of various dose forms and product strengths typically has not coincided with well-constructed formulation studies and clinical research. However, two major administration routes have so far triumphed and prevailed – by the lung (pulmonary absorption) and by the mouth (oro-mucosal or gut absorption). Most products are unapproved medicines.

Prescribing occurs predominantly in pain, in the oncology or palliative care settings, and in neurology and neurological diseases. Prescribing often occurs via special access regulations. There are a variety of strategies used to provide cannabis-based medicines to patients. A prescriber-pharmacy model, as opposed to ‘cannabis dispensaries’ or ‘cannabis clinics’, provides patients with the highest quality of care (i.e. continuity of care and patient co-management). Indeed, patients must engage with a health professional in a meaningful way to avoid medicine misuse and interactions causing harm. [32] Given the medicine is self-funded by most patients, medicine affordability may have implications for a patient’s long term use.

Cannabis-based medicines are relatively safe, however, similar to all medicines, they are not absolutely safe. [33, 34] There are a number of known medicine interactions and contraindications to cannabinoid use which limits the medicines utility. [35] Finally, cannabis-based medicines are liable to misuse, because many contain psychoactive, intoxicating substances.

**The role of the pharmacopeia**

True of most modern societies, much of the inter-generational medico-cultural knowledge was formally adopted by modern medical practice. Many of our prescription medicines were derived from plants and have lineage to...
The pharmacopeia promotes consistency and standards in preparing medicines with certain, defined quality. This means the pharma-industry, compounding pharmacies, dispensaries, and practitioners of Traditional Medicine can access quality materials to produce safe and effective medicines. Our collective responsibility is to build on the knowledge described in pharmacopeia, and apply that in the field of cannabis-derived medicines.

REGULATIONS - GLOBAL PERSPECTIVE

UN drug control conventions
Acknowledging the potential therapeutic utility of Cannabis sativa L. and its active components (the cannabinoids), the broad regulatory framework for the medical and scientific use of Cannabis and Δ9-THC is defined in The Single Convention on Narcotic Drugs, 1961 and The Convention on Psychotropic Substances, 1971.

The UN Conventions enable domestic legislation and require an international shared responsibility to control the production, manufacture, export, import, distribution of, trade in, use and possession of controlled drugs and psychotropic substances exclusively for medical and scientific purposes. International alignment to this framework is essential to international agreements, transitional trade, and the validity of cannabis as a medicine.

Regulations - why we have them
Domestic regulations provide a platform for government institutions, industry, and the health profession to define and manage the risk associated with materials and products containing controlled drugs.

There is some sound reasoning behind controlling drugs. For opioids, a public health misuse pandemic continues to exist. [5, 38-44] People who misuse opioids are at massively increased susceptibility to injury, violence, ill health, communicable disease, and death. [4, 5, 12, 19, 39, 43, 45-53]

Indeed, there is an inherent public health risk with the availability and use of all controlled drugs. This includes cannabis.67 5, 7, 54

Public health and cannabis
The major constituents of cannabis, THC and CBD, while low risk, are not benign. [55-57]

THC is psychoactive, euphoric, and has intoxicating effects.66 [58-62] The long-term negative effects of recreational use of THC are well described in youth, [11, 12, 63-66] but is sparsely described for cannabis-based medicines.

While CBD is psychoactive, it does not have intoxicating effects. [67, 68] There has been a lot of interest and investment in CBD in recent years. The rise in use of CBD products reflects a sharp rise in ‘self-medicating’, and in the use of a range of highly publicised CBD fortified consumer products. The upward trend in use is underscored by the population risk of taking high doses of a drug substance we still know very little about. [33, 67, 69-74] Instances of products inaccurately labelled for CBD, many containing THC, is also cause for concern. [54, 75]

Compounding that public health risk is the current and potential availability of substandard and falsified cannabis-derived medicines and adult-consumer products. Indeed, recently, there has been a lot of talk about the risks of ‘vaping’, their diluent or carrier agents, product contaminants (i.e., heavy metals, pesticides, and microbial content), [76-80], and in particular, reports of ‘vaping-related lung illnesses’ among adult-consumers. [81-84] While in the cannabis medicine space, there are examples of poor quality cultivation, production, and distribution practices which undermine the health sector’s confidence. Importantly, such practices place patients in risky situations, as the end user.

THE ROLE OF ASTM

Public health, safety and confidence
With increasing globalization of commerce and trade (within countries and internationally), and the rising number of companies licensed to work with cannabis, the importance of standards, practices, guideline or norms has never been greater.

Well-considered and appropriately applied regulations is key to a highly functioning industry. Materials and products should be produced to an acceptable quality, without imposing an unnecessary compliance cost burden on cultivators, manufacturers, distributors, and auxiliary sectors.

To overcome the chaos caused by variability, global harmonization of standards and practices is required. These would allow governments and regulators to develop legislation to ensure a safe supply of cannabis derived materials and products to adult-consumers and patients.

Recommendation
ASTM International is committed to serving global societal needs – to positively impact public health and safety, consumer confidence, and overall quality of life. For cannabis, regardless of if for adult consumers or patient medical use, ASTM’s mission is a priority. In response, the ASTM D37 cannabis committee has established a robust environment for the co-development of standards and practices.

This article is a call to action to join Committee D37 in advancing the development of cannabis standards. We invite industry, regulators, scientists, policy and lawmakers, adult consumers, and patient advocates to the table. The development of much needed standards specific for adult-consumer products and for medicines achieves a common goal:

- to improve cannabis-derived materials, products, and service quality,
- to enhance public health and safety,
- to strengthen market access and trade (in science and medicine), and
- to protect adult consumers and patients.

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