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Feasibility of Revising the Quality Standard for Δ9-Tetrahydrocannabinol Content in Cannabis Inflorescence within Thai Herbal Pharmacopoeia

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Abstract: Cannabis (*Cannabis sativa* L.) is a plant that is widely cultivated in Thailand. It has been used for both traditional and contemporary medical conditions. Referencing the THP 2021, the standard for cannabis inflorescence in Thailand requires a minimum 1% w/w THC content. The lack of an upper THC limit risks high-potency cannabis inflorescence entering the supply chain. Compounding requires dose adjustment, but allowing high-THC batches, which are often unnecessary, exacerbates prescriber workload and amplifies the consequences of any dosing mistake. Establishing an upper THC limit for cannabis inflorescence is therefore crucial. Thus, the authors conducted an integrated review with policy recommendation to support this concept. The review utilized data sourced from Google Scholar and reliable information obtained from governmental agencies. Based on this study, both safety and efficacy data indicate that cannabis inflorescence as a raw material with low THC content is sufficient for treating patients with Thai landraces providing sufficient potency. This contrasts with most hybrid strains, which contain THC levels deemed excessive. Therefore, the authors propose that appropriate use of cannabis inflorescence can be achieved by setting THC criteria to reflect the range found in Thai cannabis strains (e.g., 1-12% w/w) exclusively for the production of Thai Traditional Drugs originating from ancient medical texts, thus aligning with Thai Traditional Medicine wisdom. Conversely, the original criteria should apply to inflorescence used in the manufacture of other products. These preventive measures constitute a patient right and align with the legal status of cannabis inflorescence as a controlled herb in Thailand.

Keywords*:* Cannabis inflorescence, *Cannabis sativa* L., Thai cannabis strains, Thai Herbal Pharmacopoeia, Thai Traditional Drugs, Δ9-tetrahydrocannabinol

ABBREVIATIONS

CBD - cannabidiol
RD1 - Tanao Si Kan Dang
ST1- Hang Kra Rog Phu Phan
THC - Δ9-tetrahydrocannabinol
THP - Thai Herbal Pharmacopoeia
TTDKP - Thai Traditional Drugs derived from the existing knowledge of Thai Traditional Medicine practitioners
TTDOA - Thai Traditional Drugs originating from ancient medical texts
TT1 - Hang Suea Sakonnakhon
WA1 - Tanao Si Kan Khaw
11-OH-THC - 11-hydroxy-tetrahydrocannabinol

INTRODUCTION

As of October 25, 2025 cannabis remains a controlled substance under international drug conventions. Nevertheless, many countries have gradually relaxed their regulations to facilitate the use of cannabis in medical applications. This global shift has prompted regulatory bodies across the Americas, Europe, and Asia to establish comprehensive quality specifications for cannabis raw materials and finished products. These standards predominantly focus on the inflorescence (flower bud), as this part contains significantly higher concentrations of the major active compounds, namely Δ9-tetrahydrocannabinol (THC) and cannabidiol (CBD), compared to other plant parts. Consequently, quality control necessitates rigorous testing to ensure that the content of these cannabinoids meets the established regulatory thresholds.

In line with the approach of conventional medicine, the focus is placed on the mechanisms of disease treatment. Cannabis's therapeutic mechanism is associated with the binding of its active compounds to cannabinoid receptors in the human body. Consequently, treatment efficacy relies on the specific quantities of THC and CBD administered to the patient, with varying proportions of these two compounds required for different disease states. This concept has been adopted for the quality control of cannabis inflorescence.

For instance, the Herbal Medicines Compendium (HMC) defines quality standards across three chemotype groups: THC-dominant chemotype, CBD-dominant chemotype, and THC/CBD intermediate (1). It specifies appropriate ratios of THC and CBD and sets minimum thresholds. For the THC-dominant chemotype, the ratio of total THC to total CBD must be no less than 5:1, and the THC content must be no less than 10 mg/g, while the CBD content must be no more than 10 mg/g. Furthermore, it mandates that the active compounds, when expressed as a percentage of the labeled amount, must fall within 90% to 110%, mirroring the practice of stating active ingredient quantities on product labels. Similarly, the European Pharmacopoeia (Ph. Eur.) controls the quality standards for cannabis inflorescence in a comparable manner, also dividing them into three types (2). The Ph. Eur. sets minimum thresholds for active compounds and a percentage labeled amount (90-110%), but without specifying a ratio. For example, the THC-dominant type must contain no less than 5% w/w of THC and no more than 1% w/w of CBD, while maintaining the 90-110% labeled amount requirement.

In Thailand, referencing the Thai Herbal Pharmacopoeia (THP) 2021, the standard for cannabis inflorescence mandates a minimum THC content of 1% w/w (3). It is observed that this requirement differs from the specifications set by the HMC and Ph. Eur. This divergence is attributable to several reasons. For example, international cannabis utilization is strictly aligned with modern medical guidelines, meaning cannabis inflorescence may be extracted into oils or extracts for oral administration, or consumed directly via inhalation using vaporizers. Consequently, setting a clear percentage labeled amount of the active ingredient is essential to ensure precise patient dosing.

Thailand also employs cannabis in the form of extracts and oils, with corresponding standardized requirements already established within the THP. However, in the context of Thailand, cannabis inflorescence is primarily intended not as a direct end-product but as a raw material for manufacturing herbal products, such as developed herbal drugs or Thai Traditional Drugs originating from ancient medical texts (TTDOA) (e.g., Ya Thamlai Phra Sumen) or Thai Traditional Drugs derived from the existing knowledge of Thai Traditional Medicine practitioners (TTDKP) (e.g., Ganja Oil (Mor Decha's formula)). Therefore, the core objective of the cannabis inflorescence standard within the THP is primarily the control of raw material quality, which accounts for the differentiation from the specifications established by HMC and Ph. Eur (Figure 1).

While establishing the minimum content of active ingredients is a fundamental approach for determining the chemical quality of herbal raw materials in THP, cannabis possesses unique characteristics that differentiate it from other herbal raw materials listed in the THP. Specifically, in addition to its therapeutic properties, THC is a psychoactive narcotic substance that has been reported to cause various adverse health effects when used in

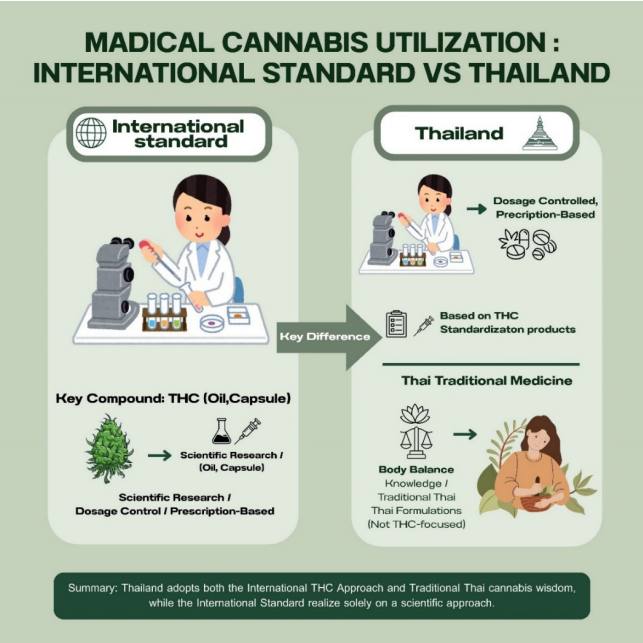

Figure 1. Overview of medical cannabis utilization in Thailand showing the major application pathways (modern medicine vs. Thai Traditional Medicine) and the associated THC control points in production. (Abbreviation: THC = Δ9-tetrahydrocannabinol)

inappropriate doses. These adverse effects include the potential to cause severe neuropsychiatric symptoms or association with impaired cognitive function, requiring caution against prescription to vulnerable populations such as children and adolescents (4,5).

Consequently, in Thailand, although cannabis inflorescence is no longer classified as a narcotic drug, it remains designated as a controlled herb under the Protection and Promotion of Thai Traditional Medical Knowledge Act B.E. 2542. Current regulations have implemented restrictions on its use in recreational settings and commercial shops. Thus, for its integration into medical practice, specific and concrete measures must be appropriately implemented. This approach is essential to promote the sustainable use of cannabis inflorescence in medicine, aligning with the intent and spirit of the aforementioned Act.

Therefore, the researchers are motivated to conduct a comprehensive literature review from various perspectives to evaluate the appropriateness of the standard specifications for cannabis inflorescence concerning THC content. The goal is to propose a conceptual framework supported by this evidence, thereby benefiting all stakeholders across the cannabis sector.

CANNABIS STRAINS IN THAILAND

Thailand features numerous cannabis strains registered with the Department of Agriculture, currently totaling 90 strains. These consist of pure Thai strains (subdivided into native Thai landraces and improved Thai strains) and hybrid strains resulting from cross-breeding Thai and foreign cultivars. Four strains have been definitively reported as native Thai landraces: Hang Suea Sakonnakhon (TT1) (THC-dominant), Tanao Si Kan Khaw (WA1) (THC-dominant), Hang Kra Rog Phu Phan (ST1) (THC:CBD ratio of 1:1), and Tanao Si Kan Dang (RD1) (CBD-dominant) (6). The THC content range for TT1 and WA1 is reported as 3-10% w/w of the dried inflorescence weight. ST1 shows a THC range of 4-8% w/w, and RD1 exhibits a THC range of 4-5% w/w. Therefore, overall, the Thai native cannabis landraces demonstrate a THC content range of 3-10% w/w. This aligns with historical reports analyzing 'Thai Sticks' samples in the United States between 1980 and 1995, which indicated a THC range of 3-6% w/w (7, 8). This consistency suggests that the THC levels in native Thai strains remain within a comparable range when cultivated in Thailand, despite an approximate 45-year gap.

There is data suggesting that the native Thai cannabis landraces can contain up to 49% w/w of THC. However, this value is inconsistent with the samples used for method validation within that specific study and contradicts findings from other academic literature. Furthermore, there is ambiguity regarding whether this value refers to the dry weight of the inflorescence or an extract. This uncertainty is critical, as simply summing the THC and CBD content in some samples yields a weight exceeding 90% of the inflorescence dry weight, which is a chemically impossible value. Consequently, the data from that particular study were not utilized in this study (9).

The improved Thai cannabis strains include those that were developed 20-25 years ago, such as Issara01 (which has a THC:CBD ratio of 1:1 in its leaves), though the THC content in its inflorescence is unreported; KD (THC-dominant), with inflorescence THC ranging from 8-9% w/w; and Keaw Phangan (THC-dominant), with inflorescence THC at 7-8% w/w. Recently improved strains that are THC-dominant include KKU01, with inflorescence THC at 5.8-7.5% w/w; the Suranaree strains, ranging from 8-12% w/w (excluding Suranaree 3 and 4); and the Petch Chomphoo strains, with THC at 1-3% w/w (excluding Petch Chomphoo 4). Furthermore, strains with a THC:CBD ratio of 1:1, such as Som Dun Suk Sor Thor Nor 10-02, demonstrate inflorescence THC content of 2-4% w/w. Overall, the THC content range for the improved Thai cannabis strains is generally between 1-12% w/w (6), a value that does not differ substantially from that observed in the native Thai landraces.

A notable observation concerns the heterozygosity of cannabis, specifically by comparing data for the tetrahydrocannabinolic acid synthase (*thcas*) and cannabidiolic acid synthase (*cbdas*) genes across various cannabis strains. Strain ST1 is reported to exhibit relatively low heterozygosity, suggesting correspondingly low genetic variability in its offspring (6). However, this value is not extremely low; thus, there is still potential for genetic variation in these two genes among the progeny, which allows for changes in the chemical expression profile of THC and CBD production. This observation is consistent with findings in several studies: although the original ST1 strain is characterized by a 1:1 THC:CBD ratio (a characteristic matching its registration with the Department of Agriculture, and supported by whole genome studies showing close proximity to the CBD Shark strain) (10), research has also found cannabis plants hypothesized to be ST1 exhibiting dominant THC levels and low CBD content (11, 12). Nevertheless, the THC content falls within the range of 4-12% w/w, which is not considered ultra-high and remains consistent with the levels typically observed in Thai cannabis strains.

Another interesting cannabis strain, likely classified as the native Thai landraces but unregistered with the Department of Agriculture, is Foi Thong Phupayol. Although there is no definitive report on its THC content, it is presumed to be the THC-dominant strain because it was used in the development of the Suranaree strains. Furthermore, although current data on the strain's heterozygosity are unavailable, it is hypothesized to be relatively high. This expectation stems from information regarding the development of Suranaree 4, which clearly indicates strain improvement utilizing Foi Thong Phupayol individuals that exhibited phenotypic and photoperiodic responses distinct from the majority of the parent Foi Thong Phupayol population. This mutant also contains a high THC content of up to 18% w/w (6). In the context of traditional Thai medicine, plants deviating phenotypically from the general population are typically excluded from drug preparations, as they are likely considered raw materials with incomplete medicinal properties. Consequently, this is the reason the authors exclude the THC content data for Foi Thong Phupayol and Suranaree 4 from the established THC ranges for the native Thai landraces and the improved Thai strains, respectively.

Regarding the hybrid cannabis strains registered with the Department of Agriculture, only a minority (around 15%) possess THC content in the range of 10-15% w/w. However, the majority exhibit significantly higher THC levels than the Thai native strains, often containing trace or non-detectable amounts of CBD. The highest THC strain cultivated in a closed indoor system is Permanent Lemonade, which reaches 32% w/w THC. This potency is 3-10 times greater than that of the native Thai landraces. Furthermore, strains suitable for cultivation in a greenhouse system include

Skunk-derived hybrids such as Sunset Master and Rainbow Zkittle, which can achieve up to 30% w/w THC. For strains grown outdoors or utilizing a one-sided greenhouse, Binturong Super OGK strain demonstrates high THC content, reaching up to 32% w/w (6). These findings are consistent with international research, which historically utilized native Thai cannabis strains for breeding program to elevate THC concentrations for both medical and recreational applications abroad, with reports indicating that modern high-potency cannabis inflorescence can achieve THC levels as high as 39% w/w (13).

Although the domestic and international markets for ultra-high THC cannabis strains may not primarily target their application in TTDOA, there are currently no explicit regulations prohibiting their use. This regulatory gap poses a risk that such cannabis raw materials could be diverted for purposes contrary to their original intent. Furthermore, this diversion may cause adverse effects in patients receiving herbal products categorized as TTDOA.

APPLICATION OF CANNABIS INFLORESCENCE IN TTDOA

The Thai Traditional Drug Formulary lists 162 medicinal formulas containing cannabis. However, only a subset of these is currently supported for clinical use by the Department of Thai Traditional and Alternative Medicine (14). These formulas incorporate cannabis in widely varying proportions. For instance, Ya Akkhiniwakana includes cannabis at a ratio of 1 part out of 27 total parts, whereas Ya Ammarit Osod contains cannabis at a significantly higher proportion of 10 parts out of 76 total parts. Consequently, when considering the aspect of daily dosage amount, formulations containing a greater proportion of cannabis and requiring a larger daily intake would lead to higher patient exposure to THC compared to other prescriptions. Nevertheless, the total duration of therapeutic use must also be taken into account.

Upon reviewing TTDOA currently supported for use, it was found that TTDOA containing cannabis inflorescence in large quantities belong to the wind-relieving drug group (Ya Kae Lom), such as Ya Phaisalee. This particular formula contains cannabis inflorescence at a proportion of 450 g out of a total weight of 1,820.63 g. Assuming a patient receives a daily dose of 6 g of the remedy, the corresponding daily intake of cannabis inflorescence is 1.48 g. Calculating the potential THC dosage (based on the inflorescence content) reveals that if TT1 and WA1 are used as raw material, the patient's daily THC exposure would be 44.4-148.0 mg/day. If ST1 is used as raw material, the patient would receive 59.2-118.4 mg/day of THC. And if the RD1 is used, the patient would receive 59.2-74.0 mg/day of THC. However, should a high-potency hybrid cannabis strain be utilized, the patient's THC exposure could reach as high as 473.6 mg/day.

Conversely, Ya Ammarit Osod contains cannabis inflorescence at a proportion of 10 parts out of 76 total parts. If a patient receives a daily dose of 4 g of the remedy, the resulting daily intake of cannabis inflorescence is 0.53 g. Calculating the potential THC dosage, if TT1 and WA1 are used as raw material, the patient's daily THC exposure would be 15.9-53.0 mg/day. If ST1 is used as raw material, the patient would receive 21.1-42.4 mg/day of THC. Furthermore, if the RD1 is used, the patient would receive 21.1-26.5 mg/day of THC. However, should a high-potency hybrid cannabis strain be utilized, the patient's THC exposure could reach as high as 169.6 mg/day.

As for Ya Kae Lom Naow Nari Wayo, the formula contains cannabis inflorescence at a proportion of 1 part out of 12 total parts. Given a patient's daily dose of 4 g of the remedy, the resulting intake of cannabis inflorescence is 0.33 g. Calculating the potential THC dosage reveals that if TT1 and WA1 are used as raw material, the patient's daily THC exposure would be 9.9-33.0 mg/day. If ST1 is used as raw material, the patient would receive 13.2-26.4 mg/day of THC. And if the RD1 is used, the patient would receive 13.2-16.5 mg/day of THC. However, should a high-potency hybrid cannabis strain be utilized, the patient's THC exposure could reach as high as 105.6 mg/day.

Although these products are formulated as TTDOA containing multiple herbal ingredients, and the compounding process relies on the principle of medicinal tastes where certain herbs either potentiate or mitigate the toxicity of others, historical Thai

formulas exclusively used the native Thai cannabis landraces. Consequently, there is no clear evidence detailing how the use of high-THC hybrid cannabis strains will impact the final compounded preparation. More importantly, the effect on patients remains unknown if the dosage is not accurately adjusted to account for the significantly increased THC concentration.

THC SAFETY

The rate at which THC affects the body, along with the duration of its effects, is highly dependent on the route of administration. This discussion focuses specifically on oral ingestion, which aligns with the administration method used in TTDOA. Generally, the oral route is characterized by the slowest onset of effect but results in the longest duration of action. Despite this traditional use, there is currently no clear evidence regarding the potential adverse effects on patients when utilizing modern high-potency THC cannabis strains in these traditional formulations (15). Therefore, the research is required in related areas, such as pharmacodynamics (studying the effects of THC on the body) and pharmacokinetics (including parameters like bioavailability, C_{max}, T_{max}, and $T_{1/2}$). However, systematic studies evaluating these crucial pharmacokinetic and pharmacodynamic parameters are currently lacking. It consists primarily data for THC derived from consumption via products other than TTDOA (16). Furthermore, predictive pharmacokinetic calculations of THC have only been performed using computational (in silico) models within an Ayurawattana traditional formulation, which did not model the ingestion of the complete remedy (17).

In the absence of definitive pharmacokinetic and pharmacodynamic studies clearly defining the profile and side effects of THC administered via various TTDOA, it remains pragmatically feasible to adopt the established oral dosage limit for synthetic THC (dronabinol)-specifically, not exceeding 20 mg/day-as a temporary safety threshold to prevent severe neuropsychiatric adverse effects (18). However, an exception must be made for certain traditional prescriptions, such as Ya Phaisalee, which contain a high proportion of cannabis, where traditional medical knowledge suggests a necessary THC intake exceeding this threshold (as patients may still receive a minimum of 44.4 mg/day of THC even when using the native Thai cannabis landraces). Definitive safety limits can only be established once clear research data are available.

The consideration presented in the previous paragraph focused on the scenario where TTDOA uses cannabis strains containing THC alone or those that are highly THC-dominant (such as TT1, WA1, and hybrid strains). This scope is incomplete because some native Thai cannabis landraces, such as ST1, also contain a significant amount of CBD, resulting in an approximate THC:CBD ratio of 1:1. Scientific data suggests that CBD, when administered in appropriate amounts, can attenuate the psychoactive effects of THC through the proposed entourage effect (19). Therefore, discussing the safety of THC derived from cannabis strains high in both THC and CBD without considering the influence of CBD is scientifically unwarranted. Nevertheless, given the continued lack of systematic pharmacokinetic and pharmacodynamic research studies concerning THC administered alongside CBD in TTDOA, adopting the established oromucosal spray dosage limit for nabiximols (THC:CBD = 1:1), typically set at not more than 30 mg/day, remains a practical approach as a temporary safety threshold.

Furthermore, it has been reported that the administration of nabiximols, reaching THC doses up to 113 mg/day, has demonstrated overall good tolerability in patients with cannabis use disorder (20). Consequently, should the ST1 cannabis strain be incorporated into TTDOA, there is an indication that a high proportion of the cannabis inflorescence could potentially be utilized, allowing THC-tolerant patients to receive up to 113 mg/day of THC from the traditional remedy. This projected dosage aligns closely with documented usage in the Ya Phaisalee formulation, where patients may receive up to 118 mg/day of THC.

However, the administration of THC via nabiximols oromucosal spray is pharmacokinetically distinct from the oral ingestion of TTDOA. Generally, oromucosal delivery allows THC to be absorbed rapidly into the systemic circulation via the buccal vasculature, largely bypassing hepatic first-pass metabolism. This results

in a faster onset of action but a shorter overall duration of effect. Systemically available THC is subsequently metabolized in the liver to 11-hydroxy-tetrahydrocannabinol (11-OH-THC), a more potent psychoactive metabolite, and finally to the inactive 11-nor-9-carboxy-THC (THC-COOH), ready for elimination (often as a glucuronide conjugate). Conversely, oral ingestion results in slow and often erratic absorption through the gastrointestinal tract, subjecting the THC to extensive first-pass metabolism in the liver. This metabolic process gradually generates 11-OH-THC in the circulation, which contributes to the prolonged somatic effects experienced by patients receiving oral administration (21).

Consequently, the side effect profile stemming from TTDOA (such as one containing the ST1 strain) may differ slightly from that of nabiximols, warranting meticulous safety monitoring. Furthermore, it should be noted that the pharmacokinetics of THC following oral administration are inherently unpredictable, contingent upon the specific excipients present within the formulation (22).

From another perspective, the THC dosage of 113 mg/day is nearly six times higher than the maximum dose typically prescribed for dronabinol. This observation might suggest that the use of an inflorescence product containing a THC:CBD ratio of 1:1 allows for a significantly higher daily THC intake compared to THC monotherapy. However, such a conclusion must be approached with considerable caution and noted as speculative, primarily because the route of administration via oromucosal spray (nabiximols) is pharmacokinetically distinct from oral ingestion (dronabinol), as elaborated in the preceding discussion. Consequently, comparing nabiximols which differs significantly from dronabinol in both delivery method and active ingredient composition makes it difficult to definitively conclude which product would elicit more pronounced cerebral effects or somatic effects, even when administering equivalent THC doses.

The native Thai cannabis landraces RD1, which exhibits high CBD content with a THC:CBD ratio of 1:5, is generally considered the most promising and potentially safest raw material for use in TTDOA. Nevertheless, the Guidance on Cannabis for Medical Use (6th Edition, 2024) continues to rely on data derived from nabiximols, establishing the safety limit for THC consumption at not more than 30 mg/day (23). Definitive research is currently lacking to clarify the safety profile of products specifically at a THC:CBD ratio of 1:5. Therefore, it is more appropriate to adhere to a foundational safety threshold centered on THC quantity to prevent severe toxicity than solely relying on the potential risk mitigation offered by the elevated CBD ratio. However, a higher CBD ratio is not universally advantageous; some research suggests that an excessive amount of CBD administered alongside THC (for instance, 640 mg CBD with 20 mg THC) may exacerbate cerebral effects, potentially because high CBD concentrations inhibit the degradation of 11-OH-THC (24).

An additional approach that can contribute to the safety profile is the implementation of real-world evidence generation through systematic data collection by Thai Traditional Medicine practitioners. If the administered THC dosage received by patients is accurately documented, this data would provide valuable information to develop critical scientific knowledge for future advancements.

Based on current safety data, it is not possible to definitively conclude the precise safe dose limit of THC contained within various TTDOA. Consequently, establishing the appropriate range of THC content in cannabis inflorescence for use in TTDOA is challenging, owing to the lack of directly supporting research. Nevertheless, the utilization of native Thai cannabis inflorescence strains according to the principles of Thai Traditional Medicine is considered to possess an inherent degree of safety. Furthermore, scientific evidence correlates with Thai Traditional Medicine principles, supporting the safe incorporation of the ST1 cannabis strain as a raw material for TTDOA production.

THC EFFICACY

The consideration of the efficacy of cannabis-containing products allows us to determine the range of THC dosages used to treat various diseases, without necessarily requiring the maximum tolerable dose. The aforementioned TTDOA are traditionally used for

the wind-relieving. The TTDOA containing large amounts of cannabis inflorescence belong to the Kae Lom Kong Yaap (Coarse Wind Relief) group of medicines, such as Ya Phaisalee, Ya Ammarit Osod, and Ya Kae Lom Naow Nari Wayo. However, there are currently no efficacy studies on these specific formulas. Conversely, there has been a study on Ya Kae Lom Kae Sen, which is a TTDOA utilizing cannabis leaves as its raw material. Although this doesn't directly address the cannabis inflorescence issue, it is highly similar and extremely valuable for comparative study. Furthermore, efficacy studies of TTDKP used to treat conventional medical conditions are equally important for comparison, exemplified by seven case studies involving different cannabis oil formulations where the daily THC dosage received by the patients is specified.

TTDOA containing cannabis generally employ products with fixed, standardized formulas and common administration methods, similar to other herbal products included in the National List of Essential Herbal Medicines. However, it is known that THC may cause severe side effects in patients. Therefore, in clinical practice, if medication is used continuously for a long period or if the formula contains a large quantity of cannabis, Thai traditional practitioners can adjust the dosage to suit each individual patient. This is done by starting with a relatively low amount of THC, setting an initial dose, and gradually increasing it based on the patient's response.

The research used the Kae Lom Kae Sen remedy, which is a powder composed of seven herbs, including cannabis leaves, encapsulated in 500 mg capsules. This formulation contained 0.156% w/w THC. Patients were administered a fixed dose of four capsules per day, resulting in a daily intake of approximately 3.1 mg of THC. The use of this dosage demonstrated significantly better efficacy than a placebo in relieving upper back muscle pain and increasing the range of motion of the muscles starting from the beginning of the treatment. It also showed a high safety profile, with minor and non-severe adverse effects reported such as dry mouth/throat and drowsiness (25).

TTDKP, which are researched for contemporary medical conditions, also employ dosage adjustment starting with low THC amounts. For example, the study on Golden Turmeric Cannabis Oil (THC-dominant), used to treat chronic rhinitis, contains 2.3 mg/ml of THC. Patients were instructed to start with 2 drops before bedtime, and the physician could adjust the dose according to the patient's symptoms. This resulted in a daily THC dose range of approximately 0.3 to 0.9 mg/day. The use of this low dosage proved safe and significantly helped reduce nasal and eye symptoms, as well as patient sleep problems and overall quality of life (26).

In patients with dementia exhibiting Behavioral and Psychological Symptoms of Dementia (BPSD), a study utilized GPO THC-dominant cannabis oil (0.5 mg/drop). The study protocol involved a plan to escalate the dosage from an initial 5 mg/day up to a maximum dose of 15 mg/day to treat the behavioral symptoms. Although the participants who completed the entire study period actually received a consistent dose of 5 mg of THC per day, this treatment demonstrated a promising trend in reducing the severity of BPSD symptoms and decreasing the burden experienced by caregivers, with no severe adverse events reported (27).

Case studies involving advanced and end-stage cancer patients revealed key dosage information. The use of GPO THC-dominant cannabis oil in advanced stage cancer patients found that the actual daily THC dosage received ranged from 0.5 to 5 mg/day, with a median dosage of 1 mg/day. This low dosage was determined to be safe and effective in helping patients sleep better, reducing pain, and increasing appetite well (28). Additionally, a study on end-stage cancer patients using GPOCE THC:CBD 1:1 (2.7 mg THC per 0.1 mL) at Lampang Cancer Hospital found that patients received an average of only 1-2 drops of THC per day (0.5 mg to 2 mg/day), yielding significantly reduced pain symptoms and increased quality of life (29). In both research studies, patients experienced few and non-severe adverse effects, such as dry mouth/throat, nausea, dizziness, and drowsiness.

In patients with Parkinson's disease, the GPOCE THC:CBD 1:1 formulation was used. Patients received medication in doses ranging from 2 to 5 drops per day, or approximately 2.7 to 6.7 mg of THC per day. The average usage increased to 4 drops per day by the end of 6 months. This low dosage was safe and showed a tendency to reduce the symptoms and severity of the disease, as well as improving sleep quality (30).

In patients with Multiple Sclerosis (MS), the GPOCE THC:CBD 1:1 formulation was used to treat spasticity. The dosage adjustment plan started at 0.1 mL per day in the first week, which is equivalent to 2.7 mg of THC, and increased to 0.1 mL twice a day in the second week, which is equivalent to 5.4 mg of THC per day. The maximum allowable dosage that could be adjusted was 1 mL per day, equivalent to 27 mg of THC. The study found that the product was useful in significantly reducing the severity level of spasticity. However, one patient experienced a serious adverse event, which was definitively diagnosed as hyperemesis syndrome. The patient developed these symptoms at 24 weeks after treatment initiation and had to be withdrawn from the study (31).

Patients with systemic sclerosis used sublingual cannabis oil with a THC:CBD 1:1 ratio, containing 27 mg of THC (a product prepared specifically for research). The patients in the treatment group received a maximum THC dosage of up to 2.92 mg/day. It was found that the cannabis oil significantly increased the level of hunger sensation (The VAS score for hunger) in the group receiving the medication compared to before treatment. Furthermore, the daily calorie intake per kg body weight also significantly increased in the treatment group. Most side effects were not severe (drowsiness, dizziness), but one patient in the treatment group developed severe hyponatremia after receiving only 1 drop of cannabis oil and had to be withdrawn from the study (32).

Although the sample sizes in these efficacy studies are typically small, comparing data from cannabis products used for Thai Traditional Medicine ailments with those used for modern medical conditions provides crucial context. This context helps determine the appropriate THC dosage whether small or large as it depends on the patient's specific disease and the product formulation (e.g., containing only THC or including other key compounds like CBD). Therefore, it is extremely necessary to conduct efficacy studies on other Thai traditional formulas to determine the appropriate THC dosage used. However, based on the cited research studies, low doses of THC (0.3-5.0 mg/day for THC-dominant products and 0.5-6.7 mg/day for THC:CBD 1:1 products) generally yield therapeutic efficacy. Only the research in MS patients may involve the use of THC as high as 27 mg/day.

Therefore, when considering the efficacy data alongside information on the use of cannabis inflorescence in Thai traditional formulas that utilize large quantities of cannabis, and safety data, it is found that using the native Thai cannabis landraces as raw material results in the THC quantity in Ya Ammarit Osod and Ya Kae Lom Naow Nari Wayo being within a range that is not excessively high and is sufficiently comprehensive for treatment. Thus, there is no need to use hybrid cannabis strains as raw material in the production of TTDOA. Ya Phaisalee, however, is an interesting formula because even though the native Thai cannabis landraces are used as raw material, patients still receive a high amount of THC. Therefore, it is highly necessary to conduct research into why ancient medicinal texts permitted the use of Ya Phaisalee, as its inclusion indicates that this formula can be safely used to a certain extent.

RECOMMENDATIONS FOR THE APPROPRIATE USE OF CANNABIS INFLORESCENCE

Based on the information presented, the authors propose a recommendation for the appropriate use of cannabis inflorescence: establishing a THC content range in cannabis inflorescence used specifically as raw material for TTDOA, supplementing the existing criteria stipulated in THP. The original criteria should apply to inflorescence used for manufacturing other products. Based on all the previously mentioned data, it is recommended that the raw inflorescence for TTDOA should contain THC in the range of 3-10% w/w. The main reason is the consistently reported THC content in native Thai cannabis landraces (3-10% w/w). Although some research reports as low as 0.1% w/w, this should be considered an outlier because the value is significantly lower and differs too much from the majority of values (33). While Thai Traditional Medicine considers the taste/flavor of the medicine, it

cannot be denied that THC is a key active ingredient. While citizens have the right to cultivate and use it for self-treatment, in cases where medical personnel use it for treatment, the raw material must be suitable for drug preparation. Other reasons include safety and efficacy data which demonstrate that using cannabis inflorescence with moderately low THC content is sufficient for patient treatment.

Setting standards in THP is intended for the quality control of cannabis inflorescence used as raw material in various products, with the underlying data collected from at least 12 sources nationwide to ensure suitability for actual production practices. The eventual use of the product, however, rests with the Thai Traditional Medicine practitioners. Therefore, another viable approach is to maintain the existing criteria in the THP (setting only a minimum threshold without defining a THC concentration range in cannabis inflorescence) but mandate the use of only the native Thai cannabis landraces as raw material for TTDOA. This could be issued through an official announcement by a relevant body, such as the Ministry of Public Health. This method offers the benefit of utilizing raw materials most closely aligned with those historically used. In addition to honoring traditional wisdom, it helps circumvent complications related to the complex composition of the raw material. This complexity arises because not only THC and CBD influence efficacy and side effects on the body, but also other compounds found in the cannabis inflorescence, such as tetrahydrocannabivarin, limonene, myrcene, and other terpenes, which are reported to further affect the action of THC (19). Practically, quantifying all key active ingredients in the final product is currently infeasible, as it would significantly increase production costs, thereby impacting the overall utilization cycle of herbal products.

However, if flexibility is desired in the two aforementioned approaches, the criteria may be relaxed. That is, in the first case, THC data on improved Thai cannabis strains may be used jointly. Thus, the cannabis inflorescence raw material for TTDOA will require a THC content in the range of 1-12% w/w. Another potential scenario involves the adoption of a combined criterion. Specifically, materials designated for TTDOA may be sourced from either strains exhibiting a THC content ranging from 1-12% w/w or the native Thai cannabis landraces. This approach deliberately avoids using a criterion that would permit the use of any Thai cannabis strain, a decision made in recognition of the historical significance of the TTDOA, where traditionally, only native Thai cannabis landraces were utilized as raw materials.

Whether establishing a THC range or mandating the use of the native Thai cannabis landraces, both approaches involve selecting raw materials that are closest to the original. The resultant benefits include promoting the widespread use of cannabis inflorescence while maintaining safety control at the source. Furthermore, this does not constitute a trade barrier, as the criteria are specified exclusively for TTDOA. It is true that dispensing by adjusting the appropriate ratio of THC in the product is a measure to mitigate the risk of patients receiving unnecessarily high amounts of THC from the formulation. However, it must be acknowledged that if the THC content varies excessively among different production batches, it significantly increases the burden on the prescriber, who must rely on detailed dose titration. Moreover, if an error occurs involving a product with very high THC content, the consequences will be more severe. Additionally, this variability causes confusion regarding medication use among patients. Therefore, the authors emphasize that implementing these preventive measures supports patients' rights and is highly appropriate.

The concept from this work can also be applied to cannabis leaf raw material for TTDOA. According to THP 2021 Supplement 2022, the standard requirement for cannabis leaves is a THC content of not less than 0.2% w/w (34). Therefore, there may be a risk if hybrid cannabis strains are used, as cannabis plants with very high THC content in the inflorescence tend to have the same in their leaves. This is especially true for formulations containing a large proportion of cannabis leaves, such as Ya Prasakancha, which is included in the National List of Essential Herbal Medicines 2023 (35). In practice, special caution must be taken regarding the cannabis strain used as raw material. Thus, increasing preventive measures is one way to support the sensible use of raw materials.

OTHER RELATED TOPICS OF INTEREST

The specifications within the THP generally apply to raw materials used in the manufacture of GMP compliant herbal products. However, certain products, such as individually compounded Thai Traditional Medicines, are currently exempted from controlling raw material quality strictly according to THP requirements. Furthermore, while there are currently two relevant ministerial notifications governing customized compounding of herbal products in this area namely, the Ministry of Public Health Notification on the criteria, procedures, and conditions for compounding traditional Thai medicine for specific patients, and the Thailand guidelines on Good Agricultural and Collection Practices (GACP) for medical cannabis plants. None of these documents mandate the labeling or specification of THC content in cannabis raw materials or cannabis containing herbal products (36, 37).

Given the above, the quantification of THC in cannabis raw materials is clearly important. The authors suggest that, to maximize benefits for both clinical treatment and research development, cannabis raw materials or cannabis containing herbal products involved in customized compounding should be required to specify their THC content. This quantification could practically be achieved by employing lower-cost yet highly accurate techniques, such as Thin Layer Chromatography (TLC) coupled with Image Analysis (38). This technique facilitates high-throughput analysis, offers rapid results, and can be implemented readily in standard chemical laboratories within educational or private institutions without requiring extensive investment, when it is compared to HPLC-UV. Additionally, it is advisable to develop a standardized, dedicated application to replace generic Image Analysis software for accurately measuring the band intensity on TLC plates.

In the case of customized compounding, many Thai Traditional Medicine practitioners do not compound medicine for dispensing immediately after patient examination, due to limitations in service time. Therefore, medicines are often prepared in advance. Although the quality of these pre-prepared medicines is controlled according to Thai Traditional Medicine standards, the scrutiny is far less strict than that of GMP (39). Thus, finally, regarding herbal products obtained from customized compounding, the authors would like to present the case study of the New England Compounding Center (NECC), a compounding facility in the United States, which violated regulations related to compounding facilities, leading to patients contracting fungal meningitis and resulting in 64 deaths (40). Although cannabis inflorescence with very high THC content in compounded Thai Traditional Medicine recipes are likely to cause fewer side effects for patients than this case study, raising this case study effectively reflects the principles and rationale behind customized compounding.

CONCLUSION

This article integrates knowledge across various disciplines, including Laws and Regulations, Pharmacy, Plant Sciences, and Thai Traditional Medicine, to establish appropriate criteria for the use of cannabis inflorescence within TTDOA. The proposed combined criterion specifies that materials designated for TTDOA may be sourced from either strains exhibiting a THC content ranging from 1-12% or the native Thai cannabis landraces. However, the original criteria should remain applicable to inflorescence utilized for manufacturing other products. This is done to ensure compliance with the intent of cannabis's designation as a controlled herb, serving as a preventive measure that finally enhances the safety of medical cannabis use in Thailand.

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