



## CLOSE UP: Healthcare

# Japan's Cannabis Law Reforms: Unlocking Medical Potential and Industry Growth

### Key Takeaways

- The recent cannabis reforms permit medical use, laying the groundwork for patient access to approved cannabis-derived medicines.
- A tiered licensing system for industrial and medical cannabis cultivation will be introduced.
- Opportunities are emerging in the market for approved cannabis-derived medicines; however, strict THC\* compliance presents challenges for CBD\*\* product producers.

On 6 December 2023, the Japanese Diet passed comprehensive amendments to both the *Cannabis Control Act* and the *Narcotics and Psychotropics Control Act*. As major provisions set to take effect on 12 December 2024, these reforms mark a pivotal shift in Japan's regulatory stance on cannabis. The new framework permits the use of cannabis-derived pharmaceuticals following government approval, creating new growth opportunities in the market. Additionally, these amendments address Japan's long-standing drug lag, ensuring patients can access internationally recognised cannabis-based treatments that were previously unavailable domestically.

Upon the enforcement of the amended laws, cannabis-derived pharmaceuticals will be authorised for medical use after successful approval, allowing the controlled use of  $\Delta^9$ -THC-containing medications under the *Narcotics and Psychotropics Control Act*. These treatments, known for their effectiveness in addressing conditions such as epilepsy, chronic pain, and multiple sclerosis, will be classified as medical narcotics and be available only by prescription. The previous *Cannabis Control Act* remained outdated and focused on regulating specific parts of the cannabis plant rather than its active components. Consequently, many cannabis-derived pharmaceuticals developed and approved globally were deemed illegal under the law and could not be utilized.

While the amendments provide a pathway for approved cannabis-derived medicines, the regulations surrounding CBD products are notably stringent, imposing strict  $\Delta^9$ -THC residual limits: 10 mg/kg for fats, oils, and powders; 0.10 mg/kg for aqueous solutions; and 1 mg/kg for other product categories. Products exceeding these thresholds will be classified and regulated as narcotics.

Further regulations expected in 2025 will establish a tiered licensing system for cannabis cultivation. *(continue to the next page)*

\*Tetrahydrocannabinol (THC), a cannabinoid found in the cannabis plant, and the main ingredient that produces the psychoactive effect.

\*\*Cannabidiol (CBD), a non-impairing cannabinoid found in the cannabis plant.

Japan's amended cannabis laws enable patients to access cannabis-based treatments





Type 1 licences, covering the cultivation of industrial cannabis (low-THC varieties, with an upper limit of 0.3%  $\Delta^9$ -THC on a dry-weight basis), will be overseen by prefectural authorities. Type 2 licences, permitting the cultivation of high-THC cannabis for medical use, will fall under the jurisdiction of the Ministry of Health, Labour and Welfare (MHLW).

The pharmaceutical sector is already responding to these changes, with both established companies and emerging startups positioning themselves to capitalise on the expanding market. The amendments create substantial opportunities for the development of innovative therapies, particularly in approved cannabis-derived pharmaceuticals.

In the CBD market, producers and importers are now required to adhere to strict  $\Delta^9$ -THC limits. This marks a significant shift from previous regulations, which permitted the legal import and sale of CBD products derived from cannabis stalks and seeds – known as broad-spectrum CBD – after passing a pre-verification process. These products, which typically contain multiple cannabinoids but no or near zero THC, were not classified as “cannabis” under the previous regulations that only restricted products made from cannabis flowers and buds with high THC levels. As a result, the introduction of these new THC limits may present challenges to the continued availability of certain CBD products. The MHLW is actively exploring partial solutions to ensure that patients with intractable epilepsy can continue to access essential CBD treatments.

Looking to the future, these amendments are poised to accelerate the growth of Japan’s medical cannabis industry. Opportunities are emerging in the cultivation of high-quality medical cannabis and the development and market entry of approved cannabis-derived pharmaceuticals. As public perceptions of cannabis-based treatments evolve and the regulatory framework matures, Japan is expected to play an increasingly important role in the global medical cannabis market. However, businesses involved in CBD products must carefully navigate stringent compliance requirements. The long-term success of this segment will depend on balancing regulatory compliance with innovation, ensuring the sustainable development of cannabis-based products in Japan.

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