Medical *Cannabis* in Europe

A legislative comparison of four regulatory models: Germany, the Netherlands, Switzerland, the Czech Republic

GERMANY

Since April 2024, medical *cannabis* has been governed by a separate law (MedCanG); cultivation is moving from the tender system to direct licensing by BfArM.

MedCanG, BfArM

THE NETHERLANDS

The OMC retains legal oversight and responsibility for quality, but since January 2026 regimes have also operated in which private parties carry out the physical transfer.

Office of Medicinal Cannabis (OMC/BMC)

SWITZERLAND

The FOPH/BAG prior authorisation was abolished in 2022, but Swissmedic requirements for narcotics continue to apply.

BetmG, Swissmedic, BAG

CZECH REPUBLIC

Reimbursement of up to 90% of the price, for quantities of up to 30 grams per month.

SÚKL

INTRODUCTION

The European Union has no common legal framework for access to, prescription of and reimbursement of medical *cannabis*; these matters remain largely a national competence, within the common European framework for medicines, manufacturing and pharmaceutical quality (EMA, EU-GMP, EU-GACP, the European Pharmacopoeia). This means that a cultivation licence issued in one state creates no automatic rights in another, and that each market is treated separately in regulatory terms.

A clear distinction must be drawn: the EU has granted a centralised marketing authorisation for at least one *cannabis*-based pharmaceutical product, Epidyolex ® (cannabidiol), approved by the European Commission on 19 September 2019 on the basis of a positive assessment by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), for treatment-resistant epilepsy (Lennox-Gastaut and Dravet syndromes). This authorisation applies equally in all Member States. What remains unregulated at European level is unprocessed *cannabis* flower and other non-standard pharmaceutical forms, access to and reimbursement of which depend on the legislation of each Member State.

Cultivation licensing and the lawfulness of consumption are two legally separate matters, not automatically linked. Fully lawful, licensed cultivation may exist in a state while personal consumption within that same territory remains prohibited; the clearest illustration is Albania itself, where Law no. 61/2023 permits cultivation and production under licence *exclusively for export*, while sale, distribution and consumption within the territory remain prohibited for any medical destination. The same logic, cultivation licensing decoupled from any right of domestic consumption, may be encountered, in different forms and degrees, in other European national frameworks; for this reason, the fact that a state permits cultivation should not automatically be taken as an indicator of the legality of consumption in that state.

This material compares four representative European models: Germany, the Netherlands, Switzerland and the Czech Republic, selected precisely because they illustrate fundamentally different institutional approaches to the same objective: guaranteeing controlled access to medical *cannabis* of pharmaceutical quality.

IMPORTANT CLARIFICATION

This material addresses exclusively the medical *cannabis* framework (prescription for therapeutic purposes under medical supervision). Some of these states have adopted, in parallel, separate legal frameworks for non-medical adult use, such as Germany with the Consumer *Cannabis* Act (KCanG, April 2024), or the Swiss federal pilot projects. These frameworks are legally separate from the medical prescription system and are not addressed in this material.

GERMANY: FROM TENDER TO DIRECT LICENSING

Until March 2024, medical *cannabis* in Germany was regulated as a controlled substance under the Narcotics Act (Betäubungsmittelgesetz, BtMG), with domestic cultivation organised through tenders coordinated by the *Cannabis*agentur, the agency within the Federal Institute for Drugs and Medical Devices (BfArM), which purchased production and resold it at its own price to physicians, pharmacists and other authorised entities.

With the entry into force of the Cannabis Act (*Cannabis*gesetz, CanG) on 1 April 2024, medical *cannabis* passed entirely under a separate law, the Medizinal-*Cannabis*gesetz (MedCanG), and was removed from the scope of the BtMG. This brought two fundamental changes: first, cultivation and distribution are now regulated through a purely licensing procedure rather than through tender; the days of centralised purchasing by the *Cannabis*agentur have ended, and entities licensed by BfArM may market their production themselves in accordance with the applicable rules. Second, medical *cannabis* is now prescribed on an ordinary medical prescription rather than on a narcotic prescription.

Regarding reimbursement by public health insurance (Gesetzliche Krankenversicherung, GKV), this is not automatic: it requires the absence of another suitable alternative and a reasonable prospect of a positive effect. Until October 2024, prescriptions required prior approval from the health insurer in most cases; since October 2024, this prior approval is no longer required where the prescription is

issued by physicians holding specific additional qualifications, while in other cases prior approval remains necessary.

Technical quality requirements likewise vary according to the stage: EU-GACP applies to cultivation and primary processing, while EU-GMP applies to pharmaceutical manufacturing and to the final product intended for distribution through pharmacies, so that not every link in the chain is automatically subject to the same standard.

THE NETHERLANDS: STATE OVERSIGHT

Medical *cannabis* in the Netherlands is overseen by the Office of Medicinal *Cannabis* (OMC, also known as the Bureau voor Medicinale *Cannabis*, BMC), a state body within the Ministry of Health. The OMC/BMC holds the legal rights and the supervisory responsibility over the cultivation, quality and export of medical *cannabis* of pharmaceutical quality.

Nevertheless, describing this model as a "state monopoly over the entire physical chain" is an oversimplification. Since January 2026, two regimes have operated simultaneously in the Netherlands: alongside the traditional model, there is also a scheme in which the physical transfer of the product and the payments take place directly between private parties, while the OMC/BMC retains the legal rights and the supervisory role over quality and destination.

The OMC applies internal specifications for cannabinoid content, in some cases stricter than the Ph. Eur. 3028 monograph itself, in order to increase product consistency between batches. Health reimbursement for patients varies according to the insurer and to individual conditions, and cannot be generalised as being the same for everyone. Comparative claims such as "leading European exporter" are not made here, in the absence of support from official comparative data between countries.

The tolerance model for "coffeeshops", known internationally as a Dutch feature, is institutionally entirely separate from the OMC/BMC system and has no connection with the pharmaceutical-quality medical *cannabis* overseen by that body.

SWITZERLAND: PROCEDURAL SIMPLIFICATION, NOT REMOVAL OF REGULATORY REQUIREMENTS

Medical *cannabis* in Switzerland remains regulated under the Narcotics Act (Betäubungsmittelgesetz, BetmG), with technical oversight by Swissmedic, the Swiss agency for therapeutic products, and with administrative roles also for the Federal Office of Public Health (Bundesamt für Gesundheit, BAG).

The most important change of recent years has been procedural: until 1 August 2022, every medical *cannabis* prescription required a specific prior authorisation from the BAG. Since that date, this prior authorisation is no longer required and physicians may prescribe directly. This does not mean, however, that regulatory requirements have been removed altogether: Swissmedic requirements for narcotic substances and therapeutic products continue to apply in full, and physicians have continuing obligations to report patient treatment data.

Reimbursement by compulsory health insurance remains limited: coverage is granted only in exceptional cases, assessed individually, not as a general rule for every prescription.

Switzerland also operates, in parallel, federal pilot projects for non-medical adult use of *cannabis*, which function under a legal framework entirely separate from the medical prescription system described above.

CZECH REPUBLIC: CLEARLY DEFINED REIMBURSEMENT, A DEVELOPING MARKET

Medical *cannabis* in the Czech Republic is overseen by SÚKL (Státní ústav pro kontrolu léčiv, the State Institute for Drug Control), the national medicines authority and the principal licensing body for cultivation, while importation also involves the role of the Ministry of Health.

The reimbursement scheme is among the most clearly documented in Europe: public health insurance covers up to 90% of the price of medical *cannabis*, for quantities of up to 30 grams per month; larger quantities may be approved in specific circumstances, within the maximum legal limit.

Beyond this verified figure, any claim regarding the rate of growth of domestic cultivation capacity or the weight of imports requires support from up-to-date official statistics from SÚKL or the Ministry of Health.

COMPARATIVE TABLE

Country	Regulatory authority	Supply model	Health reimbursement
Germany	BfArM (under MedCanG, since April 2024)	Direct licensing of cultivators; moved from tender to licensing	Case by case; insurer prior approval no longer required for certain physician qualifications (since October 2024)
The Netherlands	Office of Medicinal *Cannabis* / BMC	State oversight of quality/export; since 2026 also a regime with private physical transfer	Depends on individual insurance
Switzerland	Swissmedic (under BetmG); BAG	Direct prescription by physicians since 2022; Swissmedic requirements continue to apply	Only in exceptional cases, assessed individually
Czech Republic	SÚKL (+ Ministry of Health for imports)	A combination of domestic cultivation and imports	Up to 90% of the price, up to 30 g/month

COMMON STANDARDS

Despite the profound institutional differences between these four models, all share a common technical basis where the product is intended to circulate within the European pharmaceutical space: the EU-GACP requirements for cultivation and primary processing, the EU-GMP requirements for pharmaceutical manufacturing and, since July 2024, the common **Ph. Eur. 3028** monograph for *cannabis* flower, where it has legal effect. This common technical layer functions as the "common language" that makes cross-border trade possible between countries with institutional systems as different as the Dutch and the German.

The difference lies mainly in the institutional and financial layer built upon this technical basis: who licenses production, how patient access is financed, and what role the state plays: as a direct operator, as a supervisor, or as both at the same time.

ALBANIA IN COMPARATIVE PERSPECTIVE

The Albanian model, established by Law no. 61/2023, differs from all four models above in one fundamental element: cultivation and production are permitted exclusively for export, while sale, distribution and consumption within the territory of the Republic of Albania remain prohibited. This places Albania outside the comparative scheme of "decentralised versus centralised domestic supply" on which the German and Dutch models are built, since there is no domestic consumption market or prescription for Albanian patients.

The institutional structure comprises several clearly separated roles: the NACC organises the licensing procedure, supervises licensed entities, and administers the relevant controls and registers; the Licensing Commission assesses the applications submitted; the licence is finally approved by the minister responsible for health. The NACC is therefore not the body that "issues the licence", but the regulatory, supervisory and administrative authority within this multi-actor process.

CONCLUSION

A comparison of these four models clearly shows that no single institutional "European standard" exists for medical *cannabis*, beyond the common technical pharmaceutical requirements and specific centralised authorisations. Each state chooses its own institutional structure, the level of health reimbursement, and the balance between imports and domestic cultivation according to its context, and these structures change over time, as shown by the German reform of 2024 or the new Dutch arrangements of 2026.

For a state such as Albania, with an exclusively export-oriented model, an accurate knowledge of these different approaches and its continuous updating assists in identifying the practices best suited to international partnerships and in aligning technical standards with those of the main European destination markets.

REFERENCES

[1] European Medicines Agency (EMA). Epidyolex, INN-cannabidiol - European public assessment report; marketing authorisation granted by the European Commission on 19 September 2019.

[2] Bundesministerium für Gesundheit (BMG). "*Cannabis* als Medizin" - Fragen und Antworten zum Gesetz.

[3] BfArM. Medizinisches *Cannabis* - official information on the MedCanG and the licensing procedure.

[4] Gemeinsamer Bundesausschuss (G-BA). FAQ Medizinisches *Cannabis*.

[5] Office of Medicinal Cannabis / Bureau voor Medicinale Cannabis (Netherlands) - official regulations, Staatscourant 2025/2026; official reimbursement page.

[6] Bundesamt für Gesundheit (BAG), Switzerland. Medizinische Anwendung von *Cannabis*.

[7] SÚKL (Státní ústav pro kontrolu léčiv), Czech Republic. Úhrada z veřejného zdravotního pojištění.

[8] Law no. 61/2023 "On the cultivation and processing of the *cannabis* plant for medical and industrial purposes", Republic of Albania.