Spotlight 06/22

MEDICAL CANNABIS

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A paradigm shift is about to take place in Switzerland: In summer 2022, the revision regarding medical cannabis will come into force. The core of the revised law is a two-stage licencing procedure for the cultivation of cannabis plants. The responsibility for deciding on an appropriate therapy with cannabis medicines lies with the attending physician.

The decision of the Swiss parliament to liberalise THC-containing cannabis for medicinal purposes represents a turning point in Swiss cannabis regulation. So far, only one THC-containing medicinal product has been authorised in Switzerland. The liberalisation aims in particular to enable medical treatments and to facilitate research and development with cannabis.

In order to implement this, the legislator has adapted the narcotics law and classified cannabis as a (restricted) marketable narcotic. With the amendment of the Narcotics Act, the use of cannabis for medicinal purposes is no longer subject to the exceptional authorisation system of the Federal Office of Public Health (FOPH). Subject to compliance with the relevant regulations, cannabis containing THC may now be cultivated, processed and dispensed to patients as a medicinal product.

Products containing cannabis with a total THC content of less than one percent and products containing cannabidiol (CBD) – which, unlike THC, has no psychoactive effect – do not fall under narcotics law and were therefore not prohibited even before the revision.

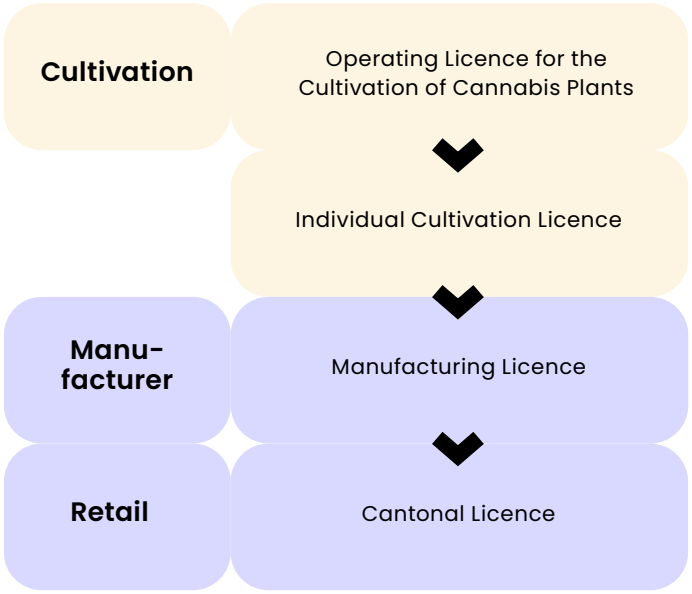
Cultivation of cannabis plants

Operating licence for the cultivation

The revised law provides for an operating licence for the cultivation of cannabis plants, which is granted by Swissmedic. The existing operating licence system for narcotics is supplemented by this special form of licence so that plants may be cultivated for the purpose of producing cannabis medicinal products.

The revised law requires that (a) the applicant is registered in the commercial register; (b) the storage of controlled substances is ensured; and (c) a person responsible for compliance with the narcotics law provisions (PRRC) is in place. In addition, the applicant must demonstrate that a system is in place that provides sufficient protection against theft and prevents the use of the plants for other purposes.

It should be particularly emphasised that an applicant must make personnel arrangements and appoint a responsible person. The PRRC must in turn fulfil the necessary personal requirements. Accordingly, it is recommendable for the applicant to include these personal elements in the written contract with the PRRC, in which the responsibilities and tasks are clearly defined.



Individual cultivation licence

In addition to the operating licence already mentioned, an individual cultivation licence is required in each case for the cultivation of cannabis plants. This adds a second, concrete level concerning cultivation to the licensing system.

In order to obtain a cultivation licence, the applicant must prove that a system is in place that enables the quality and traceability of the cultivated plants. In addition, the applicant must submit a written purchase contract with a buyer who is in possession of a corresponding operating licence. Furthermore, the ordinance requires the applicant to provide detailed information on the type of cultivation. For example, it must be stated whether this is done by means of seeds or cuttings and whether it is done in a facility or outdoors. Furthermore, it must be stated which variety is used and what quantities are to be expected from the harvest.

Production of cannabis medicinal products

According to the revised law, cannabis medicinal products can be produced and dispensed as *formula magistralis* without a marketing authorisation. This means that corresponding medicinal products can be produced either by a pharmacy or by a manufacturing company. These manufacturing companies require a manufacturing licence as well as an operating licence under narcotics law from Swissmedic. In the same way as for the cultivation licence, (a) the applicant must be registered in the commercial register; (b) the storage of controlled substances must be ensured; and (c) there must be

a person responsible for compliance with the provisions of narcotics law.

The revised law does not provide for concrete requirements regarding quality assurance. The existing practice on *formula magistralis* also allows only limited conclusions to be drawn, as such medicinal products with marketing authorisation exemption have played only a minor economic role up to now. At least the rules of Good Manufacturing Practice (GMP) for medicinal products in small quantities of the Pharmacopoeia Helvetica apply to such products. In addition, the Ordinance on Medicinal Products (VAM) contains maximum production quantities per calendar year per medicinal product.

Prescription and dispensing

The attending physician decides on the indication and the dosage form of cannabis medicinal products in compliance with the medical duty of care. These medicinal products may be prescribed in a specific composition a specific composition (for example, a specific mixing ratio) or as a ready-to-use preparation.

Public pharmacies or hospital pharmacies that have a manufacturing licence for medicinal products according to the *formula magistralis* are authorised to dispense.

Impact on the industry

Despite the considerable effort required for all the clarifications and implementation of the regulations, the liberalisation of medicinal cannabis represents a great opportunity for many companies.

It is primarily the manufacturers who must obtain the necessary licences from Swissmedic for the cultivation and production of cannabis medicinal products. In particular, this requires the establishment of quality management and safety systems that meet Swissmedic's requirements. In terms of personnel, they must appoint a responsible person, with whom a carefully drafted written contract must be concluded.

Regarding the production of cannabis medicinal products, the rules of Good Manufacturing Practice (GMP) for medicinal products in small quantities of the Pharmacopoeia Helvetica and the maximum production quantities must be observed.

Since the legislator deliberately does not make any specifications regarding indication and dosage form, there will probably be many different products on the market in the future. With regard to dispensing and sales, an interaction between manufacturers, pharmacies and physicians will be necessary.

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