Liberalisation of medicinal cannabis in Switzerland – revision of Narcotics Act enters into force

26.07.2022

On 1 August 2022, the revision of the Narcotics Act will come into force, with the aim of liberalising medicinal cannabis. The revision centres, on the one hand, on the lifting of the legal ban on the marketing of narcotics containing an effective concentration of cannabinoid for medical purposes; this topic will be examined in this legal update. On the other hand, the revision provides for a two-stage authorisation procedure for the cultivation of medicinal cannabis, as discussed in a separate legal update. The sale and consumption of cannabis for non-medicinal purposes, however, remains prohibited.

In addition, an exemption from the Federal Office of Public Health (FOPH) will no longer be required for the medical prescription of medicinal cannabis. The sale and consumption of cannabis for non-medicinal purposes, however, remains prohibited.

Pestalozzi Rechtsanwälte AG
Feldeggstrasse 4
CH-8008 Zürich
T +41 44 217 91 11
zrh@pestalozzilaw.com

Pestalozzi Avocats SA
Cours de Rive 13
CH-1204 Genève
T +41 22 999 96 00
gva@pestalozzilaw.com

pestalozzilaw.com

Key takeaways

- **Lifting of the legal ban on medicinal cannabis: The cultivation, production, processing and trade of medicinal cannabis is now subject to the authorisation and control system of Swissmedic, in line with the regulation of other narcotics used for medicinal purposes.**
- **No exemptions: There is no longer a fundamental ban on the medical prescription of medicinal cannabis. The physician is fully responsible for its use in the context of treatment.**
- **Temporary information system on medical treatments with medicinal cannabis: Prescribing physicians are required to report treatments with medicinal cannabis and transmit relevant data to the FOPH for the first few years after the revision of the law comes into force.**
- **Still no cost reimbursement: Treatment with cannabis-based medicinal products remains beyond the scope of the benefits catalogue of mandatory health insurance in Switzerland; the health insurance company only reimburses such products in exceptional cases.**
- **Legal separation of medicinal and non-medicinal cannabis: The use of cannabis for non-medicinal purposes is not affected by these amendments to the law and remains prohibited in principle.**

Background: Prohibition with exceptional exemptions

Cannabis with a THC (tetrahydrocannabinol) content of 1% or more is currently considered a prohibited narcotic in Switzerland. In principle, it may therefore not be cultivated, produced, imported or placed on the market. Medicinal use of cannabis has therefore been fundamentally excluded up to now under the regular narcotics licencing and control system. Preparations containing cannabis with a THC content of less than 1% and preparations containing CBD (cannabidiol), on the other hand, do not fall under the scope of the Narcotics Act and are already permitted (and will not be considered further in this legal update).

The current law allows the FOPH to issue an exceptional licence (i.e., an exemption) for the cultivation, production, import or placing on the market of prohibited narcotics for the purpose of scientific research, drug development or restricted medical use, provided there is no international agreement to the contrary (Art. 8 para. 5 of the Narcotics Act). Against this background, the practice to date on the use of medicinal cannabis is as follows:

- An exceptional licence from the FOPH is required for the prescription of medicinal cannabis products that are exempt from authorisation according to the formula magistralis (i.e., medicinal cannabis products that are produced by a public pharmacy or hospital

pharmacy on a physician's prescription). Currently, most medical treatments are carried out with such medicinal cannabis products that are exempt from authorisation.

- At present, such an exceptional licence is also required for any authorised medicinal product that is dispensed for an indication other than the one for which it was authorised or that is to be used in a non-authorised dosage form (known as off-label use).
- On the other hand, no exemption is required for the use of narcotics that are authorised as medicinal products. For example, Sativex®, the only ready-to-use medicinal cannabis product authorised under medicinal product law in Switzerland with a THC content of over 1%, can be prescribed for the authorised indications without an exceptional licence; for other indications, however, an exceptional licence is required (off-label use; see above).

The production and placing on the market of medicinal cannabis products intended for general medical use, independent of an individual case assessment, has been excluded up to now due to the FOPH's exemption system. The exemption procedure, which was introduced in 2011 and has been used more and more frequently since then, is also costly. Also, in view of the high approval rate, the system of exceptional licencing no longer appeared adequate overall in important respects.

Lifting of the legal ban with the entry into force of the revision

The revision of the law aims to take account of this development and intends to develop the healing and palliative potential of cannabis as a medicinal product and to simplify access to medicinal cannabis for patients. The Narcotics Act will be adapted accordingly and cannabis will be classified as a controlled narcotic with restricted marketability. This means that the cultivation, production, processing and trade of cannabis for medicinal purposes will no longer be subject to the exemption system of the FOPH, but to the authorisation and control system of Swissmedic.

In practice, this means that cannabis for medicinal purposes is no longer listed in schedule d but in schedule a of the Narcotics List. The same applies to:

- Cannabis extract, cannabis resin, cannabis oil, cannabis tincture for medicinal purposes;
- Cannabis seeds, cannabis cuttings for cultivation for pharmaceutical production; and
- Dronabinol, (-)-trans-delta-9-tetrahydrocannabinol, tetrahydrocannabinol for medicinal purposes.

This means that the handling of cannabis and cannabis preparations for medical purposes is now subject to the already known control measures to which all narcotics in schedule a (e.g., morphine, methadone, cocaine) are subject. These include but are not limited to the requirement of an establishment licence (including nominating a responsible person) and reporting obligations.

Commercial export of cannabis medicines

The abolition of the exemption licences under the Narcotics Act, including the case-by-case examination for restricted medical use, also makes the commercial export of narcotics containing an effective concentration of cannabinoid for medicinal purposes possible in principle (taking into account the relevant international regulations, in particular the 1961 Single Convention on Narcotic Drugs), whereby a licence from Swissmedic is also required for the export.

Prescription and dispensing

Treatment with medicinal cannabis products is now entirely the responsibility of physicians. The abolition of the FOPH's exemption for the prescription of medicinal cannabis thus facilitates access to cannabis medicinal products.

Public pharmacies or hospital pharmacies that have a manufacturing licence for medicinal products in accordance with the formula magistralis are authorised to dispense medicinal products. These pharmacies are thus responsible for two different tasks. On the one hand, they are manufacturers (or principals for the manufacture) of medicinal cannabis products, and on the other hand they act as dispensaries for ready-to-use cannabis medicinal products.

Temporary information system

Nationwide data collection is being carried out to enable scientific evaluation of the legal amendments. Physicians prescribing medicinal cannabis products are thus required to record certain information electronically (e.g., on side effects). The results of the statistical evaluation of this data will be made available by the FOPH to the cantonal enforcement authorities, the physicians involved in treatment and any interested research institutions, and can thus serve as guidance and basis for further research.

Provisions on non-medicinal use and remuneration remain unchanged

The revision of the law does not deal with the use of narcotics containing an effective concentration of cannabinoid with a THC content of 1% or more for non-medicinal purposes, which means that the ban on non-medicinal cannabis remains in place in this context. Accordingly, the use of cannabis for the purpose of (non-medicinal) scientific research or for the purpose of control measures still requires an exceptional licence from the FOPH (in accordance with Art. 8 para. 5 and 8 of the Narcotics Act). Furthermore, self-medication with cannabis by patients beyond the scope of medical treatment does not fall under medicinal use – and will remain prohibited in the future.

Finally, the revision does not result in any change with regard to reimbursement of medicinal cannabis products. Currently, no pharmaceutical is listed on the FOPH’s list of pharmaceutical specialities eligible for reimbursement under the mandatory health insurance scheme. Since the evidence on the efficacy and cost-effectiveness of medicinal cannabis products is still insufficient, their costs are not generally covered by mandatory health insurance; health insurance companies generally only reimburse medicinal cannabis products in exceptional cases as part of individual case reimbursements.

Conclusion and outlook

The lifting of the ban on narcotics containing an effective concentration of cannabinoid for medical purposes and the accompanying changes are to be welcomed. Switzerland is following the example of countries whose systems allow extended access to medicinal cannabis products (e.g., Canada, Germany, the Netherlands, Italy).

From an economic point of view, and especially in light of the commercial export of cannabis for medicinal purposes that will be permitted in the future, manufacturers of herbal medicines, specialised public pharmacies, and domestic growers of the raw materials are likely to benefit. For patients, the lifting of the exemption requirement will improve the situation with regard to delays in commencing therapy.

Authors: Sarah Drukarch (Senior Associate), Aline Haas (Junior Associate)

No legal or tax advice

This legal update provides a high-level overview and does not claim to be comprehensive. It does not represent legal or tax advice. If you have any questions relating to this legal update or would like to have advice concerning your particular circumstances, please get in touch with your contact at Pestalozzi Attorneys at Law Ltd. or one of the contact persons mentioned in this Legal Update.

© 2022 Pestalozzi Attorneys at Law Ltd. All rights reserved.

Christian Roos

Partner
Attorney at law, lic. iur.
Co-head Life Sciences

Pestalozzi Attorneys at Law Ltd
Feldeggstrasse 4
8008 Zurich
Switzerland
T +41 44 217 92 00
christian.roos@pestalozzilaw.com



Sarah Drukarch

Partner
Attorney at Law

Pestalozzi Attorneys at Law Ltd
Feldeggstrasse 4
8008 Zurich
Switzerland
T +41 44 217 93 23
sarah.drukarch@pestalozzilaw.com

