

Cultivation of cannabis for medical purposes

Swissmedic, Narcotics Division
2023

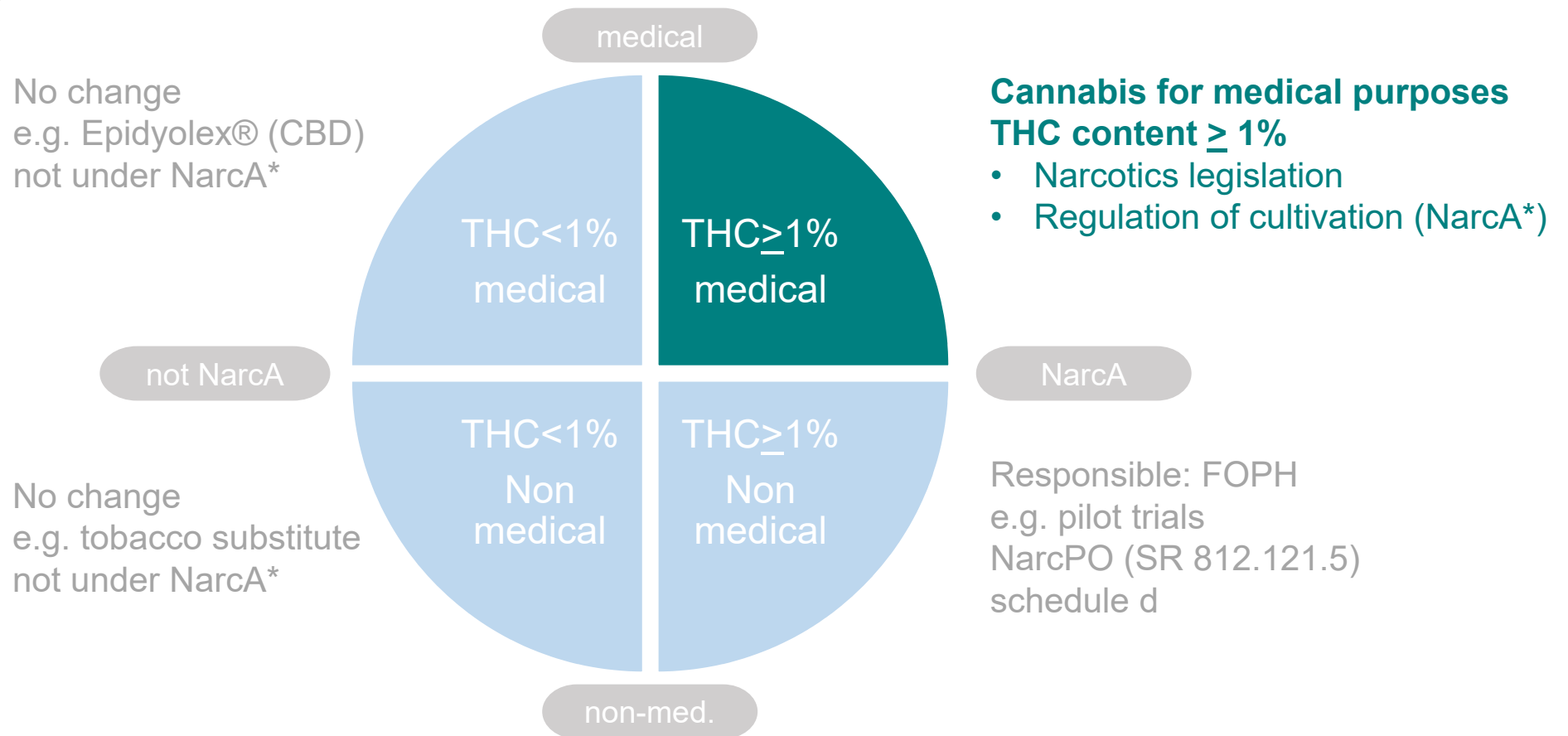
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Topics: Implementation by Narcotics Division, Swissmedic

- Subject matter
- International legal framework
- Changes to narcotics legislation
- Handling narcotics in List a = Cannabis for medical purposes
 - Establishment licence for handling
 - Import / export permits
 - Notifications in Switzerland
 - Annual Accounts (AA)
- Regulation of the cultivation of cannabis for medical purposes
 - Establishment licence for cultivation
 - Individual cultivation licence and electronic application
 - Annual Accounts (AA)

Subject





Single Convention on Narcotic Drugs, 1961

Internationally binding:

Single Convention on Narcotic Drugs, 1961 (since 1970 in Switzerland)

- Special control measures for the – legal - cultivation of opium poppy, cannabis and coca bush
 - Cannabis: Art. 28 with reference to Art. 23
 - Particularly high risk of diversion during the cultivation phases
 - Prevention of overproduction
 - Preferably possession of the total harvest by the state
 - Cannabis Agency required for the cultivation of cannabis
- **International control agency:**
 - International Narcotics Control Board (INCB), created in 1968

Revision of narcotics legislation

Revision of the Narcotics Act (NarcA)

- Removal of the prohibition in Art. 8 for cannabis for medical purposes

Revision of the Narcotics List Ordinance, NarcLO-FDHA

- Reallocation from schedule d to schedule a

- Cannabis for medical purposes

and

- Cannabis extract, cannabis resin, cannabis oil, cannabis tincture for medical purposes
- Cannabis seeds, cannabis seedlings for cultivation for pharmaceutical production
- Dronabinol, (-)-trans-delta-9-tetrahydrocannabinol, tetrahydrocannabinol for medical purposes

Narcotics Control Ordinance (NarcCO)

Handling cannabis for medical purposes:

- The control measures stipulated for all narcotics in schedule a apply
- Export possible with individual export permit
- Control authority for companies: Swissmedic
- No changes in the NarcCO relating to control measures

Cultivation of cannabis for medical purposes: an overview

- New: Implementing provisions for the cultivation of cannabis for medical purposes
- Swissmedic will become:
 - Licensing authority
 - Cannabis Agency in accordance with international agreements

No changes to the NarcCO for handling

(manufacture, procurement, distribution, import and export, delivery, trading)

-> Handling cannabis for medical purposes = Handling controlled substances in schedule a

Short overview:

- Establishment licence to handle
- Import / Export authorisation
- Domestic trade
- Annual Accounts (AA)

Handling cannabis for medical purposes

Please note:

- List a: Cannabis for medical purposes
- List d: Cannabis (excluding cannabis for medical purposes)
- An establishment licence according to TPA (SR 812.21) is therefore also mandatory for handing cannabis for medical purposes.

Required for purchasers in accordance with purchase agreement:

- Establishment licence according to NarcA and establishment licence according to TPA

Required for import:

- Establishment licence according to NarcA and establishment licence according to TPA
or
- Exemption according to NarcA

Establishment licence for handling controlled substances

Requirements

- Entered in the commercial register (main register)
- Ensure correct storage according to Art. 54 NarcCO
- Responsible Person (RP) for controlled substances
 - Healthcare professional / science degree
 - Written contract regulating the responsibility / compulsory presence according to NarcA
 - Carry out the role autonomously
 - Required expertise, experience

Validity

- Maximum of 5 years

Import and export permit for every import/export

Requirements

- Establishment licence for handling
- For export: Import permit for the recipient country
- Within the estimates

Validity

- Up to 4 months

Notification obligations

- Within 10 working days after the import or export:
 - quantity and date

System for electronic application: NDS-Web

Notifying the flow of substances in Switzerland

Notification obligation for establishments with:

- Establishment licence for handling

To be notified:

- Deliveries in Switzerland
- Notification of return shipments from retailers by recipients
- Deliveries to the cantonal authority

Time limit

- Up to the 15th day after delivery / end of the month

Notification system (electronic notification)

- MESA

Notification in Annual Accounts

Notification obligation for all establishments with:

- Establishment licence for handling

To be notified:

- Bookkeeping for the year under review
- Warehouse stocks, synthesis, manufacture, import and export, domestic purchasing and selling, losses

Time limit

- By 31 January of the following year

Notification system

- Excel and upload via NDS-Web

New Topic in NarcCO: Regulation for cultivation

Cultivation of plants and fungi containing controlled substances in List a
-> Cultivation of cannabis for medical purposes

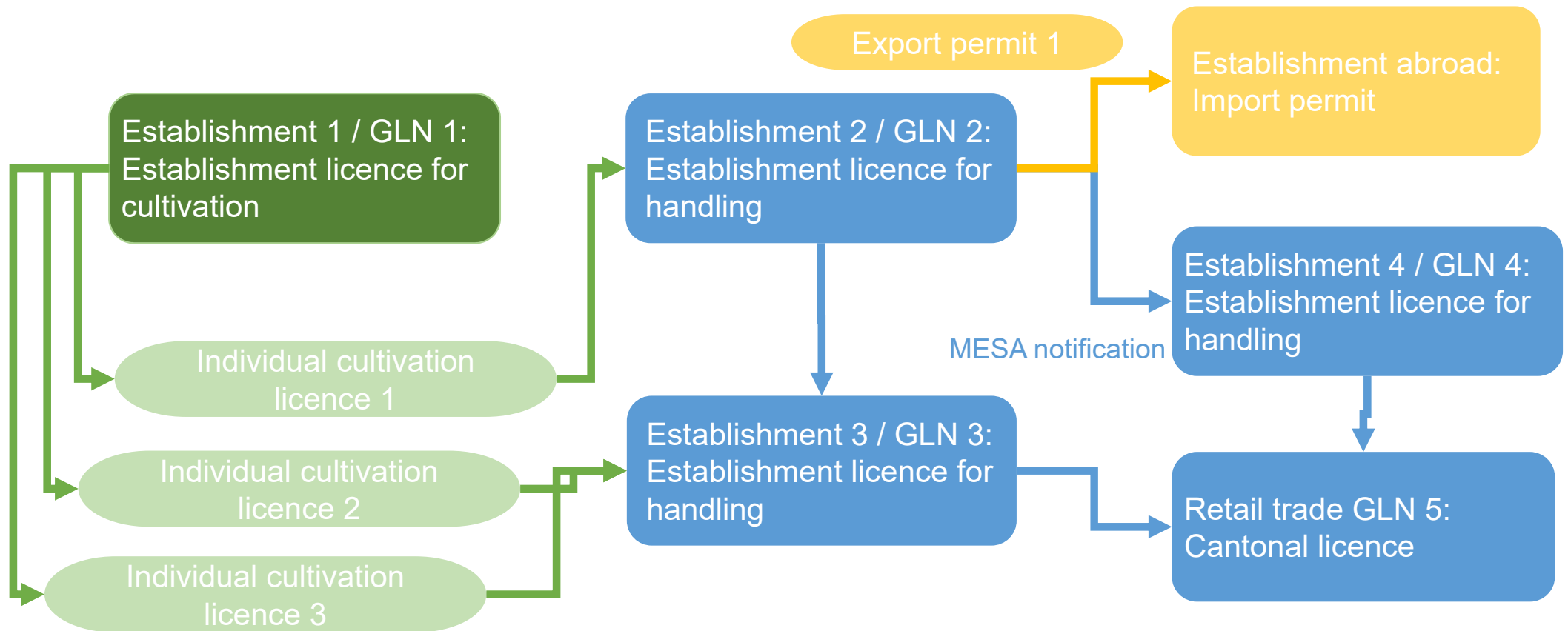
- Establishment licence for cultivation
- Individual cultivation licence
- Annual Accounts (AA)

Cannabis Agency: Cultivation of cannabis

Compliance with the international requirements for cultivation in Switzerland:

- For medical purposes, Swissmedic assumes the role of the Cannabis Agency
- Two-stage authorisation procedure for cultivation
 - Establishment licence for cultivation (following inspection by the canton)
 - Individual cultivation licence with purchase agreement and notifications to Swissmedic

Flow of cannabis for medical purposes



Cultivation of cannabis for medical purposes

- **Establishment licence for cultivation**
- Individual cultivation licence
- Annual Accounts (AA)

Cultivation of cannabis for medical purposes: [Establishment licence](#)

Establishment licence for the cultivation of cannabis for medical purposes

Requirements

- Entered in the commercial register (main register)
- Ensure correct storage according to Art. 54 NarcCO
- Adequate protection against theft and prevention of use for other purposes
- Responsible Person (RP) for controlled substances = bears the responsibility
 - Healthcare professional / science degree or diploma issued by a university or university of applied sciences in agriculture, environmental sciences or forestry
 - Written contract regulating the responsibility / compulsory presence according to NarcCO
 - Carry out the role autonomously
 - Required expertise, experience

Validity

- Maximum of 5 years

Cultivation of cannabis for medical purposes: [Establishment licence](#)

Establishment licence for the cultivation of cannabis for medical purposes

From the entry into force of the revised narcotics legislation

- Application forms from www.swissmedic.ch/betm
- Processing period after receipt of all submitted documents and completion of the inspection:
 - 10 weeks
- Fee as stipulated in FeeO-Swissmedic (SR 812.214.5)
 - Issuing: CHF 1500
 - Modification: CHF 600
- Review of the submitted application documents by Swissmedic
- Inspection by the Canton

Cultivation of cannabis for medical purposes: [Establishment licence](#)

Within the jurisdiction of the Cantons

Regular inspections (before and after issuing of the licence)

- Adequate protection against theft and diversion (cultivation through to delivery), e.g.:
 - Restricting access
 - Monitoring system
- Quality assurance system (specification documents and supporting documents)
- Bookkeeping and documentation requirements
- Other

For-cause inspections

- Case-specific

Disposal by the Canton according to Art. 70 NarcCO

What is permitted by an establishment licence for cultivation

Scope of an establishment licence for cultivation

- Precondition for individual cultivation licences
- Procurement of seeds and seedlings required for cultivation
 - Import: Import permit required
 - Within Switzerland
- Delivery to purchaser in accordance with the purchase agreement for the individual cultivation licence
- Simple treatment after harvesting that is not subject to the requirements of the TPA

Outside the scope of the establishment licence for cultivation

- Does not entitle the holder to export, deliver or distribute
- Does not entitle the holder to carry out activities subject to the TPA

Cultivation of cannabis for medical purposes

- Establishment licence for cultivation
- **Individual cultivation licence**
- Annual Accounts (AA)

Cultivation of cannabis for medical purposes: Individual cultivation licence

Individual cultivation licence

Requirements

- Establishment licence for cultivation
- System for traceability for quality assurance purposes
- Written purchase agreement
 - Details concerning the cultivation type and quantity
 - Obligation to take delivery of the total harvest
 - Purchaser requires establishment licence for handling

Validity

- One-off cultivation
- Maximum of 1 year

Cultivation of cannabis for medical purposes: Individual cultivation licence

Application for individual cultivation licence

From the entry into force of the revised narcotics legislation

- Application
 - Possible after an establishment licence for cultivation has been issued
 - Via the NDS-Web Portal
- Processing period for a completely submitted application
 - Depends on the number of applications and processing time
- Fee as stipulated in Art. 4 FeeO-Swissmedic (SR 812.214.5)
 - Fee based on time (CHF 200/hour)
- Notification obligations form part of the individual cultivation licence

Application for individual cultivation licence

Details of the specific cultivation cycle

- Type of cultivation
 - Indoor / outdoor
 - Seeds / cuttings
 - Variety to be cultivated with expected THC content
 - Location (e.g. address, GPS coordinates) and size of the cultivation area
 - Expected yield (kg) and calculation basis
- Documentation to be submitted
 - Written purchase agreement
 - Traceability for quality assurance purposes (e.g. contract)

Cultivation of cannabis for medical purposes: Individual cultivation licence

Notification obligations for individual cultivation licence

Cultivation has taken place

- | | |
|---|---------------|
| • Date of the start of cultivation | compulsory |
| • Events that affect the expected yield | if necessary* |
| • Partial harvest, losses or other, with date, quantity and residual quantity | if necessary* |
| • Total harvest with date, quantity | compulsory |
| • Handover to purchaser with date, quantity and details of the purchaser | compulsory |

Cultivation has not taken place

- | | |
|--|------------|
| • Notification in order to conclude the individual cultivation licence | compulsory |
|--|------------|

Time limit

- Within 10 working days

*If applicable, several answers possible

Cultivation of cannabis for medical purposes

- Establishment licence for cultivation
- Individual cultivation licence
- **Annual Accounts (AA)**

Cultivation of cannabis for medical purposes: AA

Bookkeeping and Annual Accounts (AA)

- **Requirements of the conventions on the international control of the flow of narcotics**
 - INCB* has an oversight function and checks the compliance of countries
 - Specific reporting: cultivation of opium poppy, cannabis and coca bush
 - Check for inconsistencies in countries' balance sheets
 - Basis for publicly accessible INCB reports
- **Review by Swissmedic**
 - Data submitted by Switzerland to the INCB are of sufficient quality and do not show any inconsistencies
 - Compliance of the licence holders (oversight function of Swissmedic)

Cultivation of cannabis for medical purposes: AA

Notification in Annual Accounts

Notification obligation for all establishments with:

- Establishment licence for cultivation

To be notified:

- Bookkeeping for the year under review

Time limit

- By 31 January of the following year

Notification system

- Upload via NDS-Web

Cultivation of cannabis for medical purposes: AA

To be notified for one reporting year from 1 Jan. to 31 Dec.

- Warehouse stocks on 1 Jan.
- Total harvest
 - Indoor
 - Outdoor
- Area used for cultivation
- Delivered to purchasers
- Losses
- Destruction
- Warehouse stocks on 31 Dec.



Contact

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