Clarification by Swissmedic re. the requirements under narcotics and therapeutic products legislation pertaining to handling cannabis for medical purposes

The provisions regarding the prescription and handling of cannabis for medical purposes have been revised in narcotics legislation with effect from 1 August 2022.
Cannabis for medical purposes appears in List a of the Narcotics Lists Ordinance (NarcLO-FDHA, SR 812.121.11) and like morphine, for example, is subject to all control measures.
Cannabis plants and parts thereof as well as preparations such as extracts, resins, oils and tinctures and the compounds dronabinol and THC are also classified as List a substances, provided there is an intended medical purpose and the defined limit of at least 1.0% total THC content is met.

The two-stage licensing procedure for the cultivation of cannabis for medical purposes comprises an ***establishment licence for the cultivation of cannabis for medical purposes*** *and an* ***individual cultivation licence.***

Holders of an establishment licence for the cultivation of cannabis for medical purposes are authorised to procure the necessary seeds and seedlings required for cultivation and to apply for an individual cultivation licence.
The following documents must be submitted to Swissmedic when applying for an individual cultivation licence:

- *a system for traceability and quality assurance for the cannabis supplied for medical purposes, and*
- *a written supply agreement with precise details on the type and quantity of cultivation and the obligation of the purchasing party to take full delivery of the harvest.*

Simple treatment after harvesting that is not subject to the requirements of the Therapeutic Products Act (TPA) comes under cultivation and can also take place within the scope of an establishment licence for cultivation.

From the time the harvest is delivered, all further activities in connection with cannabis for medical purposes such as manufacture of extemporaneous preparations, wholesaling and retailing, import and export come under the Narcotics Act and the Therapeutic Products Act. ***These activities require additional licences.***

GMP/GDP certification is ***therefore*** *a requirement for obtaining a licence to handle cannabis for medical purposes according to NarcCO.*