

## Quality control questionnaire for limited use of psychedelics

Psychedelic-assisted therapy (PAT) is possible in Switzerland with an authorization of the Federal Office of Public Health (FOPH). PAT is not a standard treatment and controlled substances are used. Therefore, documentation of efficacy and tolerability is needed. A minimal data set should be collected for each patient. The FOPH requests a report at the end of each treatment period. Additionally, the present quality control survey is conducted by the University Hospital Basel in collaboration with the Swiss Medical Association for Psychedelic Therapy (SÄPT).

Kindly complete the questionnaire **once for every patient at the end of each FOPH authorization after a maximum of one year. Please complete one report for each substance.**

Please send the completed questionnaire (**one per patient and substance/authorization**) as Word or PDF or scan via mail or e-mail to Prof. Dr. med. Matthias Liechi ([Matthias.liechi@usb.ch](mailto:Matthias.liechi@usb.ch)), Klinische Pharmakologie, Universitätsspital Basel, Schanzenstrasse 55, 4056 Basel.

Date:

Name of treating physician: \_\_\_\_\_

First authorization/first treatment

Extension of existing authorization/treatment

### A. PATIENT CHARACTERISTICS:

Year of birth: \_\_\_\_\_

Biological sex: male  female

Diagnosis (treatment reason):  
\_\_\_\_\_

Secondary Diagnoses (max. 3):  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Current psychopharmacological medication:

\_\_\_\_\_ paused before session: No  Yes

\_\_\_\_\_ paused before session: No  Yes

\_\_\_\_\_ paused before session: No  Yes

\_\_\_\_\_ paused before session: No  Yes

**B. SUBSTANCE AND ACUTE EFFECTS:**

**Substance (choose only one):**

MDMA: Dose (min-max) \_\_\_\_\_ - \_\_\_\_\_ mg

Psilocybin: Dose (min-max) \_\_\_\_\_ - \_\_\_\_\_ mg

LSD: Dose (min-max) \_\_\_\_\_ - \_\_\_\_\_ µg

**Number of sessions (during the approved treatment period of max. 12 months):** \_\_\_\_\_

Session as single patient: No  Yes

Mostly single-patient sessions: No  Yes

Group sessions: No  Yes

Mostly group sessions: No  Yes

**Duration of treatment (during the current approved treatment period of max. 12 months):** \_\_\_\_\_ months

**Total duration of treatment (all authorizations/extensions):** \_\_\_\_\_ months

**Acute effects of substance (average of all sessions):**

Any acute effect, on scale of 0-10 (0 = no effect, 10 = maximal effect): \_\_\_\_\_

Acute effect was good/positive, on scale of 0-10 (0 = not at all, 10 = maximal): \_\_\_\_\_

Acute effect was bad/negative, on scale of 0-10 (0 = not at all, 10 = maximal): \_\_\_\_\_

**C. CLINICAL GLOBAL IMPRESSION (CGI) (for all diagnoses overall)**

<b>1. Severity of illness (prior to PAT)</b> Considering your total clinical experience with this particular population, <b>how (mentally) ill was the patient before the start of the current treatment (max. 12 months)?</b>	<b>2. Global Improvement (change after PAT)</b> How has the patient's condition <b>overall</b> changed (i.e., not just as result of the substance treatment). <b>Please compare the patient's current condition with that at the start of the treatment under the current authorization (max. 12 months)</b> and indicate the extent to which the patient's condition has changed during this period.
<input type="checkbox"/> cannot be determined	<input type="checkbox"/> cannot be determined
<input type="checkbox"/> normal, not at all ill	<input type="checkbox"/> very much improved
<input type="checkbox"/> borderline (mentally) ill	<input type="checkbox"/> much improved
<input type="checkbox"/> mildly ill	<input type="checkbox"/> minimally improved
<input type="checkbox"/> moderately ill	<input type="checkbox"/> no change
<input type="checkbox"/> markedly ill	<input type="checkbox"/> minimally worse
<input type="checkbox"/> severely ill	<input type="checkbox"/> much worse
<input type="checkbox"/> among the most extremely ill patients	<input type="checkbox"/> very much worse
<b>3. Efficacy Index</b> Assess the therapeutic effect of the treatment (substance effect) and associated side effects <b>during the current treatment period of max. 12 months.</b>	
<b>3.1. Therapeutic Effect</b>	<b>3.2. Side effects</b>
<input type="checkbox"/> cannot be determined	<input type="checkbox"/> cannot be determined
<input type="checkbox"/> marked - vast improvement. Complete or near complete remission of all symptoms.	<input type="checkbox"/> none
<input type="checkbox"/> moderate - decided improvement. Partial remission of symptoms.	<input type="checkbox"/> do not significantly interfere with patient's functioning
<input type="checkbox"/> minimal - slight improvement which does not alter status of care of patient.	<input type="checkbox"/> significantly interfere with patient's functioning
<input type="checkbox"/> unchanged or worse	<input type="checkbox"/> outweigh therapeutic effect

**D. SPECIFIC SIDE EFFECTS (during the current treatment period of max. 12 months).**

			Severity (1-3)
Headache (on treatment day):	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<input type="text"/>
Nausea (on treatment day):	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<input type="text"/>
Heart palpitations/chest pain (on treatment day):	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<input type="text"/>
Sleep problems (on treatment day or day after):	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<input type="text"/>
Anxiety/panic (on treatment day):	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<input type="text"/>
Psychologically Destabilized* (within 1 month of session):	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<input type="text"/>
Suicidal thoughts (within 1 month of session):	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<input type="text"/>
Suicidality (elaborate planning/attempts; anytime):	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<input type="text"/>
Flashbacks** (anytime)	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<input type="text"/>

(\* increased anxiety, irritability, depression, etc; \*\* short (seconds-minutes) recurrences of positive or negative elements of the substance experience)

Any other side effects? If yes, please indicate:

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