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icpr 26

CONFERENCE TALK · REIMBURSEMENT & ACCESS

Are reimbursement pathways ready for licensed psychedelic therapies in Europe?

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Conflict of interest disclosures

EMPLOYMENT / OWNERSHIP	Founder and owner of Blossom (moreblossom.com), a research-intelligence platform. Co-founder of FLO Coaching, offering legal psilocybin coaching in the Netherlands.
CONSULTING / ADVISORY	Core team member at Delphi, a consultancy advising organisations across the psychedelic field.
GRANTS / FUNDING	The report underpinning this talk, “Reimbursement Pathways for Psychedelic Therapies” (2025), was funded by Norrsken Mind and co-authored with Martin Gisby (Magnetar Access).
HONORARIA	None.
OTHER	Volunteer with the OPEN Foundation, the organiser of ICPR, since 2020.

PART ONE · THE PATIENT

Meet Marieke

Marieke, 47

Secondary-school teacher, Utrecht.
Married, one teenage son.

DIAGNOSIS	Major depressive disorder, recurrent. First diagnosed in 2016.
CURRENT EPISODE	Her third. Ongoing 14 months. Now on sick leave from school.
SPECIALIST CARE	Altrecht, the Utrecht mental-health (GGZ) institution, since 2020.
TREATMENT HISTORY	Cognitive Behavioural Therapy (CBT), various antidepressants. None brought her back.
WHAT HAPPENS NEXT	She is referred for psilocybin-assisted therapy.

Marieke is a composite, drawn from real Dutch treatment-resistant depression profiles. Her clinical details match the eligibility criteria of the ongoing Phase 3 psilocybin trials.

FOUR GATES

PART TWO · THE ROAD TO ACCESS

Approval is not access

Four consecutive gates stand between a European licence and Marieke's treatment.

All these gates need to be navigated to ensure patients with need are treated, and equity of access is secured.

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GATE ONE · APPROVAL

The trial-to-licence gap

A licensed psychedelic medicine arrives with detailed dosing instructions and an empty delivery model.

WHAT A PHASE 3 TRIAL TESTS

The compound. Psilocybin, 25 mg

The setting. Clinical room, two facilitators

Psychological support. Preparation, monitoring, integration

The protocol. Eligibility, safety, follow-up

EMA GRANTS AUTHORISATION →

WHAT THE EMA LICENSES

The compound. Psilocybin, 25 mg

Patient population. Treatment-resistant depression.

~~The setting.~~
~~Psychological support.~~
~~The protocol.~~

Everything else: not regulated as medical practice

"The regulation of medical practice in clinical settings falls outside the EMA's remit."

EMA multi-stakeholder workshop on psychedelics, April 2024 (EMA/177319/2024).

01

Four problems in the trial, four in the appraisal

Each methodological challenge in the trial returns, downstream, as a problem for the body that has to price it.

Functional unblinding

IN THE TRIAL

Patients know which arm they are in within an hour.

IN THE APPRAISAL

Effect size blurs, so cost-effectiveness models turn fragile.

Comparator / placebo

IN THE TRIAL

Trade-offs in control strategy; the active-placebo debate persists.

IN THE APPRAISAL

Wide uncertainty around the what the appraiser should price.

The therapy variable

IN THE TRIAL

“Drug + support” is not one fixed thing; it varies each session.

IN THE APPRAISAL

May not transfer to a real-world model that varies even more.

Follow-up duration

IN THE TRIAL

Primary endpoints sit at six to twelve weeks.

IN THE APPRAISAL

HTA must model five to ten years, sometimes a lifetime.

Functional unblinding was named in the FDA’s August 2024 complete response letter to Lykos (Resilience).

Who reaches Marieke first

Late-stage depression programmes, June 2026. COMP360 is the first potential access test.

COMPOUND	FOR	STAGE	STATUS	EARLIEST POTENTIAL EMA
COMP360 Psilocybin · Compass Pathways	TRD	**PHASE 3**	Both Phase 3 trials met endpoint. FDA rolling review plus priority voucher.	**2027–2028** NEAREST TO MARIEKE
PSIL301 Psilocybin · Usona Institute	MDD	**PHASE 3**	Phase 3 uAspire primary completion. FDA Breakthrough Therapy + priority voucher.	**2028-2029**
HLP003 / CYB003 Psilocybin · Helus (Cybin)	MDD	**PHASE 3**	Phase 3 PARADIGM dosing underway; APPROACH topline expected Q4 2026.	**2029–2030**
DT120 LSD · Definium (MindMed)	MDD & GAD	**PHASE 3**	Three Phase 3 readouts due across 2026.	**2029–2030**
BPL-003 5-MeO-DMT, nasal · AtaiBeckley	TRD	**PHASE 3**	Phase 3 starting Q2 2026; topline expected early 2029.	**2031+**
VLS-01 DMT, buccal film · AtaiBeckley	TRD	**PHASE 2**	Phase 2 topline expected H2 2026.	**2031+**
DiMension Psilocybin · MIND/SPRIN-D/Usona	TRD	**PHASE 2**	Phase 2 (EPIsoDE) completed, fundraising for Phase 3.	**2031+**
GH001 5-MeO-DMT, inhaled · GH Research	TRD	**PHASE 2**	Phase 2 completed and clinical hold for Phase 3 lifted.	**2031+**
GM-2505 Bretisilocin · Gilgamesh/AbbVie	MDD	**PHASE 2**	Phase 2a positive, asset acquired by AbbVie.	**2031+**

Four countries, four access clocks

Same European licence. Different national decisions before Marieke's first dose.

	Netherlands	Germany	United Kingdom	Czech Republic
ROUTE	EMA central, via ZiN	EMA central, via G-BA	MHRA recognition, via NICE or SMC	EMA central, via SÚKL
PRE-APPROVAL ROUTE	Compassionate use (very rare)	§73(3) named-patient (rare)	EAMS + ILAP passport	§16 exceptional reimbursement
DAYS TO ACCESS (Spravato)	**623** days (493 avg.)	**126** ONLY SUICIDAL IDEATION 158 days avg.	**Not rec.** (NICE) 350 days avg.	**494** Days (659 avg.)
SPRAVATO FOR TRD	Reimbursed 2021; pay-for-performance	Reimbursed 2023; 'considerable benefit'	No (England/Wales); yes in Scotland	Standard reimbursement

EFPIA Patients W.A.I.T. Indicator 2025; ZIN; G-BA; NICE TA854. "Days to access" is approval-to-patient for esketamine (Spravato), the closest precedent.

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GATE TWO · ASSESSMENT

Marieke hits the wall

She has the prescription. The clinic is ready. Her insurance still has no obligation to pay.

APPROVAL

Cleared. EMA licence in hand.

ASSESSMENT

ZiN advice pending; no package coverage yet.

PAYMENT

DELIVERY

Zorginstituut Nederland (ZiN)

She still cannot start.

Spravato took about 21 months from EU authorisation to Dutch reimbursement. Psychedelics face this gate next.

02

Three uncertainties ZiN must resolve

Fundamental questions that current trials can't answer (yet).

UNCERTAINTY ONE

Comparator

Compared against what?

Not first-line SSRIs.
Relevant comparison: augmentation, ECT, tranylcypromine, or Spravato.

01

UNCERTAINTY TWO

Durability

How long does it last?

Primary endpoint: Week 6.
ZIN has to model long-term costs and health gain. That bridge is uncertain.

02

UNCERTAINTY THREE

Budget impact

How many, at what cost?

Scenario, not guidance:
€10k x 2,000 patients/year
= €20M medicine spend.

03

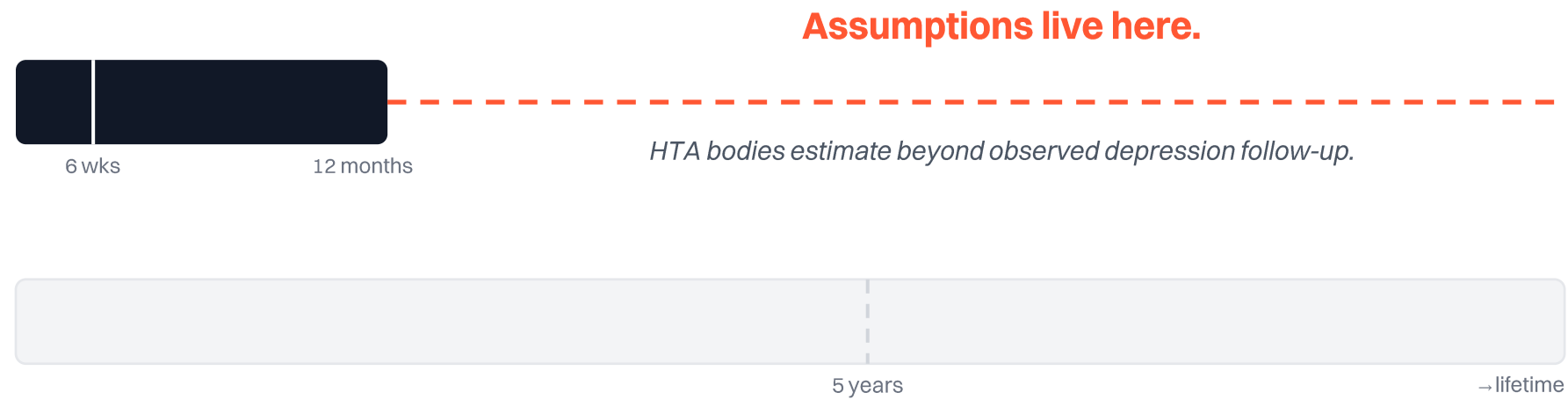
Each is a real scientific problem. **Each can slow a positive HTA decision by 18-24 months.**

Population and price are scenario assumptions; Dutch sluis thresholds count medicine costs only.

ZiN economic guideline; ZiN sluis procedure; COMPASS releases.

Trials end. HTA decisions don't.

Trial endpoints and HTA model horizons are different kinds of time.



Primary endpoint: Week 6. Current depression follow-up reaches about 12 months. **That gap is the appraisal challenge.**

Four countries, four HTA postures

The same Phase 3 data. Four bodies weigh it differently, and reach different verdicts.

	Netherlands	Germany	United Kingdom	Czech Republic
HTA BODY	ZiN	G-BA / IQWiG	NICE; SMC (Scotland)	SÚKL
COMPARATOR	Standard of care (contested)	Strict; most-used therapy	NHS clinical pathway	Flexible, case-by-case
VALUE FRAMEWORK	Broad: societal (productivity, care)	Clinical benefit first	Narrow: ICER / QALY	Less formalised
PRICING TRIGGER	'Sluis' above €10M impact	Free 6 months, then negotiated	Cost-effectiveness threshold; commercial agreement	Insurer negotiation
SPRAVATO FOR TRD	**Reimbursed 2021 (step 4)**	**'Considerable benefit' 2023**	**No (Eng/Wales); yes (Scotland)**	**Standard reimbursement**

Spravato precedent and national HTA pathway summaries.

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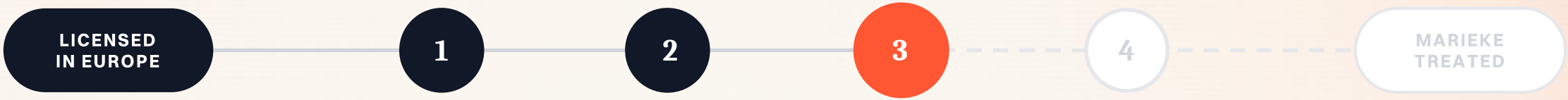
GATE THREE · PAYMENT

Who actually pays for what

Assume ZiN has said yes and the insurer must pay. Pay whom, for what, against which code?



APPROVAL

Cleared. EMA licence in hand.

ASSESSMENT

Cleared. ZiN has positively assessed her treatment.

PAYMENT

Who is going to pay; for what part of the treatment?

Insurance Company (Payer)

DELIVERY

She still cannot start.

Even if there is a positive evaluation, the healthcare payer system is not ready yet for a psychedelic treatment.

03

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GATE THREE · PAYMENT

Who actually pays for what

NO CLEAN PAYMENT ROUTE

SCREENING	PREPARATION	DOSING DAY	INTEGRATION	FOLLOW-UP
1–2h Psychiatrist	2 sessions Therapist	6–8h 2 therapists	3 sessions Therapist	6+ months Psychiatrist
Routine GGZ consult	No clean route	No clean route	No clean route	Routine GGZ consult

A positive HTA decision can coexist with a system that **does not yet cleanly pay for the full treatment.**

The drug can use an add-on route. Routine GGZ consults exist. The 6-8h, two-therapist dosing day is the mismatch.

Three payment options to explore before approval

The tools exist. The psychedelic version is still to be negotiated.

MOVE ONE

Performance-linked price agreement

Payment or rebate tied to measured response.

WHY IT FITS

Shares relapse, durability, and retreatment risk after launch.

PRECEDENT

ZiN Spravato: pay-for-performance / pay-for-proof logic.

MOVE TWO

Whole-pathway episode payment

One payment covers drug + delivery.

WHY IT FITS

Solves the drug-vs-care split.

PRECEDENT

Dutch bundled care; NHS episode-payment logic.

MOVE THREE

Managed access with evidence generation

Pays for registry + relapse monitoring.

WHY IT FITS

Turns uncertainty into an HTA-ready data plan.

PRECEDENT

NICE managed access / CDF-style evidence generation.

None of these is new. **The work before approval is design and negotiation, not invention.**

Four countries, four billing realities

The medicine can be paid for everywhere. Paying for everything around it is the hard part.

	Netherlands	Germany	United Kingdom	Czech Republic
PAYMENT ARCHITECTURE	ZPM consults + Zvw drug route	EBM / DRG + AMNOG	NHS Payment Scheme + relevant commissioner	MoH decree + insurer contracts
DRUG FUNDING	**Basic package; financial arrangement**	**AMNOG reimbursement price**	**NICE funding mandate; local funding flow**	**SÚKL reimbursement; insurer payment**
BUNDLING CAPABILITY	**No dedicated PAT bundle**	**EBM/OPS code gap; NUB bridge**	**New service/care-pathway currency needed**	**Procedure code + payer contracting**
SPRAVATO DELIVERY	Reimbursed; contracted specialist centres	SHI reimbursed; specialist settings	Private (E&W); NHS Scotland	Reimbursed; admin code exists
LOCAL VARIATION	Insurer contracting + centre access	National SHI; provider uptake variation	High implementation variation	Concentrated payers; access variation

The drug route is solvable. **The care bundle still has to be built.**

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GATE FOUR · DELIVERY

Marieke needs somewhere to go

A clinic that delivers it, a clinician trained to provide it, and a referral path to the door.

LICENSED IN EUROPE — 1 APPROVAL — 2 ASSESSMENT — 3 PAYMENT — 4 DELIVERY — MARIEKE TREATED

APPROVAL

Cleared. EMA licence in hand.

ASSESSMENT

Cleared. ZiN has positively assessed her treatment.

PAYMENT

Cleared. Payment is secured for the full episode of care.

DELIVERY

Where to go? Who provides treatment? Who trains the providers?

Healthcare

She still cannot start.

All the money questions are solved, but how do we get the right people together, in the right place?

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GATE FOUR · DELIVERY

Marieke needs somewhere to go

- Trial sites today: UMC Utrecht, Groningen, Leiden
- Possible ketamine-infrastructure sites & psychedelic-trained GGZ
- Marieke (UMC Utrecht catchment)

3–14

PAT-capable sites at launch

30,000–40,000

Dutch adults with TRD at any given time

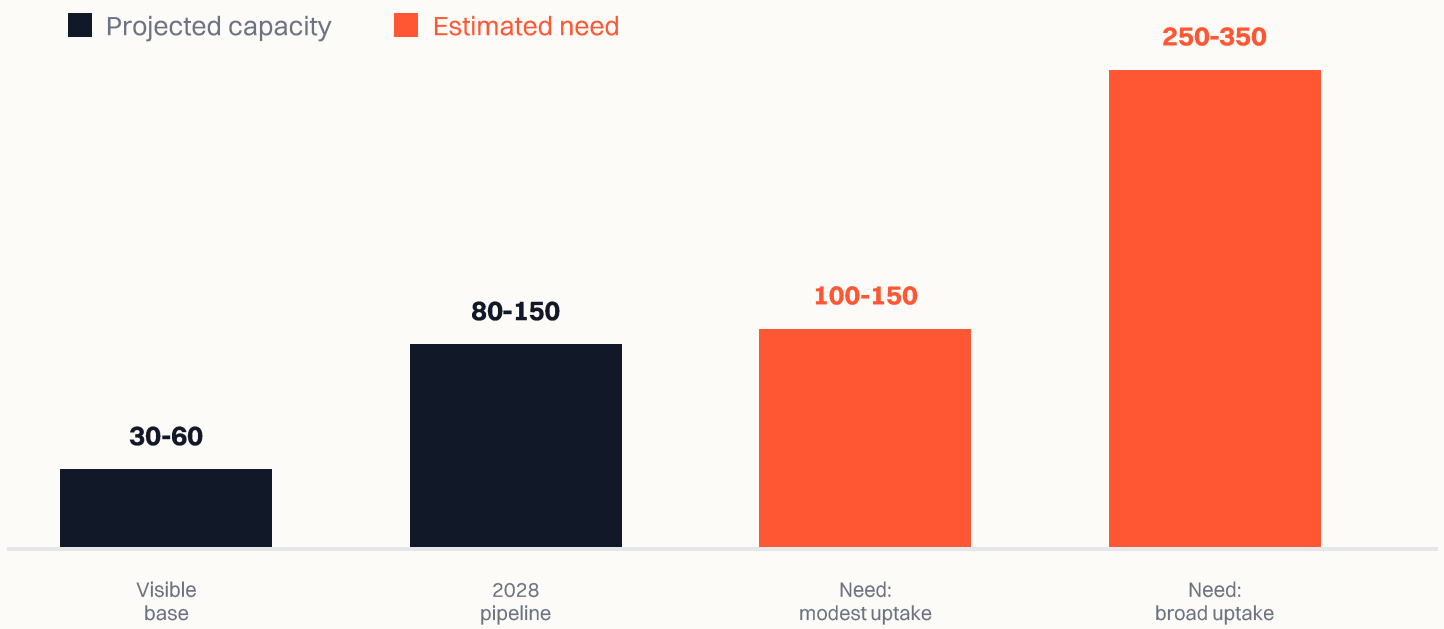
04

Capacity is the binding constraint

Scenario model: clinically deployable PAT capacity in the Netherlands.

4-8x

more clinically deployable staff needed for broad access



Assumptions: trial sites, training pipeline, protocol staffing, TRD scenario.

Training exists. Accountability still must be built.

The missing layer is standards, supervision, and accountable roles.

Training

Who provides the (therapist) training?

OPEN Foundation (ADEPT)
Compass protocol training (e.g. Fluence)
MIND Foundation (APT)
Pharmacists, nurses, etc.
Other private trainings

01

Certification

Who approves and certifies?

NVvP platform + guidance (no PAT cred.)
BIG professional register
Protocol-specific certification
No settled PAT credential

02

Responsibility

Who is responsible at which stage?

Clinic governance (medical doctor)
Treating psychiatrist
Protocol therapist
Payer responsible just for payment

03

Three solvable coordination problems. ECT, EMDR, and DBT all became credentialed specialisms the same way. None of these is solved yet.

In the Netherlands care is already being delivered

It can absorb some demand, but not Marieke's reimbursed clinical pathway.

MORE SUPERVISED — MORE RISK

Professional, clinical(-adjacent)

WHAT IT IS

Spravato (hospital + GGZ)
Off-label ketamine care (hospital + GGZ)
Psychiatry-linked screening
Clinician-led coaching

NOT PAT

(semi-)Professional, non-clinical

WHAT IT IS

Legal truffle retreats
Guild-of-Guides coaching
Group ceremonies

CAN'T 'TREAT' INDICATIONS

Personal and underground

WHAT IT IS

Self-administration (legal + illegal)
Illegal substances 'therapy'
Party-context psychedelic use
Research chemicals

HIGHEST RISK

MISSING LANE

Reimbursed, protocolised, clinically accountable psilocybin-assisted therapy

Four countries, four delivery realities

Scale, visibility, academic depth, and flexibility are not the same kind of readiness.

	Netherlands	Germany	United Kingdom	Czech Republic
TRAINED CLINICIANS (working estimate)	30–60 active	100–200 active	50–100 active	20–40 active
TRAINING INFRASTRUCTURE	OPEN ADEPT + retreat ecosystem	MIND APT + OVID/CIMH	Imperial/KCL trial training	Psyon + NUDZ/PSIKET
DEDICATED SETTINGS	Academic sites + retreats/ketamine	Research/EAP sites; fragmented	Research sites; private ketamine	Psyon + NUDZ; psilocybin route emerging
GREY-AREA LANDSCAPE	Large legal truffle market	Underground; small EAP channel	Abroad/underground; ketamine separate	Less grey; regulated route emerging
PRE-LICENSURE ACCESS	Legal truffles; no medical psilocybin	Psilocybin EAP; exceptional	No psilocybin/MDMA access; trials only	**2026 psilocybin route (§16); rollout pending**

Same future drug. Four different starting positions, and **four different scale-up trajectories.**

PART THREE · THE AGENDA

Who does what, by when

	PRE-LAUNCH	AT LAUNCH	POST-LAUNCH	ALL PHASES continuous
Drug developers	**Comparator + durability trials**	Managed-entry pricing	Long-term registry data	Engage HTA early
Regulators	**Combination-product guidance**	Conditional approvals	Post-authorisation safety	Multi-stakeholder workshops
HTA bodies	**Tailored methodology**	Managed-entry decisions	Real-world reassessment	Cross-border alignment
Payers / insurers	**Pre-launch dialogue**	Bundled + outcome-based pay	Long-term management	Risk-sharing
Professional bodies	**Define core competencies**	Activate credentialing	Continuing education	Supervision + ethics
Providers / clinics	**Site + protocol readiness**	Workforce + billing	Outcomes capture	Patient-centred design
Independent researchers	**Comparator + durability studies**	Real-world evidence base	Long-term effectiveness	Push for state funding
Patient advocates	**Trial-design input**	Education, stigma	Equity monitoring	Public communication

Five actions to elevate

The highest-leverage moves, pulled out of the grid. Each one shortens Marieke's wait.

1

Parallel HTA / payer evidence advice

WHY

Locks comparator, endpoints, durability, and resource-use capture before Phase 3

PRECEDENT

EMA–HTA parallel advice; EU JSC

2

Whole-pathway payment pilots

WHY

Pays the care episode, not just the medicine

PRECEDENT

Dutch chronic-care bundles; NHS best-practice tariffs

3

National training standards

WHY

Converts trained therapists into reimbursable clinical capacity

PRECEDENT

ECTAS; EMDR/DBT credentialing

4

National access implementation platform

WHY

Aligns regulators, payers, providers, training bodies, and patients

PRECEDENT

WHO/Europe Access to Novel Medicines Platform

5

Interdisciplinary research

WHY

Generates evidence pharma will underproduce

PRECEDENT

Health~Holland, ZonMW, HORIZON

All five exist as concepts. **Need to be executed for psychedelics in Europe.**

36 months to Marieke's first dose

From today (ICPR 2026) to first reimbursed treatment, mid-2029. The optimistic case, with no slippage.

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Same diagnosis. Same country. Same year.

Marieke at 50, three years from today. Two futures.

REIMBURSED PATHWAY

UMC Utrecht · 2029

€0

covered by insurance

Insurance covered the medicine, preparation, dosing day and integration. A six-month follow-up. Back teaching by new school year.

SELF-PAY PATHWAY

Self-pay retreat, Brabant · 2029

€4k-5k

self-pay example

Careful work, but not a clinical service. No screening for her treatment history, and no psychiatric follow-up. Her Altrecht team does not know.

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Approval ≠ access

*The next three years decide which Europe **Marieke** gets.*

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Full report → psychedelicsandreimbursement.com

Road to Access → moreblossom.com/implementation

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