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PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

LEGAL STATUS OF PSYCHEDELICS AND IMPACT IN RESEARCH AND DEVELOPMENT

EMA multi-stakeholder workshop on psychedelics – Towards an EU regulatory framework

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PAREA, Founder and Executive Director

COI

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Tadeusz Hawrot: I have no conflicts of interest to disclose

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A COLLECTIVE VOICE

& one-stop-shop in Europe

FULL MEMBERS

ECL Association of European Cancer Leagues

BECKLEY FOUNDATION

EBC European Brain Council

ecnp Neuroscience applied

EFNA EUROPEAN FEDERATION OF NEUROLOGICAL ASSOCIATIONS

ΨEPA

Drug Science

GAMIAN-EUROPE

MIND FOUNDATION

OPEN FOUNDATION

norrsken mind

Pain Alliance Europe

PsyPAN Psychedelic Participant Advocacy Network

ASSOCIATE MEMBERS & OBSERVERS

LAW ENFORCEMENT ACTION PARTNERSHIP
ADVANCING JUSTICE AND PUBLIC SAFETY SOLUTIONS

ICEERS

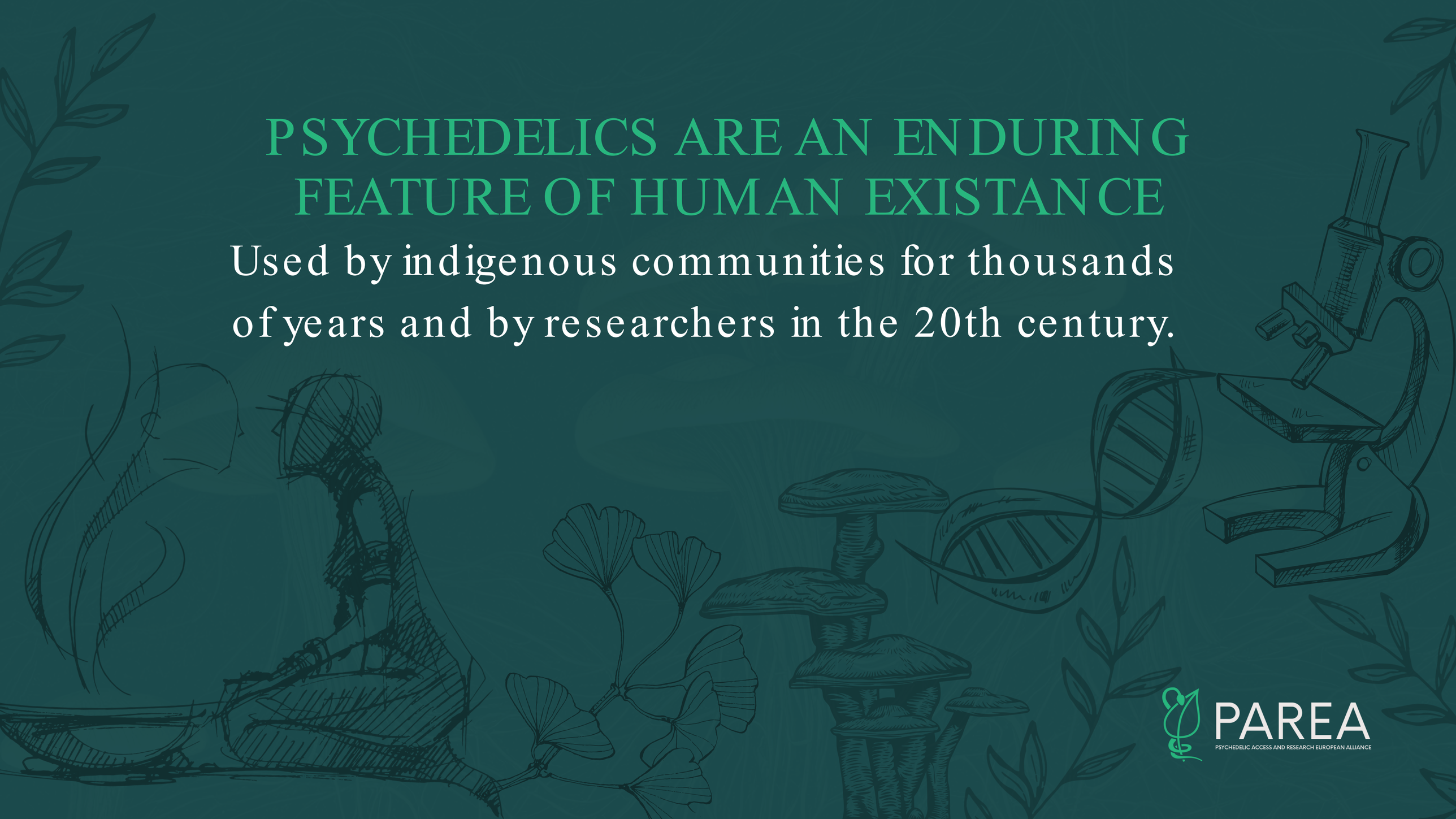
INDUSTRY PARTNERS

Cybin

MindMed

PSYCHEDELICS ARE AN ENDURING FEATURE OF HUMAN EXISTANCE

Used by indigenous communities for thousands of years and by researchers in the 20th century.



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SCIENTIFIC RESEARCH STOPPED WITH SCHEDULING

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Single Convention on Narcotic Drugs
New York, 1961

Convention on Psychotropic Substances
Vienna, 1971

Convention Against Illicit Traffic in Narcotic and Psychotropic Substances
Vienna, 1988

Control and limit the use of narcotic and psychotropic drugs according to their therapeutic value, risk of abuse and health dangers

Minimise the diversion of precursor chemicals to illegal drug manufacturers

"Drugs won the war on drugs"

Art Carden

Prof. of Economics

CONTROL OF PSYCHOTROPIC SUBSTANCES

"As a researcher, I always hesitate to go into doing research with Schedule I drugs. I do research in human subjects [and] it's much more cumbersome"

Dr. Nora Volkow, NIDA

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- 1971 UN Convention on Psychotropic Substances places psychotropic drugs under international control, with usage limited to medical and scientific needs.
- It established 4 Schedules for control, with Schedule I being the strictest.
- The reasoning behind classifying these psychedelics in Schedule I is not fully transparent – might be driven more by political motives and prejudices.

Schedules	Harmfulness	Degree of control	Examples of listed drugs
I	Substances presenting a high risk of abuse, posing a particularly, serious threat to public health which are of very little or no therapeutic value	Very strict; use is prohibited except for scientific or limited medical purposes	LSD, MDMA (ecstasy), mescaline, psilocybine, tetrahydrocannabinol
II	Substances presenting a risk of abuse, posing a serious threat to public health which are of low or moderate therapeutic value	Less strict	Amphetamines and amphetamine-type stimulants
III	Substances presenting a risk of abuse, posing a serious threat to public health which are of moderate or high therapeutic value	These substances are available for medical purposes	Barbiturates, including amobarbital, buprenorphine
IV	Substances presenting a risk of abuse, posing a minor threat to public health with a high therapeutic value	These substances are available for medical purposes	Tranquillisers, analgesics, narcotics, including allobarbital, diazepam, lorazepam, phenobarbital, temazepam

BEFORE SCHEDULING

Evidence of efficacy and safety pooled analyses in the 1960s

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Example of clinical interest in LSD in the 1950s & 1960s

- Hundreds of psychiatrists worldwide
- 140 NIH grants
- 1000 clinical papers
- 40,000 patients
- 40 books
- 6 International Conferences

Showing promising results

(Masters and Houston, 1971)

Confirmed by new work in the 2000s

Many thousands of treatments given in research studies

> “The worst censorship of any research in the history of the world”
>
> Prof. David Nutt
>
> Prof. in neuropsychopharmacology

POST SCHEDULING

Psychedelic research went into DEEP FREEZE

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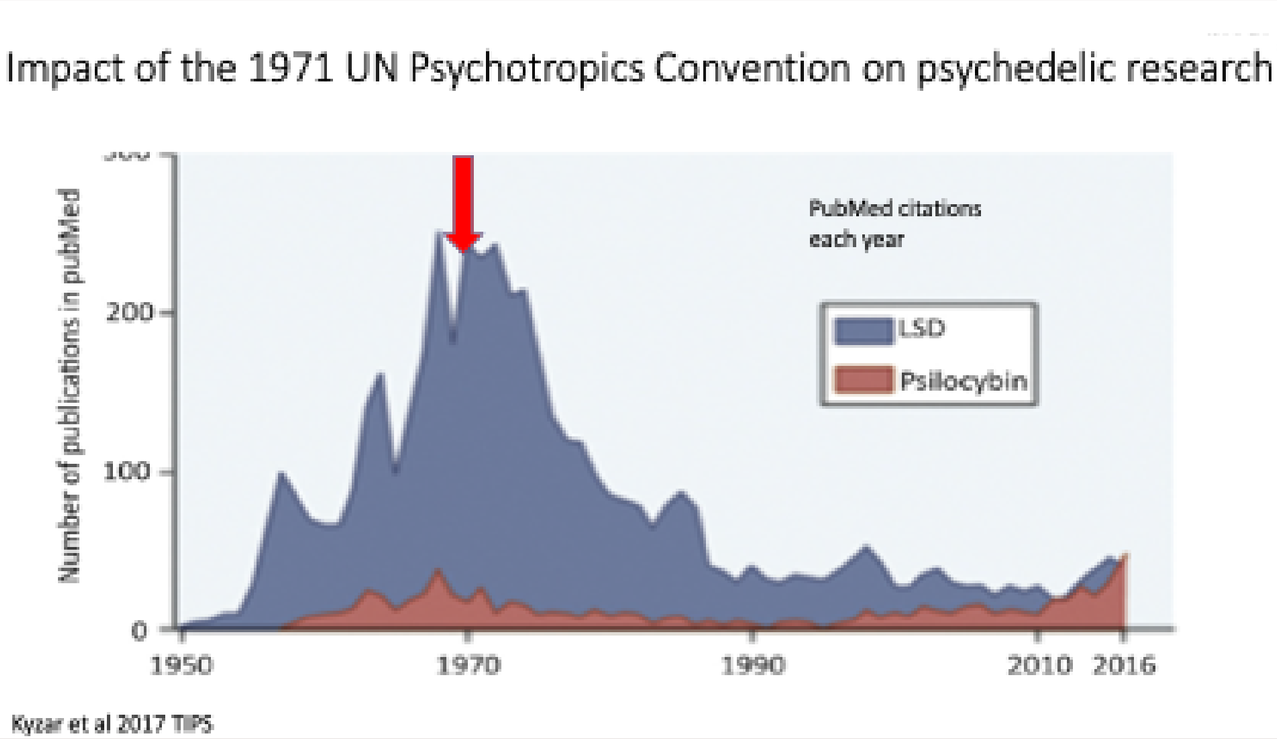

"Millions of people across the world continue to suffer because of inadequate access to and availability of controlled medicines. In many communities, illicit drugs are available; controlled medicines are not. This leads us to conclude that the international drug control system as it is currently applied needs rethinking based on concrete evidence"

Joint statement of 62 countries (including 27 EU MS) UN CND, 14 March 2024 calling for the reform of the international drug control system.

* Other reasons included Sandoz reducing access to LSD due to concerns related to black market circulation.

THE EU SYSTEM

The EU does not have its own classification for illicit drugs. It has specific regulations in place to control them:

- Schengen Agreement (2000) MS should harmonize laws and regulations, including on narcotic drugs
- Regulation (EC) No 273/2004: Governs the intra-EU trade of drug precursors.
- Regulation (EC) No 111/2005: Sets out the rules for monitoring trade between EU countries and non-EU countries in drug precursors.
- Both regulations have been updated by amendments in 2013 to enhance control and trade monitoring.

Programmatic instruments - need to be transposed into domestic law by each MS - any restrictions to use of drugs, including therapeutic/research use of psychedelics, are provisioned in national legal frameworks

The provisions in the EU regarding substances in Schedule I provide for a level of regulatory control and supervision that is substantially more onerous than for drugs under Schedules II - IV.

”

Our first psilocybin depression trial took 32 months to get permissions to buy and import psilocybin for al largely due to regulations”

David Nutt

Prof. in neuropsychopharmacology

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by the European Medicines Agency

BARRIERS

to research and medical use of schedule-I substances

> “DOI is a gateway drug, in a scientific way”

Mario de la Fuente

PhD in Medicinal Chemistry

(DEA currently attempts to place a psychedelic DOI in Schedule I)

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LEGAL IMBALANCE It takes minimal anecdotal evidence for substances to be classified under schedule I, yet extensive phase 3 CT data necessary to reconsider

- The only currently active rescheduling pathway is through the regulatory approval process.

SCIENTIFIC COLLABORATION Scheduling interferes with collaboration which is foundation to scientific research.

FINANCING AND PATENTS Large scale trials with schedule-I substances cannot typically be paid by public funds. Therefore, industry and private donors fund these trials.

- The system favors well-resourced players rather than academic researchers, let alone Indigenous communities.

- This leads to patentable and potentially expensive synthetic substances over less expensive naturally occurring generics. Patents make it more complicated for academic researchers to study those products. It skews pharma environment and hinders research breadth.

BARRIERS

contd...

> “DOI’s current legal status and subsequent accessibility is the reason our scientific community has been able to advance the understanding of serotonin receptor activity”

Alyssa Gillies

Molecular Synthesis Student

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PUBLIC FUNDING Scheduling has a drastic impact on the availability of funding. The usual governmental grants are typically unavailable.

RESEARCH POTENTIAL Even if a substance lacks obvious medical use, affordable research could uncover new therapeutic knowledge without the need for the substance to be sold commercially.

BIFURCATED SCHEDULING If a psychedelic receives an approval, only that specific form and method of use might be reclassified. Unapproved versions would stay in Schedule I. This could lead researchers to prefer approved forms, while the owning company might limit or control the use of research data.

BEYOND RESEARCH Scheduling restricts researchers and therapists from giving harm-reduction advice to people who are determined to seek psychedelic therapy after trials. It subjects individuals seeking potentially the only effective treatment for their intractable conditions to the threat of criminal charges.

CONCLUSIONS

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- Scheduling is a barrier that hampers research, artificially restricts clinical trial enrolment, stifles competition and innovation, and inhibits access. All this amid a worsening mental health crisis.
- Scheduling breaches the principle that science should be independent from political intervention.
- It limits who can successfully pursue the research needed to achieve regulatory approval putting non-industry scientists at a disadvantage.

Rescheduling would have a very specific effect: benefiting scientific researchers. The law change would have no effect on psychedelics availability or use in a recreational context.

> “Scheduling does not prevent the harms associated with substance use. Scheduling hasn't prevented opioid overdose deaths. I don't know that there's any evidence to suggest that scheduling improves safety in any meaningful way. It does, however, inhibit the ability to do research”

Mason Marks
Health Law Professor

BEYOND SCHEDULING: EU POLICY RECOMMENDATIONS

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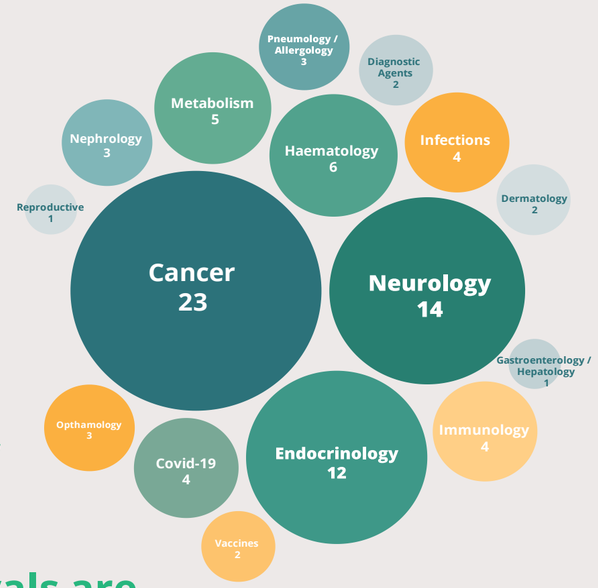
We are in a mental health crises coupled with a decades-long innovation stagnation:

In 2022, out of the 89 new medicines recommended for approval by the EMA

Not a single one targeted mental health conditions.



We need to support/steer innovation towards areas where it can generate the greatest added value such as mental health, where true innovation finally started taking place but

- Psychedelic drug developers focus on the US market, **no approvals are in sight in the EU.** To catalyze innovation, a shift needed towards a more supportive regulatory framework. This could encompass:
  - **Incentives such as regulatory protection**
  - **Enhanced EMA support, PRIME**
  - **Accelerated assessments, CMA, adaptive pathways**
  - **More predictable reimbursement environment**

ADDITIONAL ENABLERS

- Creation of a **European Hub for Mental Health R&D**
- Amplify **EU-funded research.**
- **Embrace RWE** to bolster pre- and post-authorisation evidence generation and evaluations.
- **Increased role of patients and their representatives** in the procedures of new products' assessments.

EU Commission On Novel Mental Health Therapies

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Supporting the transition from CTs to national HC settings :
Mechanism needed for structured collaboration to build an infrastructure and expertise for safe and equitable access.

- **A pan -European multidisciplinary advisory body or commission on novel therapies to combat the mental health crisis is needed** → establish a comprehensive framework for psychedelic care models, addressing standards of care, training and licensing, ethical guidelines, safety standards, etc. This synergistic approach would unify MS' efforts, rather than have countries addressing one by one the same issues.

- This **collaborative effort** could be supported by an EU4Health project (e.g. an EU-led JA), EMA pilot, EU Expert Group on Public Health subgroup, European Mission/ Partnership on Innovative Mental Health Treatments as part of the next R&I FP, and an EU high-level conference.

The EMA is ideally positioned to stimulate these efforts.

Thank you for your attention

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