



Psilo
Nautica



Drug
Science

Public Attitudes to Psilocybin-Assisted Therapy



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1. Foreword

PsiloNautica

PsiloNautica is the UK's first psychedelic-focused think-tank, supporting the future of psychedelic medicine and integrated therapy. PsiloNautica was born out of frustration that psychedelic-assisted psychotherapy is increasingly recognised by the scientific community as a powerful tool to fight difficult-to-treat mental health conditions, while governments continue to stymie potentially life-changing research and treatment by imposing restrictions on use that are completely at odds with the harm profile of drugs like psilocybin, MDMA and LSD.

Drawing from experience in medical psychedelic regulation, drug policy and ethics, PsiloNautica works in concert with stakeholders in the psychedelic space to undertake project-specific work that addresses critical research questions, and nurtures the growth of a principled, patient-centred industry.

We are pleased to present our first public report in collaboration with Drug Science: findings from our YouGov poll, commissioned in May 2021, to explore the public's attitudes towards reforming psilocybin policy in the UK. The results speak for themselves, and will be of interest to everyone invested in the future of mental healthcare.

Eddie Jacobs

Director of Research

Drug Science

Drug Science works to provide an evidence base free from political or commercial influence, creating the foundation for sensible and effective drug laws, and equipping the public, media and policy makers with the knowledge and resources to enact positive change.

Founded in 2010 by Professor David Nutt following his removal from his post as Chair of the Advisory Council on the Misuse of Drugs, Drug Science is the only completely independent, science-led drugs charity, uniquely bringing together leading drugs experts from a wide range of specialisms to carry out ground-breaking research into drug harms and effects.

The Scientific Committee play a vital role in society, providing the public in the UK and internationally with high quality, scientifically based information on drugs and evidence-based comment and analysis of new research. Led by founder Professor David Nutt, the committee is made up of the UK's most accomplished, respected and authoritative individuals in science, academia and policy, united with a passionate belief that the pursuit of knowledge should remain free of all political and commercial interest.

Together, they work tirelessly to emphasise the role of science in the public discourse, providing information on the actual harms and benefits of various drugs, and challenging the myths that surround drug classification and legislation in the UK. Drug Science's mission is founded on their efforts, and their many hours of work delivering, reviewing and investigating scientific evidence relating to psychoactive drugs, with one single minded message – to tell the truth about drugs.

2. Executive Summary

Mental health conditions remain the single largest cause of disability in the UK, representing not only a significant source of distress and suffering, but are also responsible for a wider economic cost estimated at more than

£100 billion per year.

Our first line treatments for a number of mental health conditions, pharmaceutical antidepressants, cost the NHS nearly **£650,000** every day, despite high levels of incomplete response or non-response, and unpleasant side-effects that reduce patient adherence.

Therapy assisted by psilocybin, the psychedelic component of 'magic mushrooms', is increasingly being recognised as a radically novel treatment option that could meet this treatment gap.



Contemporary trials have been completed with psilocybin showing extraordinarily strong efficacy and therapeutic potential when administered to patients with some of the most difficult-to-treat mental health conditions. Psilocybin-assisted therapy works in a wholly different way to antidepressants, not by numbing symptoms, but by allowing patients to more easily access, address, and emotionally metabolise the sources of their distress.

Historical judgements about psilocybin's potential for harm have been clearly demonstrated to be incorrect.

This resulted in psilocybin being subjected to the tightest controls permissible under UK drugs laws - Class A of the Misuse of Drugs Act 1971, and Schedule 1 of the Misuse of Drugs Regulations 2001.

While research with Schedule 1 drugs remains technically legal, the bureaucratic delays, financial burdens, and myriad regulations associated with this status inordinately raise the barriers to performing research with psilocybin. As such, only a few of the most well-resourced and doggedly determined scientists are able to overcome the additional obstacles put in place by its Schedule 1 status.



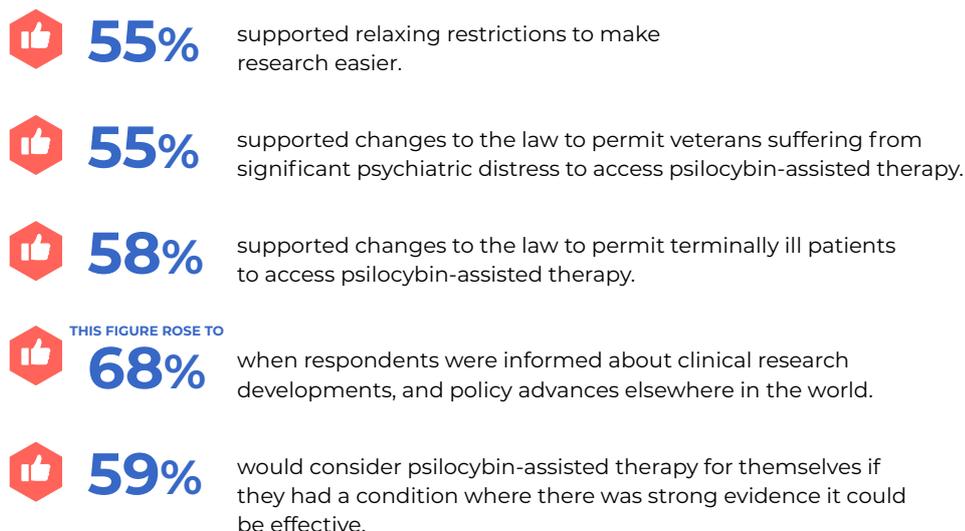
In May 2021, PsiloNautica, working with Drug Science, launched the first nationally representative poll of UK attitudes towards the medicalisation of psilocybin and support for policy changes to make this happen.



PsiloNautica worked in collaboration with YouGov to ask 1,763 adults, representing all demographics and regions of the UK, questions about psilocybin-assisted therapy: **for researchers, for patients with exceptional clinical need, and for themselves.**



We found majority levels of support across all regions, demographics, and political groupings for reform to psilocybin policy. Nationwide:



- Moving psilocybin to Schedule 2 of the Misuse of Drugs Regulations would mean that hospitals and research departments still had to secure, oversee, and administer it with as much care as they have to treat far more harmful drugs like heroin and cocaine. But this shift in status would make potentially life-transforming clinical research with psilocybin **vastly** quicker and more streamlined, ultimately allowing it to reach patients in need. Both of the patient groups identified in the survey need immediate intervention as the current treatment options are not meeting the clinical need within these cohorts.
- The potential risk of moving psilocybin to Schedule 2 would be a proliferation of inappropriate prescribing in the private sector, with some actors seeking to capitalise on the increasing media attention around psilocybin by making it available for treatment at a wide-scale, in advance of the marketing authorisation that all new drugs are ultimately required to secure.
- Moving psilocybin to Schedule 2 with restrictions, for now, to use only within legitimate research studies would still allow patients with exceptional clinical need to access psilocybin-assisted therapy. Without the restrictions of Schedule 1 status, researchers will be better able to recruit such patients into tailored open-label trials to explore the potential for psilocybin-assisted therapy to effectively treat them. Both veterans and terminally ill patients are populations with complex psychiatric distress who respond poorly to the currently available conventional treatments. Such research would provide valuable early clinical data to guide the further development of psilocybin-based treatments, supporting the evidentiary case for funding from grant-making research sponsors and industry.
- Politicians across the political spectrum have been calling for psilocybin rescheduling for some time. Scientists, obstructed from pursuing vitally important research by Schedule 1 restrictions have urged for the same. The release of this report is confirmation that doing so would be a politically safe move. In the context of a political discourse that has become increasingly polarised, it is striking that every age group and region of the UK, and majorities of 2019 voters for each of England's three main parties, support changes to the law. It is time for the Home Secretary to act. It is time to reschedule psilocybin.
- In line with statutory procedure, we call upon the Home Secretary to commission the Advisory Council on the Misuse of Drugs to review the scheduling of psilocybin, with a commitment to act on its recommendations.

3. Introduction

Mental health conditions, chiefly depression and anxiety, remain significant sources of distress and suffering in the UK, with a fifth of men and a third of women having received a diagnosis at some point in their livesⁱ. As well as significantly impairing quality of life and social functioning, depression is a major contributor to suicide, itself the leading cause of death for men under 50 and women from 20-34ⁱⁱ. Mental health conditions are not only the single largest cause of disability in the UKⁱⁱⁱ, but also incur wider economic costs -including direct costs of services, lost productivity at work, and reduced quality of life - that have been estimated at more than £100 billion each year^{iv}.

The growth in mental health diagnoses in the last two decades has been matched by an increasing reliance on antidepressant medication^v. Antidepressant drugs, chiefly among them selective serotonin reuptake inhibitors (SSRIs), are prescribed for a range of conditions in addition to depression, and in 2017 the NHS in England spent approximately £644,000 a day on them^{vi}. Although SSRIs can reduce depression symptoms in many who take them^{vii}, and are sometimes very effective, they can take several weeks to work, and are associated with unpleasant side-effects and variable patient adherence^{viii}. Meanwhile, between 30-50% of patients fail to achieve a satisfactory reduction in symptoms, with as many as 30% experiencing no treatment response from two different antidepressants^{ix, x}.

The Berlin Wall was still standing when SSRIs - the last substantive development in psychiatric medicine - were first licensed. There is a clear and urgent need to support the development of new, effective treatment options.

As recognised by increasing numbers of scientists, politicians, and members of the public, therapy assisted by psilocybin - the active, psychedelic component in 'magic mushrooms' - represents a radically novel treatment option for a number of mental health conditions, with significant potential to meet this urgent need.

Psilocybin-assisted therapy is understood to treat mental health conditions in a wholly different way to traditional antidepressants^{xi}. Whereas a patient on SSRIs will standardly take daily tablets at home for weeks, months, or longer to support the suppression of symptoms, psilocybin is administered only a few times in a clinical setting, with the support of specially-trained therapists. The psychedelic 'trip' that psilocybin induces is thought to be key to treatment success, with the nature of the subjective experience often predicting treatment outcomes^{xii, xiii, xiv}. These experiences are not distracting, numbing, or merely pleasurable drug highs. Rather, they allow patients to more easily access, explore, and emotionally metabolise the sources of their psychiatric distress, as well as offering new insights into their traumas, relationships, and other problems they are facing. Patients in registered clinical trials often report the experience as one of the most meaningful of their lives.

Positive findings from clinical research into psychedelics like psilocybin and LSD were frequently reported after their discovery in the late 1950s and early 1960s. However, the moral panic and political backlash that followed these drugs' escape from the lab and into wider society, the hippie counterculture, and the anti-war left in the US, effectively led to a halting of a promising research programme, with the UK following in lockstep.

In the UK, these drugs were immediately placed into Class A of the new Misuse of Drugs Act 1971, ostensibly reserved for the most harmful of drugs. This was followed in 2001 by placement in Schedule 1 of the Misuse of Drugs Regulations, which dictates the rules and procedures for legitimate scientific and medical uses of otherwise controlled drugs.

Despite early press and media coverage emphasising that psychedelic drugs were associated with a range of harmful outcomes, population-level studies spanning different time periods confirm that use of psilocybin and LSD is actually associated with decreased rates of mental health problems, suicide and violent crime^{xv, xvi, xvii}. Although psychedelics like psilocybin and LSD have powerful subjective effects, meaning that they are best used with care and caution, they display very low physiological toxicity^{xviii, xix}, and addiction potential^{xx}. Moreover, the magic mushrooms in which psilocybin is found are ranked by experts and users alike as the least harmful of recreational drugs^{xxi, xxii}, and their use in uncontrolled recreational settings is associated with the lowest rate of emergency medical treatment call-outs^{xxiii}.

As such, the placement of psilocybin in Class A of the Misuse of Drugs Act, and Schedule 1 of the Misuse of Drugs Regulations, is at odds with scientific understanding about its associated risks of harm. The consequences for this misplacement are stark, and have been particularly damaging to clinical research.

Schedule 1 of the Misuse of Drugs Regulations imposes the strictest of controls on drugs that are deemed to be especially harmful and of no medical value. While working with Schedule 1 drugs remains technically legal, the bureaucratic delays, financial burdens, and myriad regulations associated with this status inordinately raise the barriers to performing research.

In the UK and the US, the most doggedly determined and well-resourced scientists have nonetheless managed to clear these barriers, and as a result have produced clinical evidence that gives serious cause for optimism. Trials of some of our most difficult-to-treat mental health conditions, including addiction^{xxiv, xxv}, treatment-resistant depression^{xxvi}, OCD^{xxvii}, and anxiety and depression secondary to life-threatening cancer^{xxviii, xix, xxx}, have found that psilocybin-assisted therapy can offer significant therapeutic benefit. In one study, treatment effects from a single dose have been recorded to persist as long as four and a half years, with the vast majority of patients attributing positive life changes to the experience^{xlvi}. On the strength of this evidence, the United States' Federal Drug Administration has granted psilocybin 'Breakthrough Therapy' designation, reserved for treatments for serious and life-threatening conditions with the potential to work substantially better than other available therapies. In Canada, the Minister for Health has granted exemptions for 28 terminally ill patients to access psilocybin-therapy.

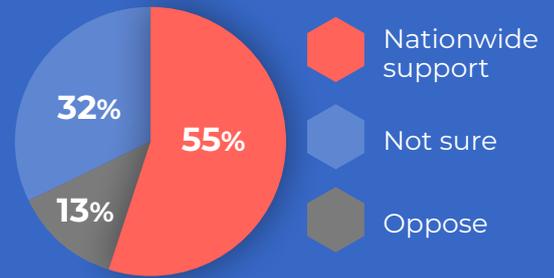
The scientific case for pursuing research into the medical use of psilocybin-assisted therapy has never been stronger. However, drug policy in the UK regrettably remains highly politicised, and is all-too-often not responsive to scientific evidence. In this political context, PsiloNautica and Drug Science sought to capture the British public's attitudes towards psilocybin-assisted therapies. In May 2021 we commissioned YouGov to run a nationally representative poll investigating three main areas:

- (i) support for easing the restrictions that currently hamper research into the benefits of psilocybin,
- (ii) support for permitting particular patient populations to access psilocybin-assisted therapies in controlled medical context, and
- (iii) the public's attitudes towards mental health treatment - how confident they would feel if offered conventional talk therapy or course of antidepressants, and how likely they would be to consider psilocybin-assisted therapy if offered

4. Key Findings

Support for Rescheduling

To what extent **would you support or oppose the government relaxing restrictions on research into the medical use of magic mushroom-based treatments** (psilocybin-assisted therapies) for mental health conditions if this didn't affect how it was classified in criminal law (e.g. as a class A drug)?



Support for relaxing research restrictions:



Country average

55%

London

52%

Rest of South

60%

Midlands & Wales

51%

North

52%

Scotland

55%

Northern Ireland

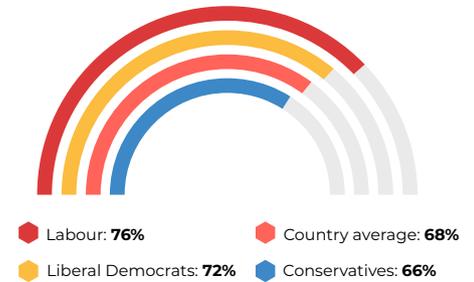
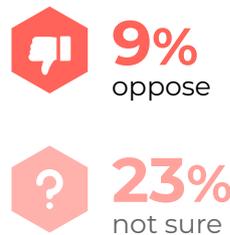
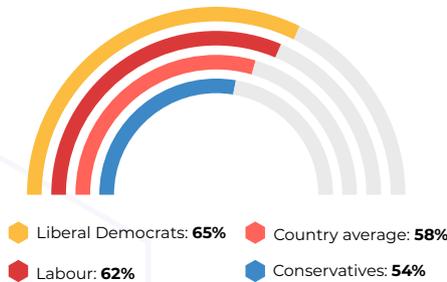
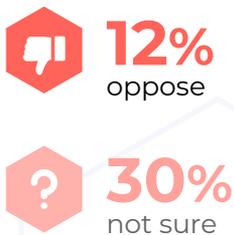
59%

Support for changing the law to allow people with terminal illnesses to access psilocybin-assisted therapy

58%

When informed about findings from clinical research, and moves to allow limited patient access in Canada, support jumped to

68%



59%

of Brits would consider psilocybin-assisted therapy if offered to them

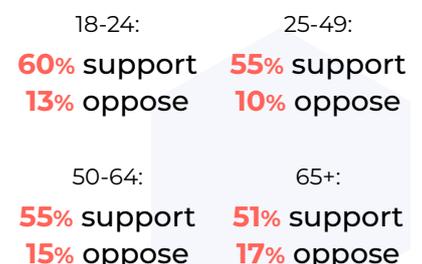


Changing the law to allow **military veterans suffering from psychiatric distress** to legally access psilocybin-assisted therapies

55% support



By age



4. Key Findings

- Majority support, across demographics, for relaxing research restrictions:

55% Support

15% Oppose

31% Not sure

- Majority support, across demographics, for changing the law to allow medical use of psilocybin-assisted therapy in:

Terminally ill patients 58%

Armed forces veterans 55%

- Support for access for terminally ill patients rises to **68%** when respondents are informed about research and policy developments in Europe and North America
- Most Brits (**59%**) would **'probably'** or **'definitely'** consider psilocybin-assisted therapy if they had a condition for which there was strong evidence it would be effective
- Among those unlikely to consider psilocybin-assisted therapy, significant numbers base their hesitance on misunderstanding (e.g., **24%** are worried about becoming addicted - in fact, psilocybin is not addictive, and psilocybin therapy involves just one or two doses)

5. Relaxing government research restrictions on psilocybin

The handful of clinical trials of psilocybin-assisted therapy that are underway in the UK are both fewer in number, and smaller in size than they might otherwise be, thanks to the inappropriate placement of psilocybin in Schedule 1 of the Misuse of Drugs Regulations (2001).

The five Schedules of the Misuse of Drugs Regulations, which govern the permissible uses of controlled drugs, impose increasing degrees of restrictions on scientists seeking to investigate drugs in research trials, and doctors wishing to administer them in clinical settings. Schedule 2 drugs, including heroin and cocaine, are subject to rigorous record keeping and storage requirements to minimise the risks of diversion and other harms, and can be held as a matter of course by both university research departments and hospital pharmacies. In comparison, a drug with Schedule 1 status can only be held with a controlled drugs licence from the Home Office. The downstream consequences for researchers seeking to investigate Schedule 1 drugs are enormous. The protracted licensing process, typically subject to lengthy delays, demands that all staff must be vetted, drugs must be kept in specially-manufactured safes and subject to 24-hour perimeter surveillance, as well as other extremely strict security requirements. The licence costs more than £3,000, and frequently takes months to be secured. For a single research trial, this licensing process must be undertaken separately by each stage in the supply chain, i.e.: the research department running the study, the dispensing pharmacy which bottles, labels, and delivers the drugs, the analytical company that tests and confirms the quality and purity of the drug, as well as the drug manufacturer. The excessive costs and administrative burden associated with these requirements, as well as frequent delays in the licensing process, drastically impede the research process.

In theory, Schedule 1 is reserved for drugs with no medical value and particularly high risk of harm or misuse. In reality, scientific consensus recognises that psilocybin does not cause dependence or addiction, and has significantly lower than Schedule 2 drugs like heroin, cocaine, and methamphetamine. Meanwhile the US Federal Drugs Administration has awarded psilocybin 'Breakthrough Therapy' designation given its potential to treat major depressive disorder and treatment resistant depression.

When challenged about the significant extent to which Schedule 1 status hampers research into psilocybin in July 2020, the Home Office responded that

“The current classification of psilocybin under Schedule 1 does not prevent research or clinical trials under a Home Office licence.”

Such a response fails to engage with the realities that researchers face. The problem is not that psilocybin research is absolutely prohibited by law. The problem is that the excessive costs, delays, and administrative burdens associated with acquiring the multiple licences that are needed to run a single study artificially compound the entry barriers to pursuing legitimate, potentially life-saving research.

The YouGov/PsiloNautica poll found that the British public supports a shift from this status quo. When asked to consider whether the government should relax restrictions on research into the medical use of psilocybin-assisted therapies for mental health conditions, if this didn't change the status of psilocybin in criminal law, 55% of people supported such a move, with majority support in every region of the UK, and among Conservative, Labour, and Liberal Democrat voters alike. Resistance to relaxing research restrictions was low, with only 15% of people opposed, and 31% unsure.

Dr James Rucker, Head of the Psychedelic Trials Group at the King's College London, commented on the findings:

“It’s interesting to see from this poll that a majority of people questioned support a revision of current legislation towards controlled medical use and research with psilocybin... Schedule 1 restrictions hinder our efforts whilst being unlikely to provide any meaningful reduction in the risk of diversion, when compared to Schedule 2 restrictions. The UK has an internationally recognised reputation in developing new treatments. We have an opportunity to be world leaders here as well, if government acts to reclassify those treatments that are showing therapeutic promise into Schedule 2.”

Politicians from both major parties have called for change, with Jeff Smith MP, founder of the Labour Campaign for Drug Policy Reform, rejecting the boiler-plate response issued by the Home Office:

“While technically possible, it is extremely slow, difficult and expensive to attempt medical research into psilocybin while it remains in Schedule 1. Despite what the Home Office may claim, this scheduling is undeniably a huge barrier to research, as evidenced by how few studies have been able to take place over the last 50 years.”

MP for Reigate, Crispin Blunt, who chairs the Conservative Drug Policy Reform Group, said:

“In the here and now, psilocybin’s enduring placement in Schedule 1 makes it all but impossible for our researchers to conduct the calibre of research necessary to develop treatments that would alleviate the suffering of millions. Demurring on rescheduling psilocybin to enable treatment research not only flies in the face of a growing body of evidence refuting any justification for its current status, but is also against the will of a British public who have now evidenced their compassionate demand. But rescheduling is only the start. The government must now actively enable safe patient access to make up for the inexcusable delay policy unsupported by evidence has inflicted on suffering patients.”

The advantages to rescheduling psilocybin to facilitate research are clear. As well as lowering the costs of developing potentially life-changing treatments, thereby allowing psilocybin to become a licensed medicine more quickly, it also has the potential to support a world-leading industry. Alongside its major centres of psilocybin expertise at King's College London and Imperial College London, the UK would have the world's most supportive regulatory environment towards psilocybin research, capturing a significant portion of the global research budget - an outcome that would dovetail with the UK government's aims to support the Life Sciences as a major industry in the post-Brexit economic landscape.

6. Changing the law to allow medical access to psilocybin

Evidence continues to accrue that psilocybin-assisted therapy will be a viable treatment option in the future of mental health care. A recent study by Imperial College London, published in the *New England Journal of Medicine*, found that psilocybin-assisted therapy was as effective as the antidepressant escitalopram in relieving moderate to severe depression, but with faster reductions in symptoms, and higher remission rates by the end of the trial^{xxxvi}.

Early work has also provided positive signals for psilocybin's therapeutic efficacy in treating depression and anxiety secondary to life-threatening cancer, obsessive-compulsive disorder, treatment-resistant depression, alcohol use disorder, and tobacco addiction^{xxxvii, xxxviii, xxxix, xl, xli, xlii, xliii}.

Currently in the UK, the only legal route to accessing psilocybin-assisted therapy is through one of very few, limited-scale and oversubscribed, registered clinical trials. Although the introduction of large-scale, routine use of psilocybin-assisted therapy into the NHS should wait for the drug to be licensed at the conclusion of phase 3 clinical trials, there is already a strong scientific consensus that psilocybin is of very low toxicity, and is not associated with dependence or withdrawal. Nor have there been any serious adverse events reported in contemporary clinical trials with psilocybin, in which the drug was taken in a safe, controlled environment.

With this in mind, there are strong grounds for immediately allowing limited access to psilocybin-assisted therapy for some patients with exceptional clinical need, as is currently the case in Canada. For other unlicensed drugs that are not Schedule 1, there are well-established mechanisms for supplying medicines for specific patients as special medicinal products or 'specials'. In such cases, prescriptions must be written by a doctor on the Specialist Register of the General Medical Council, who expect that clinicians do not prescribe unlicensed medicines where they do not have expertise, as well as abiding by various professional codes of conduct. In addition, the prescription of 'specials' must be approved by the local NHS Trust and Clinical Commissioning Group. In effect, for any unlicensed drug to be prescribed to a specific patient, even where there is exceptional clinical need, the decision must be approved by many senior clinicians and decision-makers. Were psilocybin to be moved to Schedule 2 of the Misuse of Drugs regulations, institutional guardrails within the NHS would ensure that applications for treatment in advance of full licensing would be treated with the appropriate degree of caution.

One potential downside of an unrestricted move to Schedule 2 would be the risk of a proliferation of inappropriate prescribing within the private sector, with some actors seeking to capitalise on the increasing media attention around psilocybin by making it available for treatment at a wide-scale, in advance of the marketing authorisation that all new drugs are ultimately required to secure. Striking the balance between permitting greater access to patients with exceptional clinical need, while avoiding a growth of inappropriate prescribing, is achievable within the powers that the Home Secretary has used in recent memory. One approach to achieving this balance has been suggested before, in a 2020 report by the Adam Smith Institute and Conservative Drug Policy Reform Group^{xliv}.

By applying statutory limits to the Schedule 2 status of cannabis-based products for medicinal use (CBPM) in 2018, the Home Office was able to facilitate prescription of CBPMs while establishing additional controls against diversion and inappropriate prescribing. The rescheduling of psilocybin into Schedule 2 with research-specific restrictions, as proposed by the July 2020 report 'Medicinal Use of

Psilocybin - Reducing restriction on research and treatment', would remove obstructions to developing psilocybin as a licensed medicine, while supporting some limited access to patients.

Although contemporary evidence supporting psilocybin-assisted therapy is positive, the half-century in which research has been halted by excessive restrictions has left considerable gaps in our understanding of its clinical application in a wide variety of mental health conditions. But while psilocybin remains in Schedule 1, many clinical researchers wanting to explore its therapeutic properties cannot do so, with smaller, exploratory trials financially infeasible due to the associated costs. Moving psilocybin to Schedule 2, even with research-specific restrictions, will dramatically reduce the barriers to entry to perform exploratory, first-in-patient open-label trials in small numbers of patients. Not only could this afford access to those who have not been helped by conventional treatment options, it would also provide valuable early clinical data to guide the further development of psilocybin-based treatments, supporting the evidentiary case for funding from grant-making research sponsors and industry.

Professor Allan Young, Director of the Centre for Affective Disorders at the Institute of Psychiatry, Psychology and Neuroscience at King's College London, acknowledged the current treatment gap, saying:

“People with severe mental health problems are in desperate need of more effective treatment. One way to help this come about would be to change law to increase the possibility of research to evaluate the benefits and harms of psilocybin.”

Our research found that, in addition to supporting the relaxation of research measures, a substantial majority of the British public would support changes in the law to allow specific populations to access psilocybin-assisted therapy. We contend that moving psilocybin to Schedule 2, even with access restricted to research studies, can achieve both aims.

6.1 Access for veterans

More than half of Brits (55%), including majorities in every region of the UK, support moves to make psilocybin-assisted therapy available to armed forces veterans suffering from PTSD, depression and anxiety, with less than 1 in 7 (13%) opposed, and 32% not sure.

There is a particularly urgent need for effective treatment options among military veterans, a population known to suffer from complex, multi-layered psychological distress. As such, mental health treatment outcomes in this group are poor in comparison to the general public.

The Heroic Hearts Project UK, led by former paratrooper Keith Abraham, seeks to meet this need by facilitating access to psilocybin experiences for veterans in the Netherlands. There, the legal availability of psilocybin-containing truffles has permitted the development of retreat centres providing supportive environments and professional sitters, to people seeking psychotherapeutic relief.

Of the results, Abraham said:

“We are very encouraged by these promising results showing that the British public support veterans accessing psilocybin-based treatments to help relieve symptoms of conditions such as PTSD, depression and anxiety. These terrible conditions contribute to significant numbers of suicides within our community each year. We therefore fully support the call to reschedule

psilocybin and respectfully ask the Home Secretary to acknowledge the existing scientific evidence of psilocybin's medicinal use and safety profile, as well as this new, very positive show of public support for psilocybin-based therapy treatments."

The Heroic Hearts Project UK is in contact with many veterans who have been unable to find relief from their PTSD, depression, or anxiety with conventional treatments. Currently, those interested in trying psilocybin medicinally are forced to choose between travelling abroad or breaking the law by self-administering magic mushrooms in an uncontrolled environment.

There are good theoretical grounds for thinking PTSD will be amenable to treatment with psilocybin-assisted therapy. However, despite personal testimony from veterans, and pre-clinical evidence supporting the use of psilocybin-assisted therapy to treat PTSD, data from clinical trials of psilocybin is not yet available as it is for other conditions, reducing the appeal to sponsors and pharmaceutical companies of investing in this research. By removing unnecessary obstacles to open-label, exploratory trials of PTSD in veterans, moving psilocybin to Schedule 2 will simultaneously facilitate the generation of the clinically robust data, and offer a lifeline to a patient group for whom conventional treatments are often ineffective.

6.2 Access for terminally-ill patients

Perhaps the strongest evidence base so far obtained in contemporary psilocybin research is for the treatment of depression and anxiety secondary to a cancer diagnosis, with placebo-controlled trials finding positive results in studies at UCLA, NYU, and Johns Hopkins University. Up to 40% of cancer patients develop depression, demoralisation and anxiety^{XLVII}, which are associated with lower survival rates, higher rates of suicide, and an increased desire for hastened death. Although standard antidepressant drugs and therapies are less effective in this group, these patients are particularly responsive to psilocybin-assisted therapy. Patients credit psilocybin-assisted therapy with providing them with a renewed sense of optimism, acceptance, and meaning, with the long-term follow-up of the NYU study finding that the positive effects on well-being from a single dose of psilocybin could last as long as four and a half years^{XLVIII}.

Dr Lauren Macdonald, a stage IV cancer survivor, and now a trainee psychiatrist, travelled to the Netherlands to access psilocybin legally:

"It took one small dose of psychedelics, lasting no more than a few hours, to help me cope with the crippling thoughts, fear and anxiety around my cancer diagnosis. Years later, I continue to lead a fuller life because of it. I know that these drugs could really help people at the end of their life. The rules need to change."

The psychiatric distress that often accompanies a life-threatening condition can rob people of any real quality of life in what might be their final days. Perhaps unsurprisingly, our research found that the British public very strongly supported changes to the law to allow terminally ill patients to access psilocybin-assisted therapy. 58% of people are in favour of such a change, including majorities in every age bracket, and amongst the 2019 general election voters for each of the three main political parties. Less than 1 in 8 of the population (12%) are opposed to such a move, with 30% unsure.

In comparison to medical cannabis, which has been an issue in the news for decades, research into the medical applications of psilocybin has only reached mainstream news recently. As such, we anticipated

that people may be unfamiliar with recent developments, leading to a lack of certainty about their own position on psilocybin. Because of this, as well as asking for ‘top-of-the-head’, unprompted support, we later asked the same question again, providing information about research into psilocybin-assisted therapy, and policy developments in North America.

Our final survey question informed respondents that clinical trials had found that psilocybin can support reductions in symptoms in some mental health conditions, with these treatments being given ‘Breakthrough Therapy’ status in the US for the treatment of depression. We provided additional context that the Ministry of Health in Canada has approved psilocybin-assisted therapy for 28 patients suffering end-of-life distress. With this in mind, public support for changes in the law to allow terminal patients to access psilocybin-assisted therapy became even more pronounced: **68%** of people were in favour of such a change, including two-thirds (66%) of Conservative voters and three-quarters (75%) of Labour voters. In light of this information, opposition to such a change shrank to just 9%, with 23% remaining unsure.



7. Attitudes towards conventional treatments and psilocybin-assisted therapies

As well as investigating public support for policy changes to facilitate research and speed patient access to psilocybin-assisted therapies, our research sought to understand the British public's sentiments about currently available mental health treatment options.

We found substantial levels of scepticism about conventional treatments for depression, with almost half (**46%**) of respondents lacking confidence in antidepressants, and one third (**33%**) not confident in talk therapies.

These attitudes cohere with sentiments shared by patients at Imperial College London's first trial of psilocybin for treatment-resistant depression^{XLIX}. All patients in this trial had previously tried multiple treatments without success. Of antidepressants, participants said^L:

"It's like taking a painkiller for a toothache, you don't get to the source of the problem."

"Medications just suppress, it never feels like it's making a change."

The offering of talking therapy that trial participants - all with moderate-to-severe depression - received was also seen as insufficient:

"I got nothing out of it. I had 4 or 5 different people for a few sessions each."

"I tried so many talking therapies, nothing made a difference, they are all so short you never get anywhere, just as you settle in you have to stop."

We also asked participants about their personal attitudes towards psilocybin-assisted therapy, specifically whether they would consider it as a treatment option.

59% of people said they probably or definitely would consider psilocybin-assisted therapy, if they were suffering from a medical condition where there was strong evidence that it could be effective. This figure included more than half of those who were sceptical of antidepressant medications (58%) and traditional talking therapies (55%). Considering the scale of depression diagnoses across the UK, and the level of scepticism surrounding established mental health treatments, this figure suggests that, when psilocybin-assisted therapies have gone through the full clinical trials process to become licensed treatments, there will be significant demand for their incorporation into mental health services. Rescheduling psilocybin will make the research needed to get to such a point much easier, so that patient choice can be expanded to include this novel, viable alternative to those who want it.

Psilocybin-assisted therapies are best conceived of as supporting and augmenting traditional treatments, rather than being marketed as a replacement. It will not be the right treatment for everyone, with data from the first wave of psychedelic research in the 1950s and 1960s suggesting that drugs like psilocybin and LSD might aggravate psychosis and related conditions. As a precaution, contemporary psilocybin research excludes participants with a personal or family history of psychosis, a practice that is set to continue until the link between psychedelics and psychosis is much better understood. Moreover, personal reservations about psilocybin-assisted therapy, borne out of uneasiness about the psychedelic experience, previous bad encounters with magic mushrooms in uncontrolled settings, or enduring negative associations with stigmatised drugs, will make the

treatment an unappealing option for some. Maximising patient choice will depend on providing accurate information about psilocybin-assisted therapy, including where necessary correcting factual misunderstandings, without pushing a narrative that it should be the first-line treatment of choice for everyone.

14% of respondents said that they probably wouldn't, or definitely wouldn't consider psilocybin-assisted therapy, even if there were strong evidence that it could effectively treat a medical condition they suffered from. Additionally, 28% were unsure whether or not they would consider it.

We asked respondents who would not consider psilocybin-assisted therapy, or who were unsure, to list the reasons for their hesitance. The most reported answer (34%) was a concern about the prospect of having a psychedelic 'trip' - itself a key component to psilocybin-assisted therapy - or 'losing control'. Nearly one quarter (24%) were worried that they could become addicted, 29% believed that 'magic mushrooms' might (further) harm their mental health, and many wrote that they did not currently have sufficient understanding of the treatment to make a decision. Of those who would not consider psilocybin-assisted therapy, or weren't sure, 15% felt that because use of magic mushrooms is a criminal activity, it should not be used in healthcare.

These findings suggest that, despite the increasing number of news headlines about psilocybin-assisted therapy, public perceptions remain subject to some misunderstandings, and many feel under-informed. Psilocybin is not habit-forming or addictive^{LI}, and data from carefully controlled contemporary trials, which screen for contraindicating factors, have not found evidence of serious adverse events^{LI}. Psilocybin continues to suffer image problems, due to its relationship to (Class A status) magic mushrooms. Leaving to one side the matter of whether magic mushrooms - perceived by both experts and users to have very low risks of harm to users and society - should be Class A, resistance to psilocybin-assisted therapy on the basis of the illegality of magic mushrooms should give cause to reflect. A sizeable number of drugs that are controlled under the Misuse of Drugs Act nonetheless have legitimate, and widespread, use in medicine. Work is needed to understand how best to communicate the distinction between psilocybin administered legally in a medical or research setting, and magic mushrooms taken recreationally and illegally, such that patients with strong feelings about criminal drug use are not unduly deterred from a treatment that may be very effective for them.

8. Recommendation

This report adds to the debate surrounding psilocybin reform by providing the first nationally representative data concerning public attitudes to potential shifts in government policy. Reforms to relax restrictions on research into psilocybin, as well as to facilitate medical access to specific, limited patient groups, received majority support across demographics, with every region of the UK consistently in favour of moves away from the status quo. Fewer than 1 in 6 (9-15%) actively opposed changes to the law, with a larger minority still unsure about their attitudes towards reform.

For some time now, scientists and researchers, as well as a variety of politicians, have called for psilocybin to be rescheduled, in order to cut the red tape that slows potentially transformative research, and ultimately impedes access for those with exceptional clinical need. The mental health conditions that psilocybin can treat are responsible for widespread suffering that is too frequently resistant to available treatments. Moreover, a substantial economic case can be built for establishing the UK as the world's leader in psychedelic science: a research-supportive regulatory structure, coupled with the country's existing expertise, will make the UK a clear favourite for investment and scientific talent.

We now know that the majority of the public are supportive of such a move.

It is time for the Home Secretary to act. It is time to reschedule psilocybin.

In line with statutory procedure, we call upon the Home Secretary to commission the Advisory Council on the Misuse of Drugs to review the scheduling of psilocybin, with a commitment to act on its recommendations.

All figures, unless otherwise stated, are from YouGov Plc. Total sample size was 1,763 adults. Fieldwork was undertaken between 20th - 21st May 2021. The survey was carried out online. The figures have been weighted and are representative of all UK adults (aged 18+).

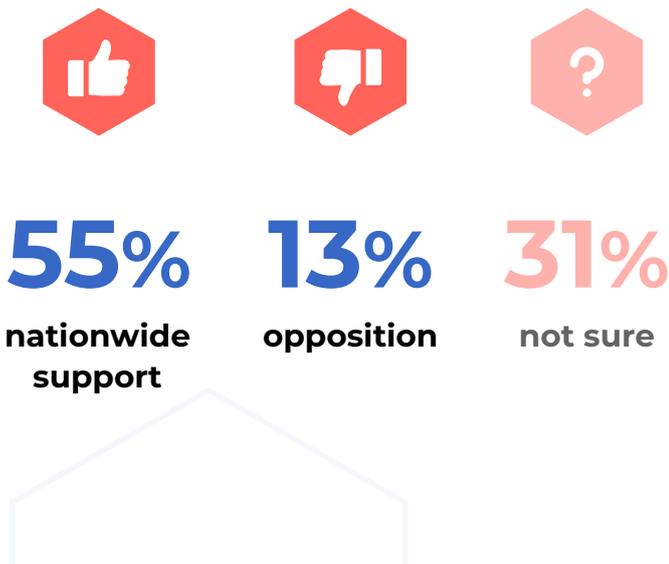
[To see the results of this poll click here](#)

9. Findings in Full

Research into the therapeutic benefits of psilocybin will be significantly facilitated by **moving psilocybin to Schedule 2 of the Misuse Drugs Regulations.**

We asked the public:

To what extent would you support or oppose the government relaxing restrictions on research into the medical use of magic mushroom-based treatments (psilocybin-assisted therapies) for mental health conditions if this didn't affect how it was classified in criminal law (e.g. as a class A drug)?



Support for relaxing research restrictions

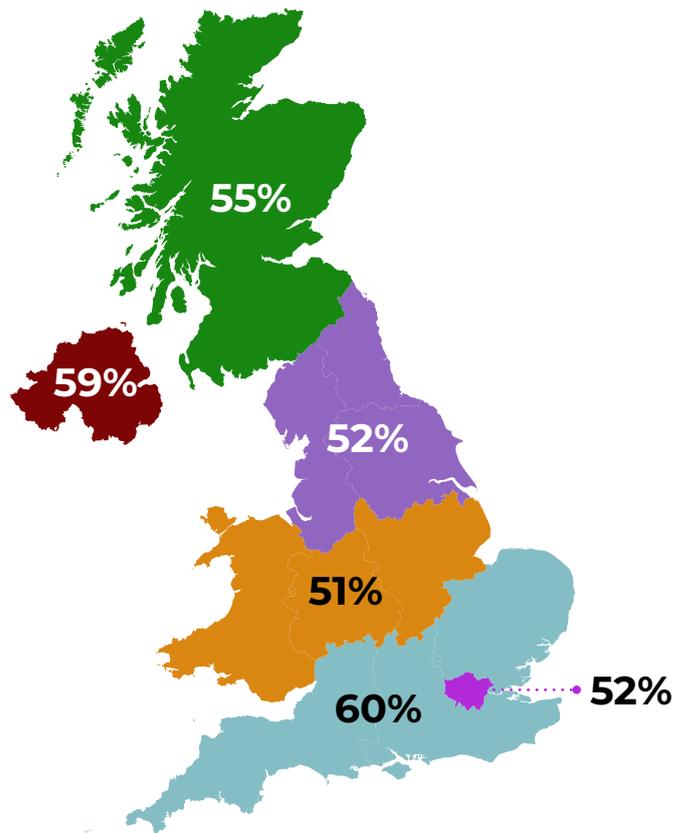
Country average

55%

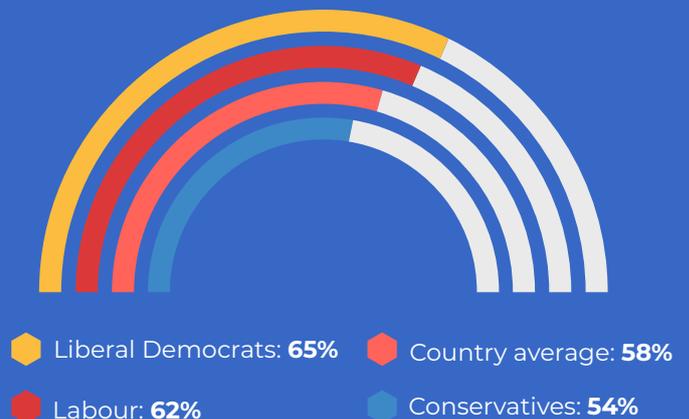
Conservative voters: **51%**

Labour voters: **60%**

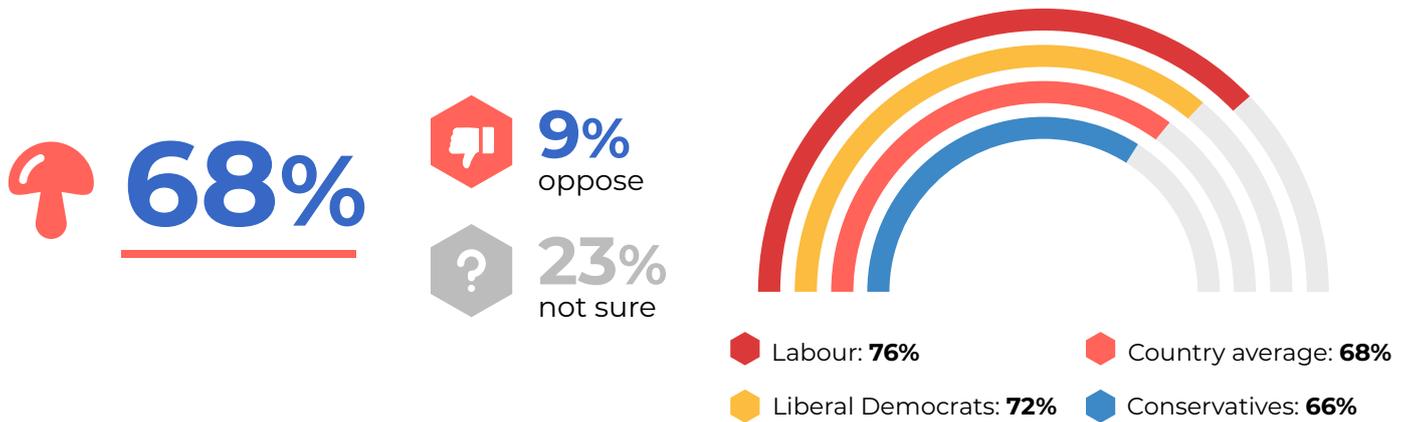
Lib Dem voters: **64%**



Approval for changing the law to allow **people with terminal illnesses** to access psilocybin-assisted therapy



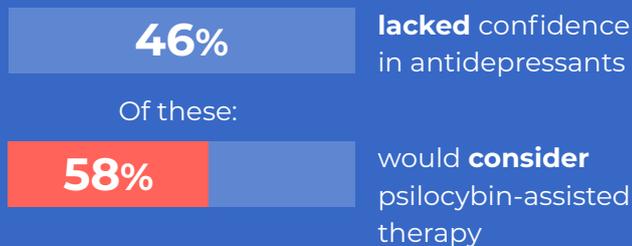
With psilocybin only having very recently been subject to media attention, we anticipated high rates of 'not sure'. So, at the end of the survey we provided respondents with information about clinical research into psilocybin, its 'Breakthrough Therapy' designation in the US, and the Canadian government's decision to allow 28 terminally ill patients to access psilocybin-assisted therapy. When provided with this additional information, support for changes to the law to allow terminally ill patients to access psilocybin-assisted therapy rose to:



If you had a bad bout of depression, **how confident would you feel about trying the following treatments?**



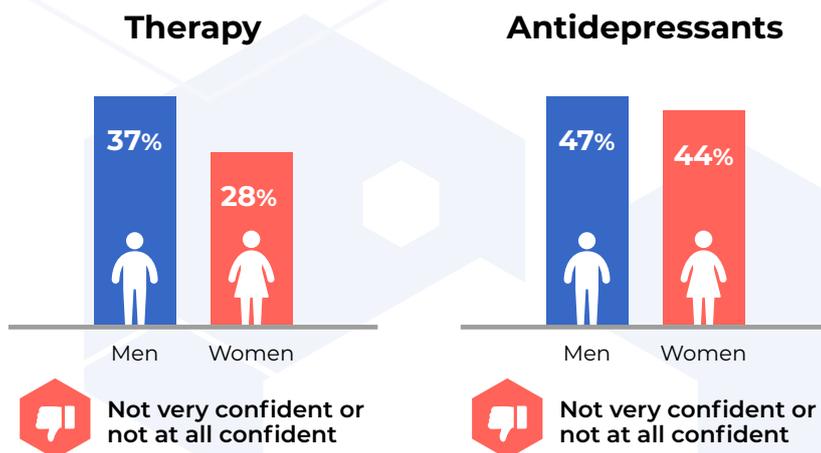
Antidepressants



Therapy



Men are more sceptical about traditional treatments:



The reverse is true for psilocybin-assisted therapy.
If they had a medical condition where there was strong evidence that psilocybin-assisted therapy could be effective:

62% of men would consider it

55% of women would consider it

Appendix. The Home Office's position on psilocybin

This report is not the first call for psilocybin rescheduling, though it is the first to do so with evidence that there is considerable public support for such a move. Previous comment from the Home Office has sadly been dismissive, with responses showing a lack of engagement with social, medical, and scientific realities. We include two of these responses below, and urge the Home Secretary not to rely on such mistakes in responding to our report.

(May 2019) In response to an inquiry about psilocybin rescheduling from the author

“There is strong scientific and medical evidence that psilocybin is a harmful drug which can harm people’s mental and physical health [and] can damage communities. The government is clear - we must prevent drug use in our communities and help those dependent on drugs recover”

1. This argument is predicated on the assumption that moving psilocybin to Schedule 2 will increase diversion to the black market. Familiarity with the practicalities of psilocybin-assisted therapy make it clear that this is extremely unlikely. Schedule 2 controls are deemed sufficient to deter diversion of other drugs including heroin and cocaine. Risk of diversion of research psilocybin is significantly lower: the main route of diversion of scheduled drugs to the black market is via prescriptions. But the nature of psilocybin-assisted therapy is such that psilocybin is only delivered under supervision in clinics, rather than being prescribed to the patient to take home and self-administer. This much is attested to by those who run psilocybin trials. Dr James Rucker of KCL, who runs a (government funded) trial of psilocybin for treatment-resistant depression: *“Schedule 1 restrictions hinder our efforts whilst being unlikely to provide any meaningful reduction in the risk of diversion, when compared to Schedule 2 restrictions.”* In addition, in the judgment of the Advisory Council on the Misuse of Drugs, outlined in a letter to the Home Office in 2017, *“the risk of diversion and misuse [of controlled drugs] in a research setting is likely to be minimal.”*
2. These claims are out of step with the weight of evidence about the risk profile of psilocybin. Although no drug use is harm- or risk-free, psilocybin mushrooms are consistently ranked among the least harmful of recreational drugs, including alcohol, and are associated with the lowest rate of emergency medical call-outs and a low physiological toxicity.
3. There is scant evidence for the claim that psilocybin damages communities. The black market associated with magic mushrooms, which were legally sold in truffle form until 2005, does not manifest the pattern of harmful dynamics displayed by the markets for other drugs. There is no ‘county lines’ or ‘cuckooing’ crisis for magic mushrooms. Moreover, Freedom of Information requests to constabularies across Great Britain from the Conservative Drug Policy Reform Group, due to be released later this year, indicate that magic mushrooms are associated with less than 0.1% of drug-related crime in the UK.
4. The allusion to ‘help[ing] those dependent on drugs recover’ suggests an unfamiliarity with the realities of psilocybin as a drug. Not only is psilocybin well established to be non-dependence forming, survey studies of naturalistic magic mushroom use, as well as clinical trial data, increasingly suggests that appropriately used psilocybin is an addiction interrupter. There is growing evidence for its efficacy in treating of addiction to tobacco and alcohol, and trials are underway in the US for the treatment of cocaine and opioid addiction. Given the Home Office’s

concern in helping those dependent on drugs to recover, we recommend that they facilitate research into new treatments that can help.

(July 2020) In response to the Conservative Drug Policy Reform Group's report, 'Medicinal Use of Psilocybin - Reducing restrictions on research and treatment'

"We need to strike the right balance between enabling legitimate research to take place in a secure environment while ensuring that harmful drugs are not misused and do not get into the hands of criminals. The current classification of psilocybin under Schedule 1 does not prevent research or clinical trials under a Home Office licence."

5. As above, risk of diversion of medical or research psilocybin is low, and Schedule 2 restrictions are deemed sufficient to deter the diversion of more harmful and addictive drugs that pose more serious risks of damaging communities.
6. The case being made for the rescheduling of psilocybin does not rest on research currently being completely prohibited. The trials that have been completed in spite of onerous research restrictions have shown powerful signals that psilocybin-assisted therapy could make significant inroads to treating mental health conditions - the first major pharmaceutical advance in psychiatry for thirty years. Any other drug that could make this claim would be fast-tracked through development by the government. It is not enough that psilocybin research is technically legal. It is inappropriate to continue obstructing legitimate research into so promising a treatment by artificially compounding barriers to entry with excessive legal red tape.



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