

**EMBARGOED TO 00:01AM BST MONDAY
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THE HODGES REVIEW

EXECUTIVE SUMMARY

How the UK can become a world leader in
cannabinoid innovation

Professor Christopher Hodges

Dr. Parveen Bhatarah

Blair Gibbs

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Association for
the Cannabinoid
Industry



The Centre for
**MEDICINAL
CANNABIS**

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Background

- This report's main objective was to examine the current landscape and outline how best to support the safe and responsible growth - economic and social - of a **sizable and dynamic legal cannabis sector that is already established in the UK**. Despite the growth potential and dedication within this industry, it is clear that this **market has evolved by accident, without coordinated government action** or a coherent strategy to steward it to maturity.
- Thus far, **the government has neglected to plot a course for the sector**, or even recognise its potential to be successfully scaled with the right regulatory and grant support - like the UK Space Industry has. Furthermore those working in the UK sector feel incredibly restricted by current regulatory conditions and shut out of policy engagement with key decision-makers on issues like patient access and education.
- The result of this is that the country which produced the first cannabis unicorn is struggling to find its feet in the international market. **The legal sector is not as attractive to investors because it is hamstrung by the UK's own rules**. As a result the UK is missing the opportunity to learn from other jurisdictions and craft a set of policies that will give the sector the best chance for future growth.
- This report describes a **vision that moves beyond a policy of control and containment to one of support and stewardship**, so that the UK can maximise the potential it has to advance scientific discovery and innovation, improve well-being, create jobs and investment in local economies, and enhance the health outcomes of potentially millions of people.
- Cannabinoids now make up a fast-growing global industry, and by not being a first-mover, **the UK holds an advantage in that it can learn from the successes and failures of other comparable regimes**. Moreover, **Brexit has given the UK the freedom to choose to align or differentiate itself from the markets with which it is competing**, for example on hemp cultivation and consumer/CBD regulation.
- The report summarises the respective sectors - medicinal, consumer and industrial - as they stand today, exploring the policy gaps and incoherences, and draws on original public attitudes research to understand where the public sits on these issues. It then sets out some **shared goals for the sector and outcomes to be adopted**, alongside actions by government and industry to bring these goals closer, comprising a **suite of 20 policy recommendations**.

Regulations matter

- **The law and rules which govern any regulated industry are fundamental to how it develops, and its ultimate growth trajectory**. Case studies on the evolution of the legal (medical) markets in Canada and Australia demonstrate this. Regulations should at least be crafted in a way that attempts to be coherent and consistent, but this is not the case for the UK cannabis industry currently.
- **Regulations around a product are designed to safeguard citizens from harm - but they must do more than this**. The regulations around cannabis and how it may be used under licence must be justified in terms of risk and protection of the public from harm, but simultaneously not depress economic growth and scientific and technological innovation.

Outcome-Based Cooperative Regulation

- The report views the cannabinoid sector through the lens of Outcome-Based Cooperative Regulation (OBCR), a regulatory philosophy pioneered by Professor Hodges which centres on an ethical and trust-based regulatory schema.
- The report argues that for regulations to be effective, the science supports them being based on **trust and collaboration**, not top-down enforcement and sanctions. This provides

a valuable framework for thinking about how the legal cannabinoid sector can develop in the UK, as it necessarily involves industry-wide coordination, and a different, more permissive approach from government and regulators to the trusted actors in the sector.

- When **applying OBCR to this sector** the report recommends that the legal cannabinoid industry should coalesce around the following shared goals:
 1. **Demonstrate that the sector is trustworthy**, legitimate and responsible
 2. **Improve the evidence base** and generate new insights in the UK
 3. **Improve health outcomes for patients** and maximise access to these benefits
 4. **Fully explore and exploit the value of the cannabis plant**
 5. **Set a world standard for regulatory and scientific best practice** and innovation with a level playing field for producers
- The report also identifies some **outcomes** that everyone in the legal sector should be united in seeking to deliver:
 - **Reducing harm and improving health and well-being**
 - **Expanding knowledge and evidence**
 - **Increasing confidence**
 - **Securing competitive advantage**
 - **Delivering collaboration between industry, end-users and regulators**
- Currently the **UK's legal cannabinoid sector lacks some key elements of an OBCR approach** - namely lack of legal clarity, clear rules, or ethical codes or vision statements, and there is poor data availability, poor feedback mechanisms and a lack of effective intervention mechanisms.
- The report argues that **the sector needs to**

work to develop trust, and more freedom should be given to the **trusted actors already in the market** (prescribers, pharmacists, regulated suppliers, government-funded trial sites, licensed researchers).

Public support for the sector and its future

- A new survey of public attitudes by STACK Data Strategy should give the industry and government renewed confidence that the British people have embraced the concept of a legal cannabis sector. Clear majorities support it as a healthcare concept, being optimistic about its potential, and not fearful, cynical or dismissive.
- The UK's legal cannabinoid sector is a relatively new industry, and yet **the public do seem to show a high level of experience and/or awareness** of some of its elements, especially medicinal access and the general availability of CBD:
 - **Almost two-thirds of people were aware of CBD products before taking the poll**, with women showing generally higher levels of awareness than men
 - **1 in 10 people said they had 'tried/used/purchased' CBD in the last year.**
- There is a deep and broad level of support for the idea that cannabis can be an effective medical treatment:
 - **One in five (19%) respondents said they personally know someone whose health has benefited from medicinal cannabis**
 - **A big majority (63%) of respondents would be supportive if a family member was taking medicinal cannabis** to address a health condition, with only 8% saying they would be somewhat or very opposed to it
 - **Almost 1 in 7 people (14%) admitted that they have used cannabis 'for health**

reasons or to treat a medical condition' at some point in their lives

- Of those who had used for medicinal reasons (whether prescribed by a doctor or not) - a smaller sample of 215 - **the vast majority (90%) experienced positive benefits, including a fifth (21%) whose symptoms were 'completely resolved'.**
- When asked about consumer/CBD:
 - **More than a third (38%) of respondents said they buy their CBD products online, and 30% in high street shops**
 - 6% of all those surveyed - a higher than anticipated number - said they had given CBD products to their pet
 - **The most concerning thing for 43% of respondents was if the product was synthetic and not from natural ingredients, or if the product was not tested for purity (42%)**
 - Hesitant CBD considerers would be most likely to try a CBD product if there was more public information about CBD and how to take it (32%) and if the government made it clear that CBD was legal (32%)
- On the reforms for the sector:
 - There was strong support for allowing all doctors, not just specialists, to prescribe cannabis as a treatment. **Two-thirds of respondents (65%) believe GPs should be allowed to prescribe medicinal cannabis** and family doctors/GPs scored highly on who would be trusted to prescribe it to you - more than a third (37%) of respondents would trust their GP to prescribe them medicinal cannabis
 - **People believe the government should help lower the cost of cannabis supplied by private clinics (59%) so more people can afford it**
 - Almost half of respondents (46%) agreed that the government should allow British

companies with a licence to grow cannabis here to export it overseas, and only 13% disagreed

- **A large majority (64%) of respondents believe the government should do more to support scientific research into cannabis in the UK**
- **At (23%), respondents thought cannabis medicines rank as an important future industry where Britain could try and become a global leader, alongside green technology and sustainable energy**
- Respondents were also asked whether they thought in ten years the medical benefits of cannabis would be more widespread and accepted, with a majority (59%) agreeing and only 8% disagreeing

Conclusions

- **It is not sustainable or acceptable for the government to continue to take an uncoordinated, disinterested or laissez faire attitude to the sector** as a whole, as it has done since the cannabis sector's 2018 inception.
- **The seeds are there for rapid growth but it cannot happen without a clear strategy built upon coordinated government stewardship and the ambition to not just tolerate, but actively nurture the sector to expand and mature, so it attracts more investment, jobs and innovations, and secures political support and public recognition.**
- The regulations encompassing the cannabis sector are wide-ranging and complex, but right now **the present rules are poorly calibrated to the risks associated with each product and stifling of economic opportunities.** Our conclusion from this research was not that the UK's legal cannabis sector is over-regulated, or merely suffering from outdated rules, or simply needs red tape and unwarranted regulations to be stripped back.
- In some areas, such as **hemp farming**, not only are there insufficient incentives, but existing

regulations are too restrictive, disproportionate to the risks involved and antithetical to the growth of a UK-industry and the economic opportunity hemp cultivation could offer to rural economies, not to mention environmental benefits.

- In other areas, such as consumer cannabinoids and **CBD**, we have seen the result of too little regulation that caused the emergence of a large grey market that now needs tighter rules in order to safeguard the consumer and build up and sustain public trust, backed up by targeted but sustained enforcement
- And in the arena of **medicinal cannabis**, the picture is far more complex, with regulations too onerous and restrictive in some areas, and too lax or entirely absent in others.
- If adopted, the regulatory framework outlined in this report will achieve three important objectives:
 - **Competitive advantage for the UK post-Brexit**, helping the country to leverage its historic and economic strengths in a rapidly growing and unprecedented global industry;
 - **Regulatory best practice giving early mover advantage**, helping to pioneer new approaches to regulating a novel industry that other jurisdictions on a similar path can choose to emulate;
 - **Scientific advances and innovations**, with pioneering new treatments, manufacturing methods, and end-user product innovations, helping the UK to reinforce its reputation as the home of world-leading inventions and discoveries that improve our environment, our health and our quality of life.

clear responsibilities and could become the home for developing a specialist agency with expert staff recruited from a range of sectors.

2. **Provide long-awaited legal clarity in respect of trace amounts of controlled cannabinoids in retail products and revise the 2001 MDR to set the permitted 'zero THC' level.** This will give industry the confidence to invest in a high quality supply chain with robust analytics to support proof of compliance, and clear up any remaining confusion among retailers and ultimately consumers.
3. **Encourage the creation of a UK 'Centre of Excellence' to advance the evidence base for cannabinoids and their applications.** Drawing on the strength of the UK's higher education sector, this institute could be established with the support of major universities.
4. **Roll-out a national trial for GP prescribing of CBPMs based on an opt-in model for doctors' consent and systematic data collection to inform future guidelines.** Another dimension could be that such prescriptions, when issued in the private or public system, would need to involve patient enrollment in a national registry to help gather real world evidence.
5. **Update hemp farming rules to permit licensed growers to extract the controlled parts of the cannabis plant on site under the right conditions.** Farmers would need to partner with an approved transport provider or third party distributor to move controlled substances to market and maintain more detailed records of their seasonal yields.
6. **Modernise the Proceeds of Crime Act provisions to create an explicit exemption for private enterprise by entities operating in legal jurisdictions.** Modelled on the changes already incorporated into law in Jersey, the UK government should update POCA to permit investment by entities involved in cannabinoid commerce
7. **Permit licensed suppliers to export CBPMs in bulk outside the UK where their customer is**

Key Recommendations

1. **Establish a single 'steward' authority to govern and guide the entire sector, at arms length from ministers.** This new agency would require legislation to set up but it would inherit

- a licensed party in the overseas jurisdiction. This would help UK-based CBPM companies with supply chain efficiencies such that medicinal patients in the UK could benefit from reduced costs for their treatment.
8. **Consult with patient groups and police forces to introduce Home Office guidance for frontline officers to check and verify patients who have a valid, current CBPM prescription**
 9. **Take forward commitments for a national patient registry** and begin coordinated data collection efforts for real world evidence.
 10. **Create and mandate a consistent set of manufacturing and labelling standards for CBPMs that provides more information to patients and links to a batch-specific Certificate of Analysis (CoA).** Modelled on the Rule 93 Guidance imposed by the TGA in Australia, this would require CBPM suppliers to adopt best practice around product safety with, for example, child-proof containers.
 11. **Require end-product testing for all CBPM and consumer cannabinoid products (imported or locally produced) using independent ISO accredited laboratories in the UK.** This would also stimulate expansion in ancillary services like laboratories for ensuring the industry standards are adhered to. In time the sector should adopt an industry-wide set of benchmarks for testing quality.
 12. **Permit licensed CBPM suppliers to utilise mainstream, trackable, signed-for delivery options to reduce the cost to patients of private CBPM prescriptions.** With auditable records of licensed pharmacists and new rules requiring child-safe packaging, it is no longer necessary to require expensive controlled drug couriers for delivering CBPMs to patients.
 13. **Create a single formulary of available CBPMs which provide doctors with an up-to-date list of medicinal cannabis products available in the UK market.** This would enable patients to request certain types of product and for prescribers to have a wider view of what types of quality assured products are currently available.
 14. **Provide clarity on the legal status of CBD vaping products and issue guidance on the permitted ingredients in a vaporizer used for cannabinoids,** either as a consumer CBD or CBPM delivery device.
 15. **Establish an expert committee to review the approach of the Veterinary Medicines Directorate to explore options for a more proportionate approach to CBD use by veterinarians.** A rethink on the approach announced in 2019 would reflect how pet owners and farmers are already using CBD unofficially, and would bring consistency with the pragmatic approach of the FSA.
 16. **Examine and integrate policy on hemp cultivation activity into broader Net Zero efforts.** DEFRA should begin a policy development process to devise incentives within the new post-Brexit agricultural subsidy regime that rewards farmers for carbon sequestration and soil remediation using hemp cultivated domestically, with the possibility of such licensed activity generating tradable carbon credits for off-setting.
 17. **Develop and roll-out more comprehensive surveillance of the UK border to detect illicit imports and non-compliant CBD products entering the UK by sea or air freight.** UK Border Force should resource a suite of methods to discourage the importation of illicit cannabinoid material and deter the grey market from seeking to exploit the UK's large consumer market.
 18. **Clarify with guidance that any product derived from synthetic cannabinoid synthesis is by definition novel** and must follow the conventional risk-based route for approval as a medical treatment or as an ingredient in food.
 19. **Proactive and proportionate enforcement from regulators to pursue breaches of food law.** The FSA, working with Trading Standards, needs to develop a strategy for enforcing the

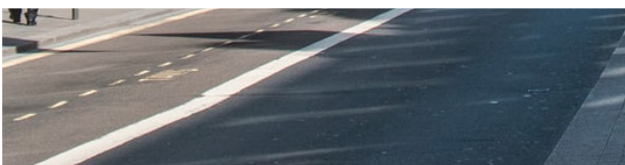
Novel Food regime based on a proportionate approach.

- 20. Collaborate on an education initiative to improve general understanding among distinct professional and public audiences.** Institutional partners in respective sectors could partner with industry bodies to support education and training to improve understanding about cannabinoids and help inform consumer and patient choices.

Three Quick Wins

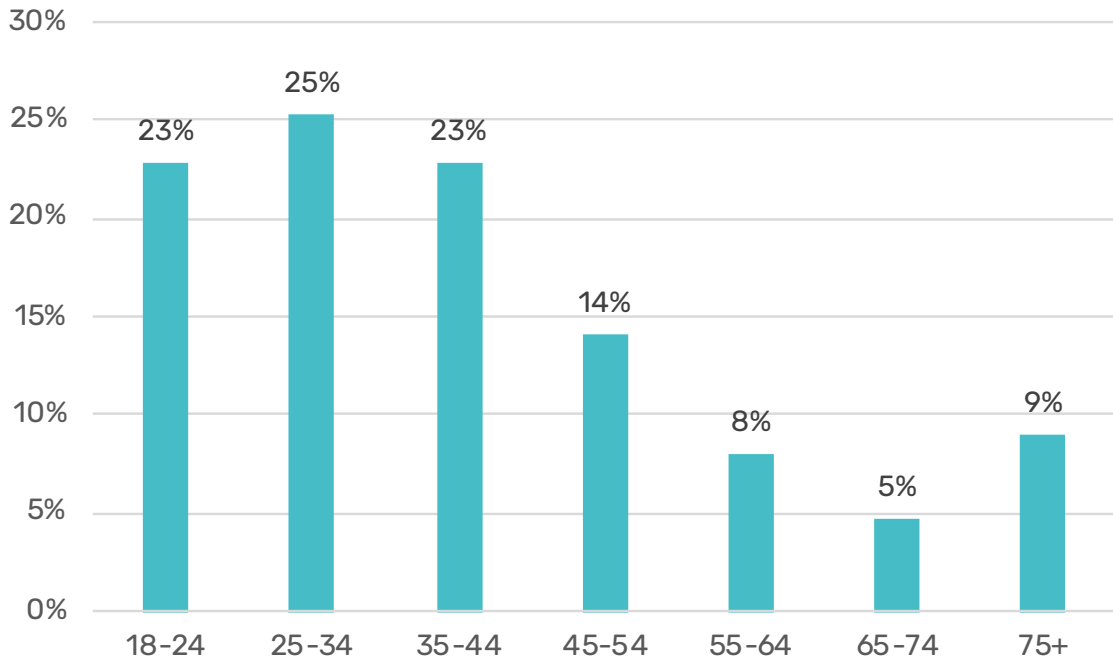
In the next 12 months, the following would represent the first steps on the road of reform:

- **Set up a single online portal** - designed to bring together all government advice and guidance in a single place, covering the three distinct sub-sectors. This portal would help inform the market and guide applicants, as well as hosting the most recent published data relevant to the industry
- **Establish a legal industry roundtable** - taking inspiration from the Canadian Government's commitment to do the same in 2022, this new arrangement would give the legal sector a conduit to policy-makers and provide a single forum for raising issues, and offering constructive proposals to government. It could also act as the venue for deliberating on a future industry-wide Ethical Code or equivalent to help foster trust.
- **Publish more and better data** - on prescribers, licence holders, prescriptions, and enforcement, so that the political and policy debate can be informed with real data on the current state of the sector. Prescriber and prescription data should be published quarterly, on an anonymised basis, in line with current GDPR requirements.

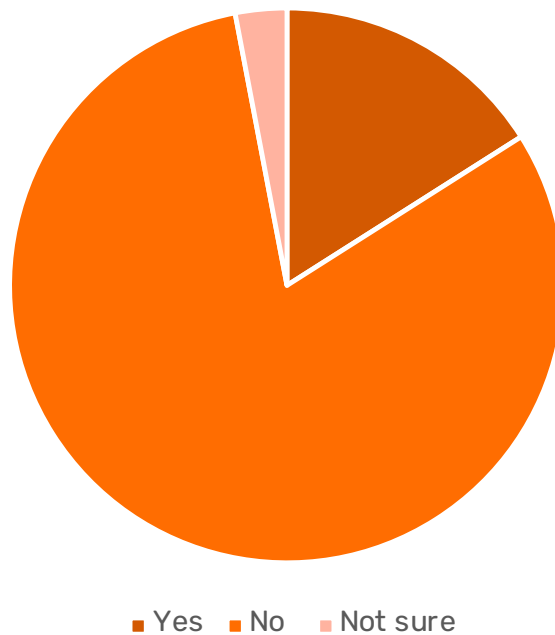


Public attitudes, experience and understanding

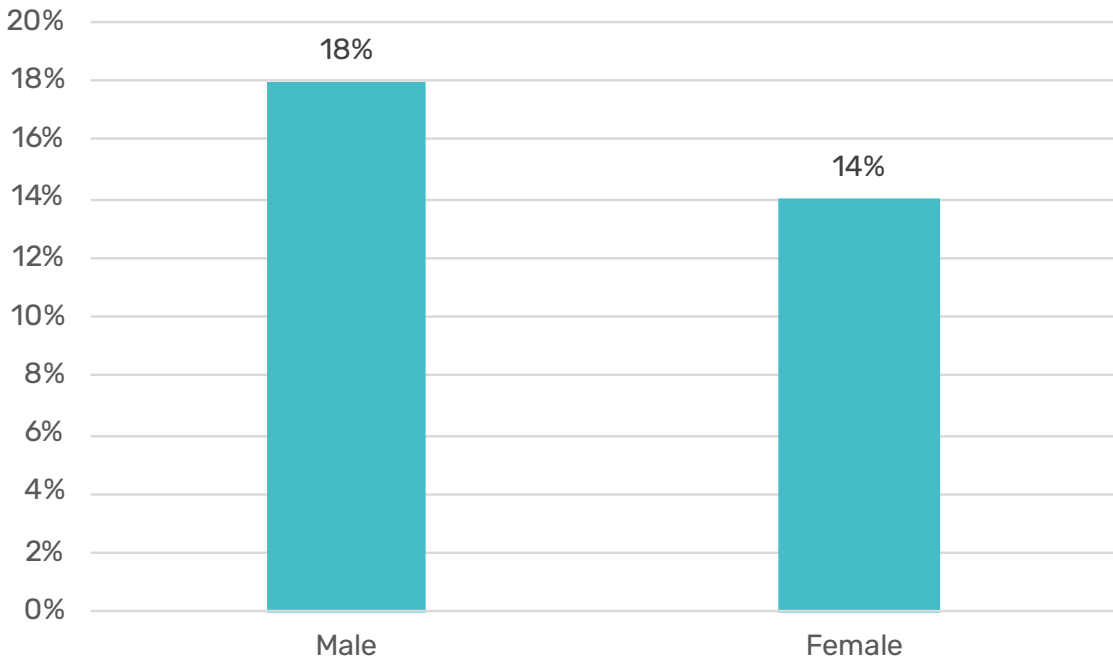
Have used CBD/cannabis oil for medicinal reasons?



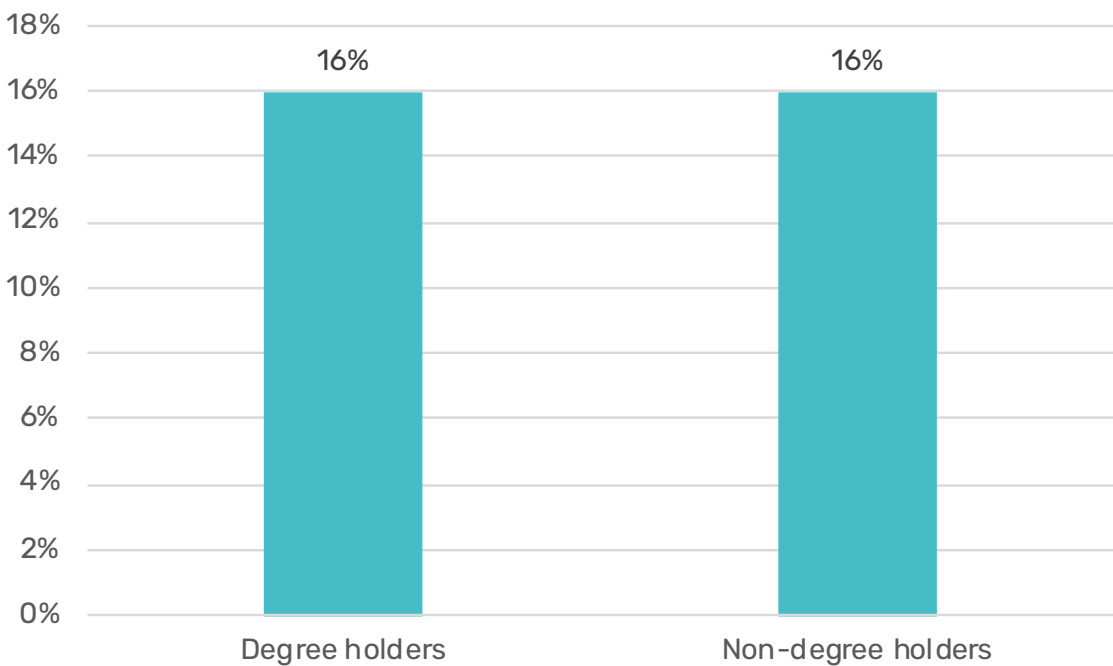
Have you ever used CBD/cannabis oil for medicinal reasons?



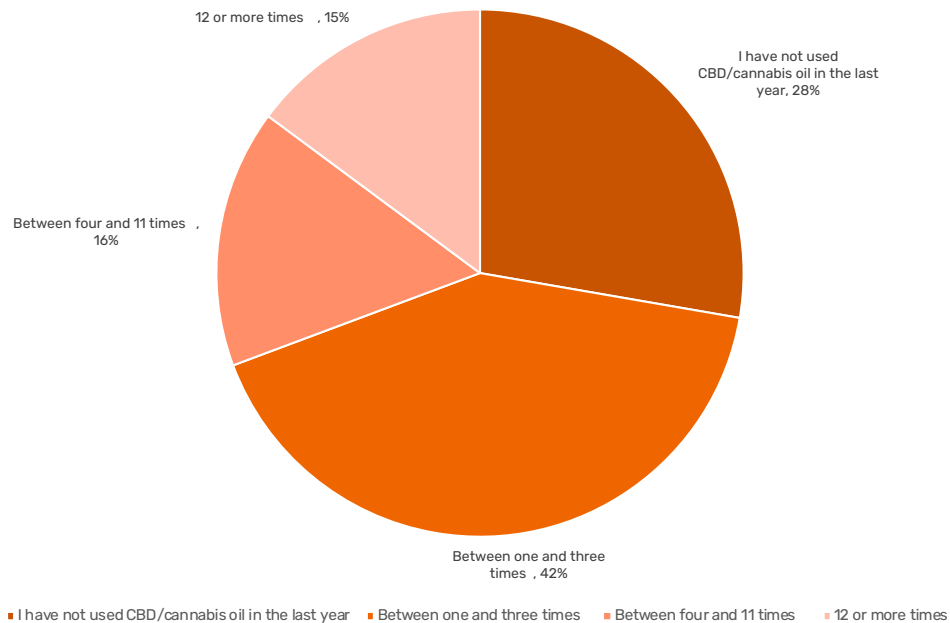
Have used CBD/cannabis oil for medicinal reasons?



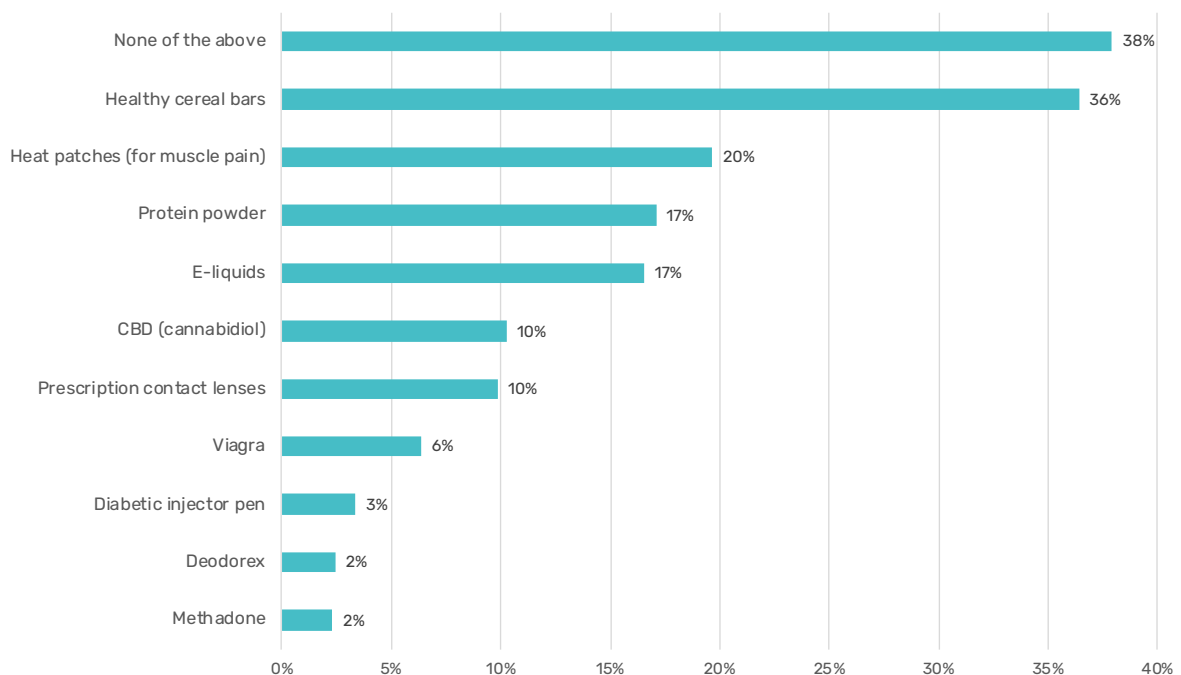
Have used CBD/cannabis oil for medicinal reasons?



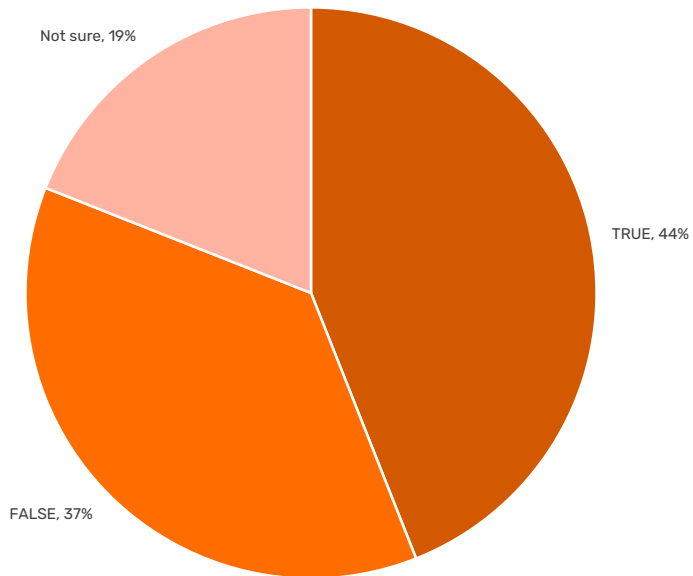
In the last year, how often have you used CBD/cannabis oil for medicinal reasons? [Only asked to respondents who have ever used CBD/cannabis oil]



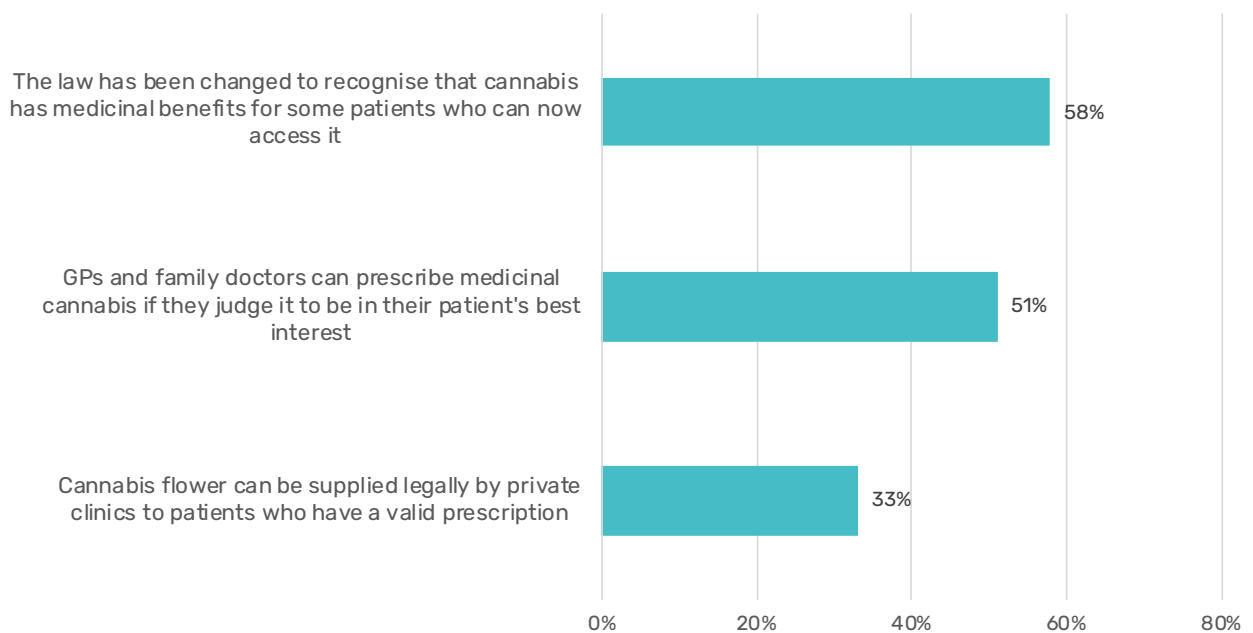
Have you ever tried/used/purchased any of the following products in the last 12 months? Please select all that apply.

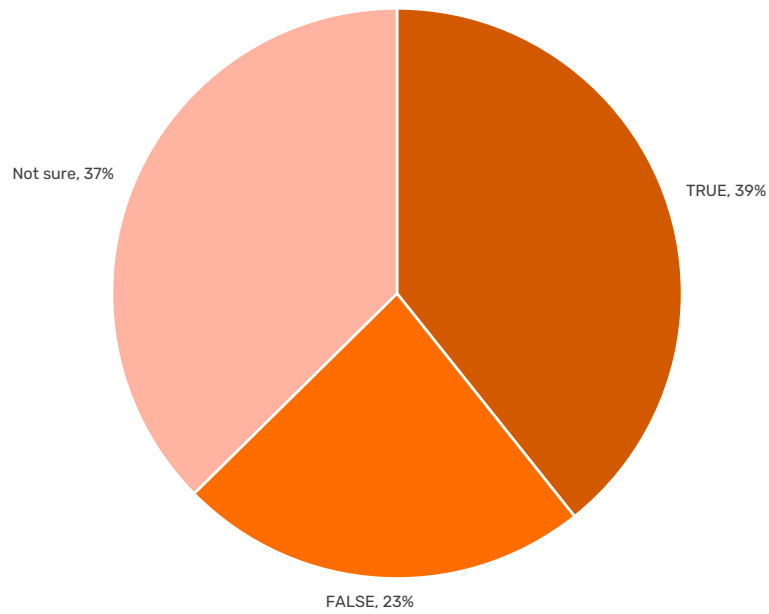
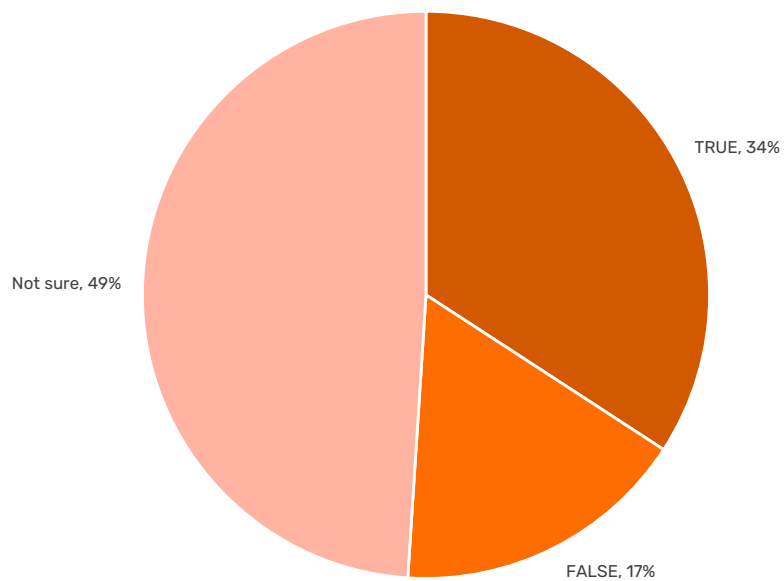


It is legal for adults to possess small amounts of cannabis for their own personal use, but they cannot sell it or supply to under 18s - True of False

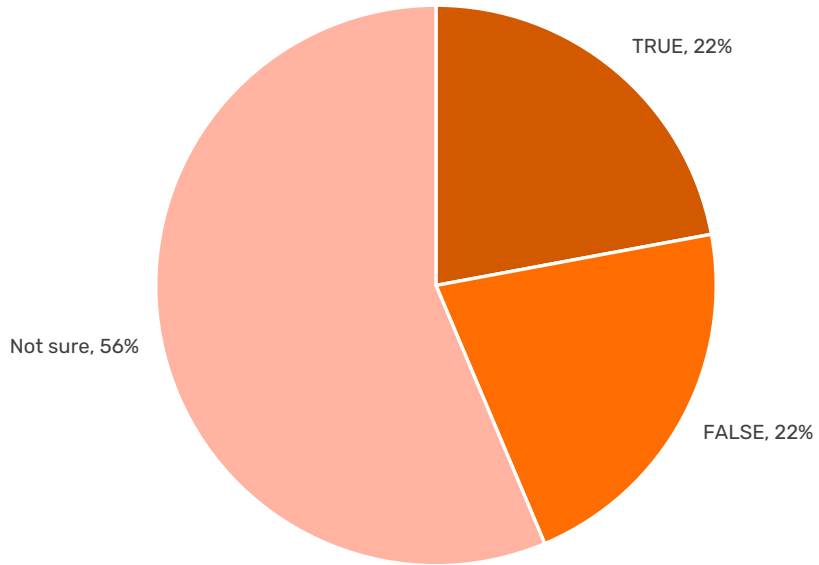


% of respondents that felt the following statements were true

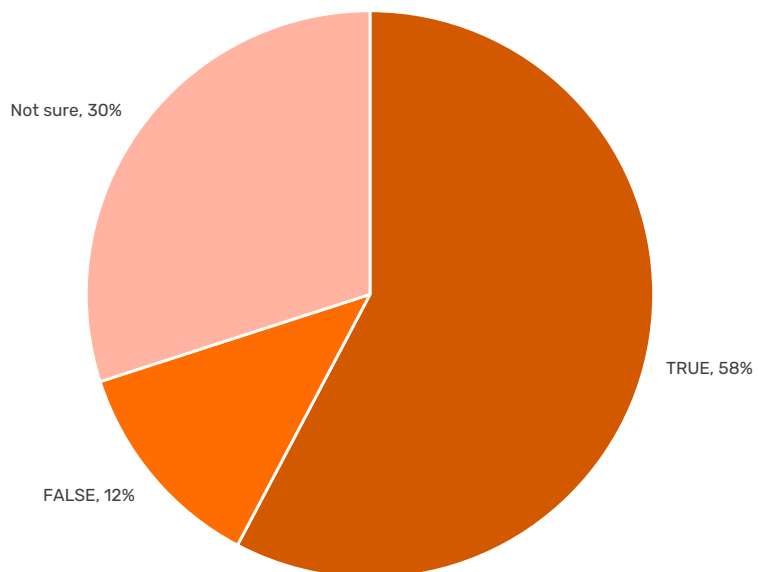


CBD is a new product invented in the last twenty years - True of False**Hemp has only been grown in Britain in the last few decades, but for longer in other parts of Europe - True of False**

Most of the CBD / cannabis oil sold in shops comes from hemp grown in Britain - True of False



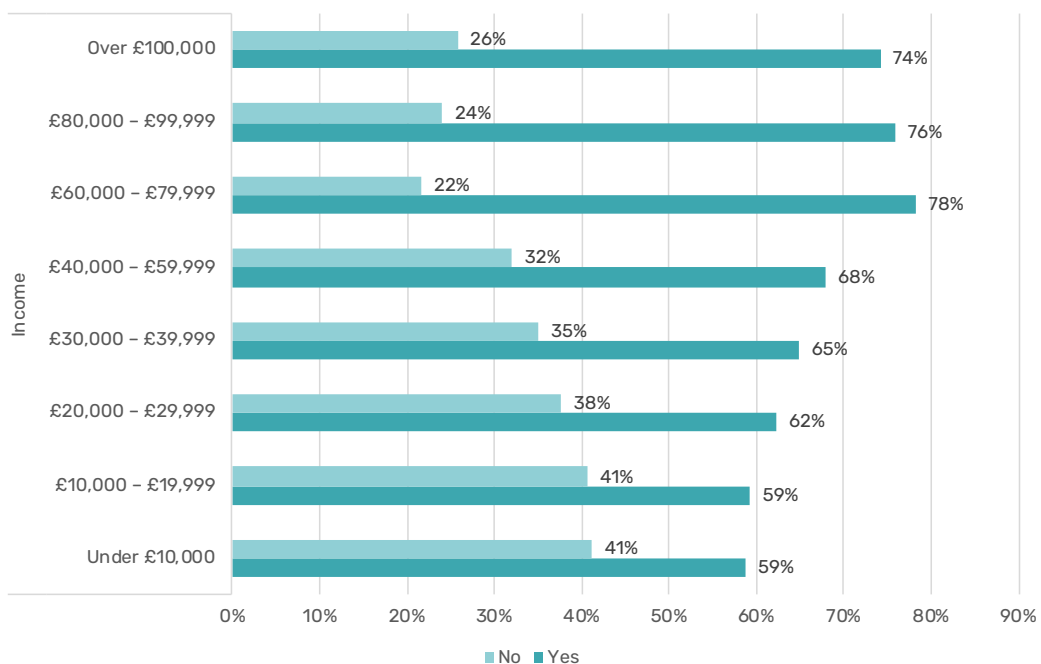
CBD has proven health benefits - True of False



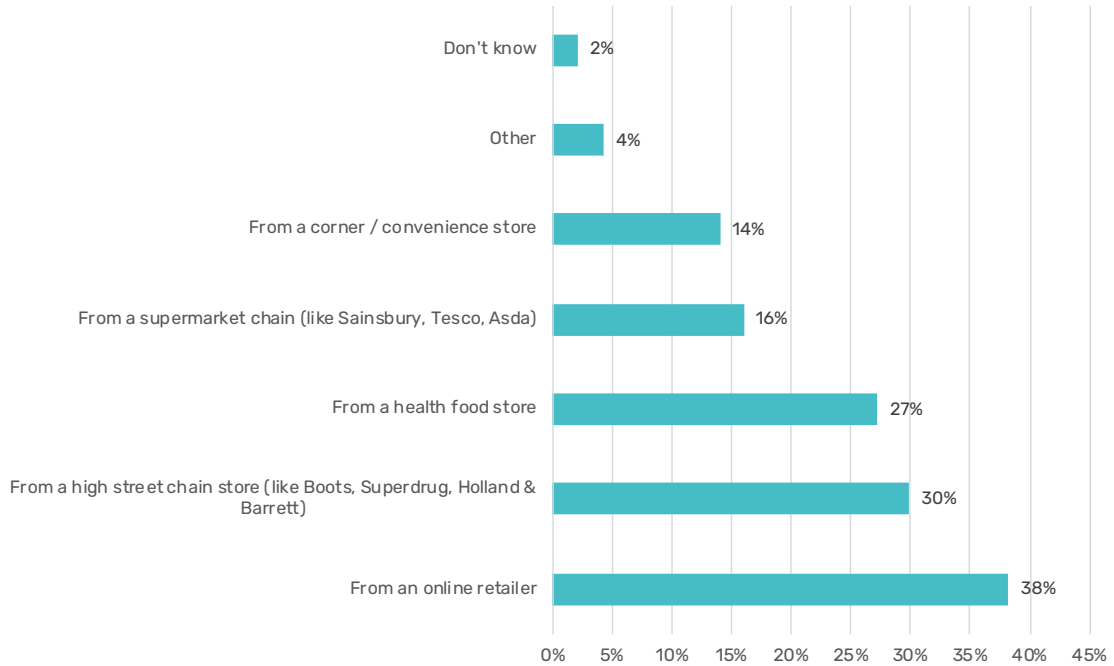
When thinking about the law on cannabis, do you think the following statements are true or false?
Many families with sick children who benefit from cannabis medicines cannot access it easily

60% of respondents felt many families with sick children who benefit from cannabis medicines cannot access it easily

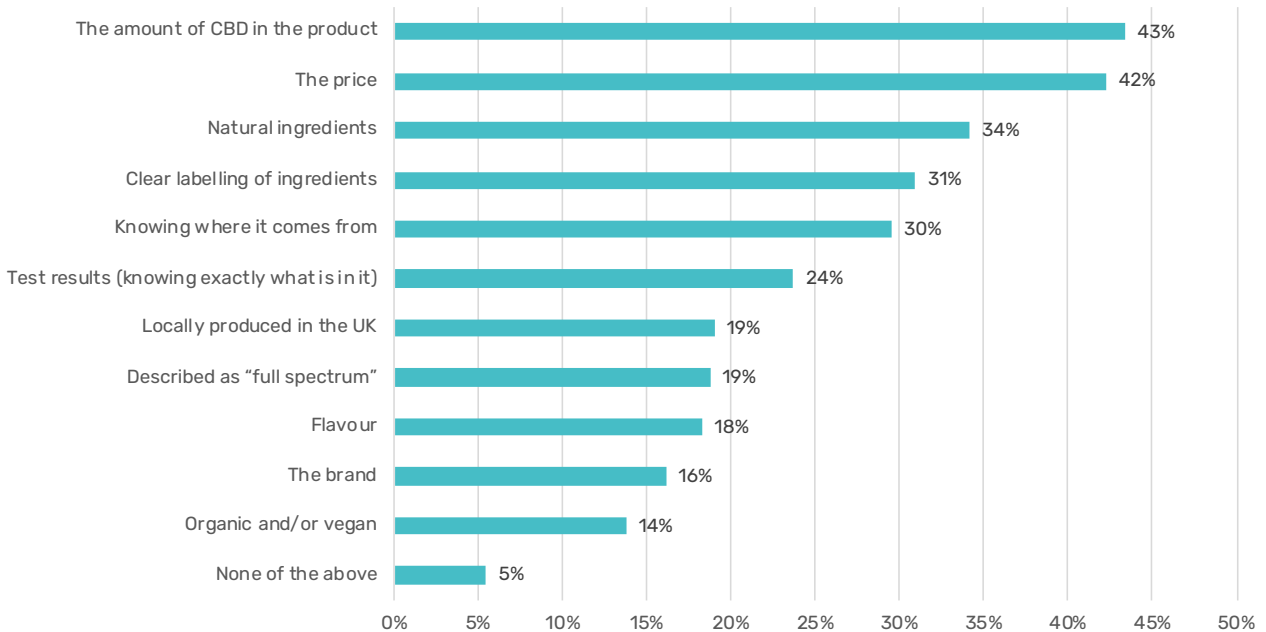
Before taking this survey, were you aware of any cannabidiol (CBD) based products?



Where participants who had recently purchased CBD-based products usually buy from
(sample size: 270)

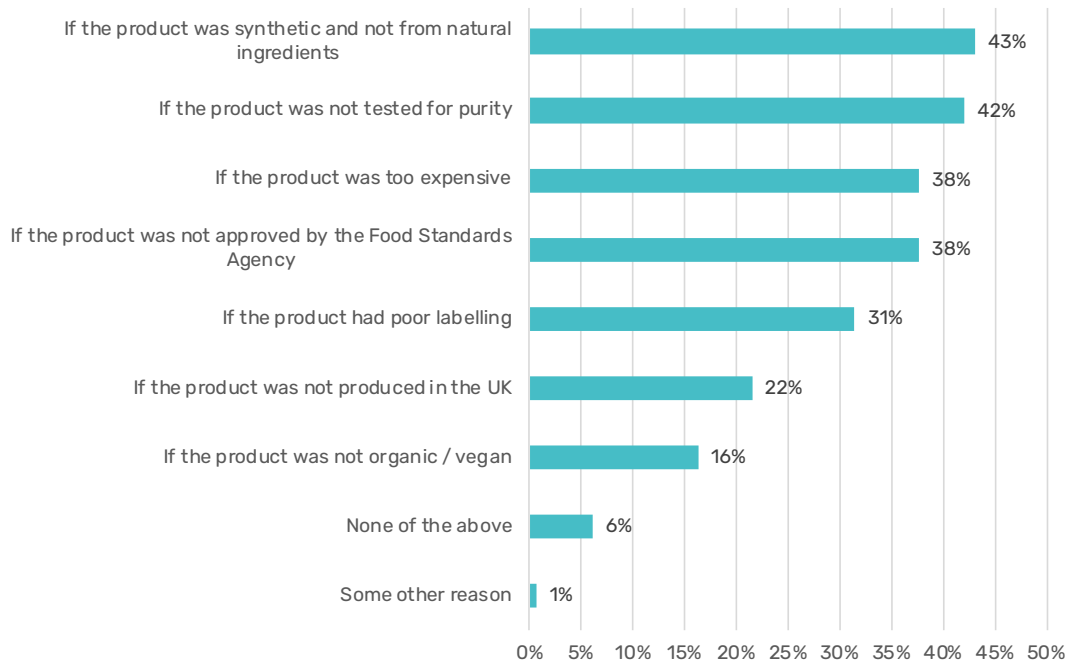


What is important to you when purchasing CBD-based products?
(sample size: 270)

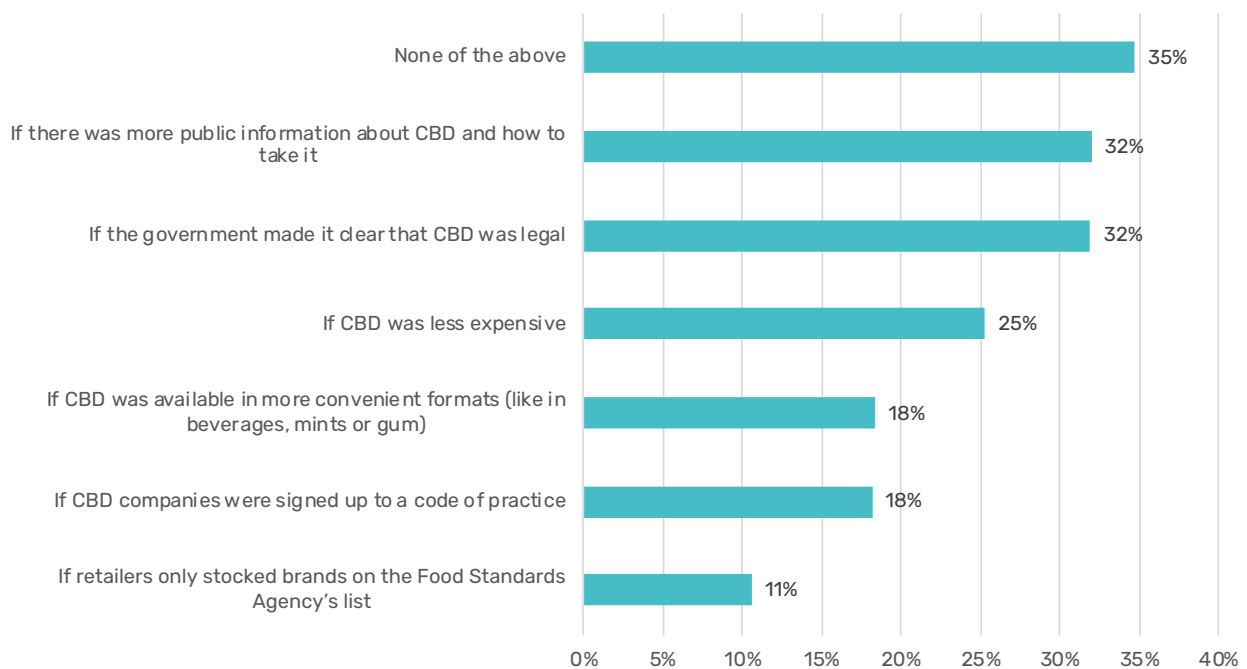


When it comes to purchasing CBD, which of the following would you find most concerning?

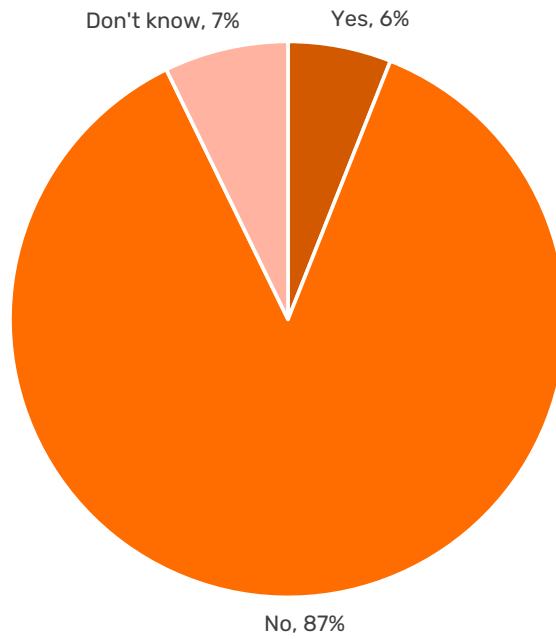
(sample size: 270)



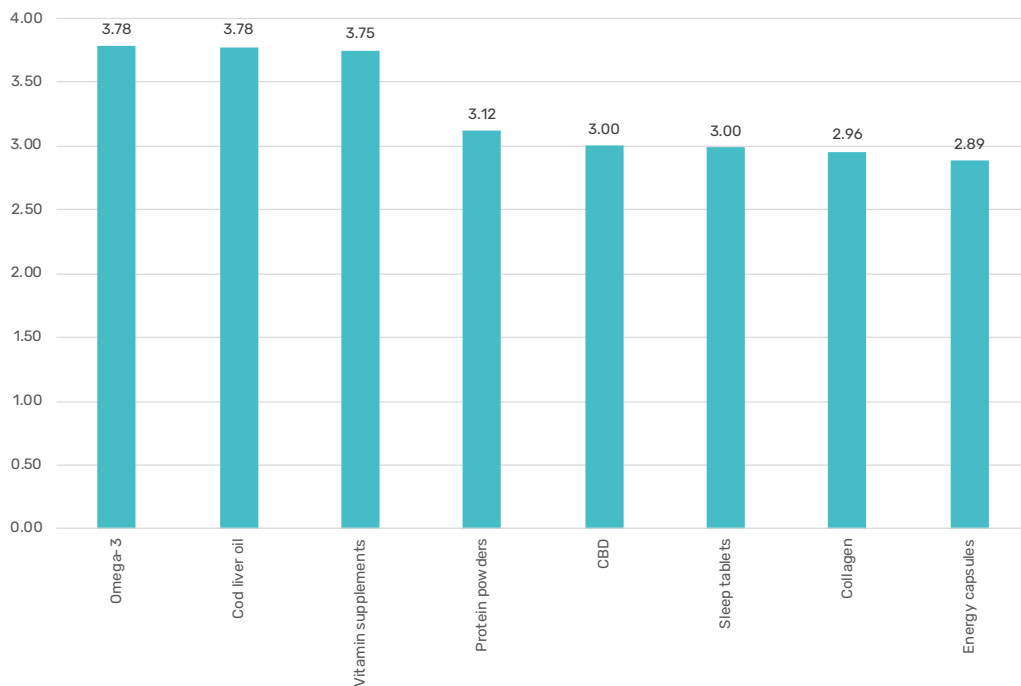
For respondents who have not purchased CBD before the following would make them more likely to try CBD in the future



Do you currently or have you ever given any type of CBD products to your pet (dog, cat, horse)?



Level of trust in consumer wellness or nutraceutical bought off the shelf (Mean average rated on a scale from 1 to 5, 1 is "very low trust" and 5 is "very high trust")



Since medicinal cannabis was made legal for a doctor to prescribe in 2018, do you know anyone personally who has had a medicinal cannabis prescription?

18%

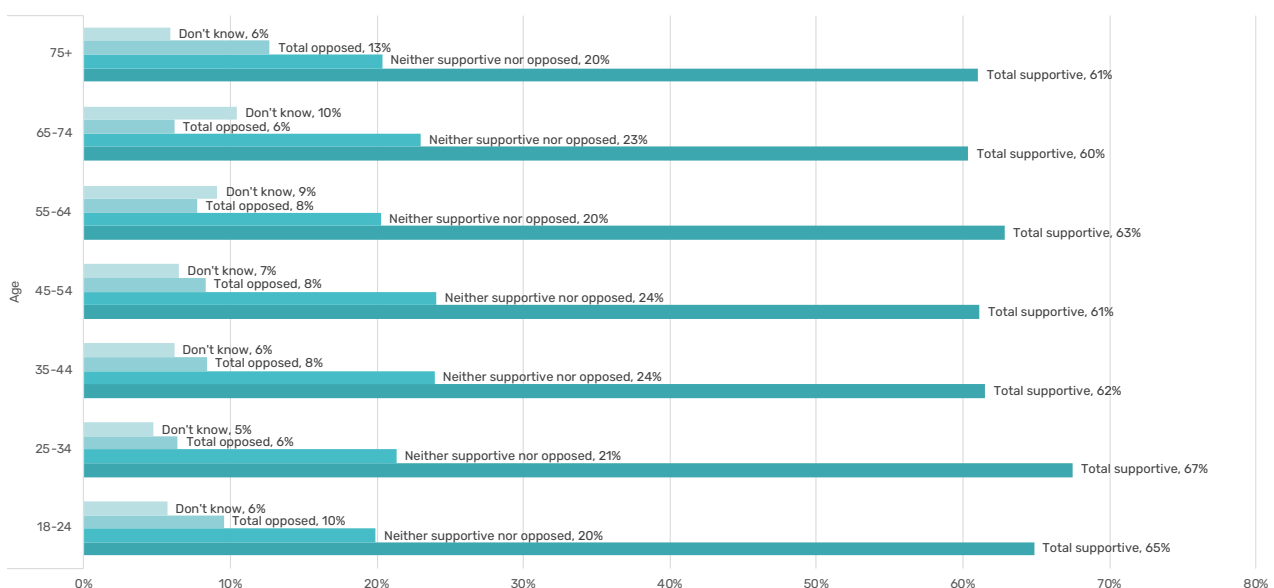
of respondents know someone personally who has had a medicinal cannabis prescription

Do you personally know anyone whose health has benefited from medicinal cannabis?

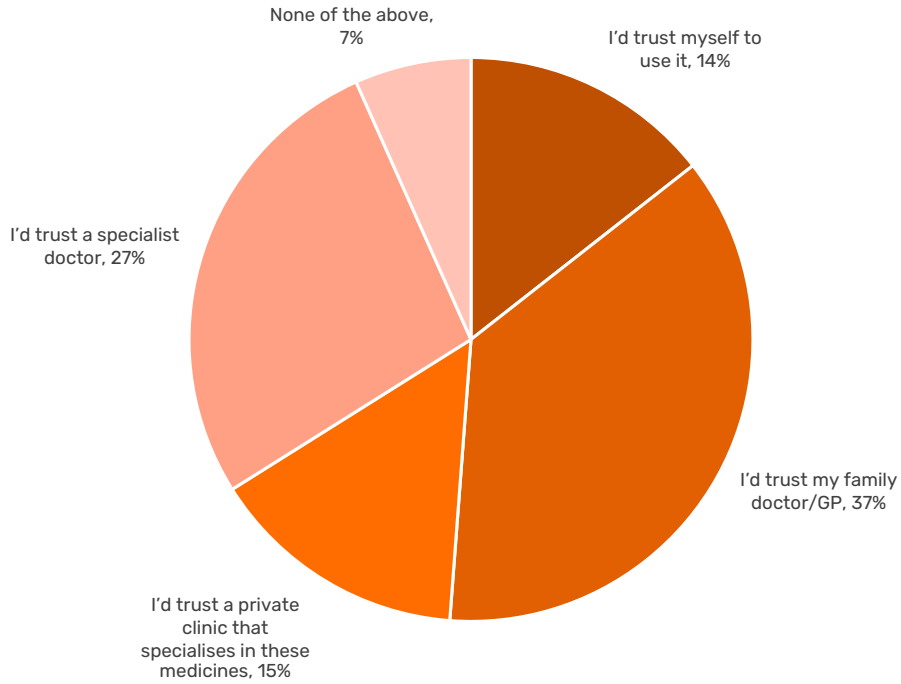
19%

of respondents know someone whose health has benefited from medicinal cannabis

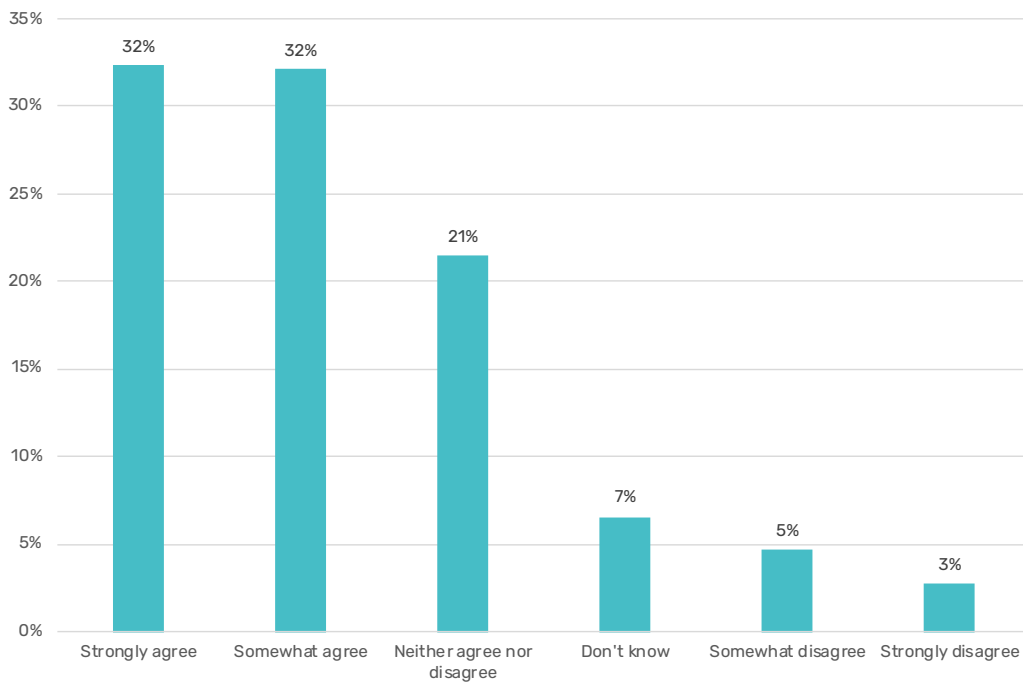
How would you feel if a family member of yours was taking medicinal cannabis to address a health condition?



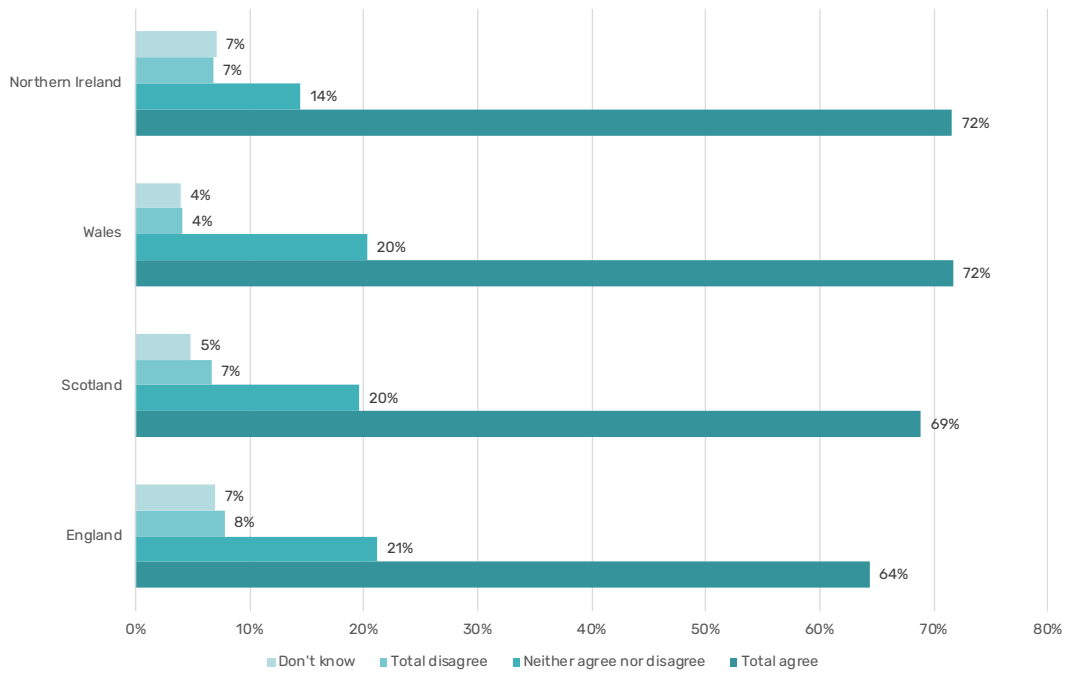
If you had a health need, who would you trust to prescribe medicinal cannabis to you?



To what extent do you agree with the following statements? The government should do more to support scientific research into cannabis in the UK



To what extent do you agree with the following statements? *The government should allow family doctors and GPs to prescribe medicinal cannabis*

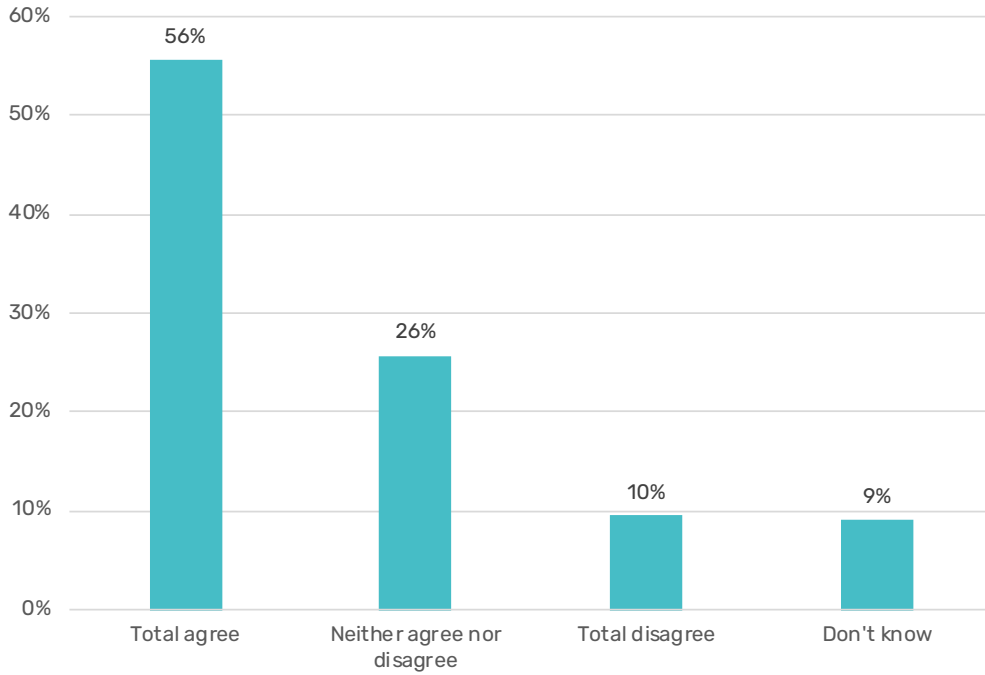


To what extent do you agree with the following statements? *In ten years time, there will be widespread understanding and acceptance of the medical benefits of cannabis*

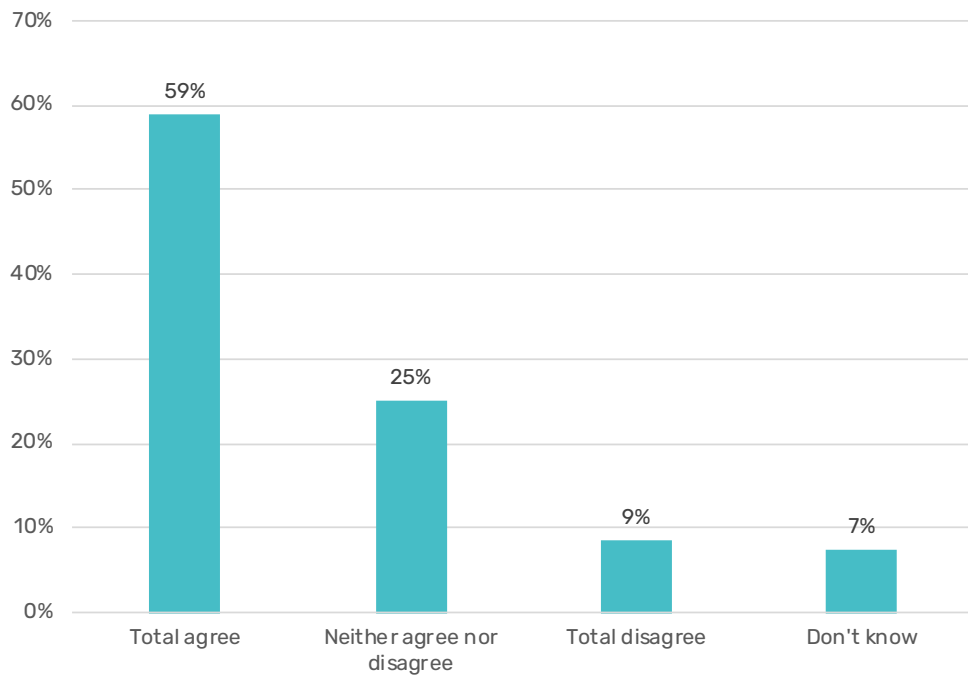
59%

of respondents think that in ten years time, there will be widespread understanding and acceptance of the medical benefits of cannabis

To what extent do you agree with the following statements? *The government should make an exception to drug licensing rules and make medicinal cannabis flower available on the NHS*

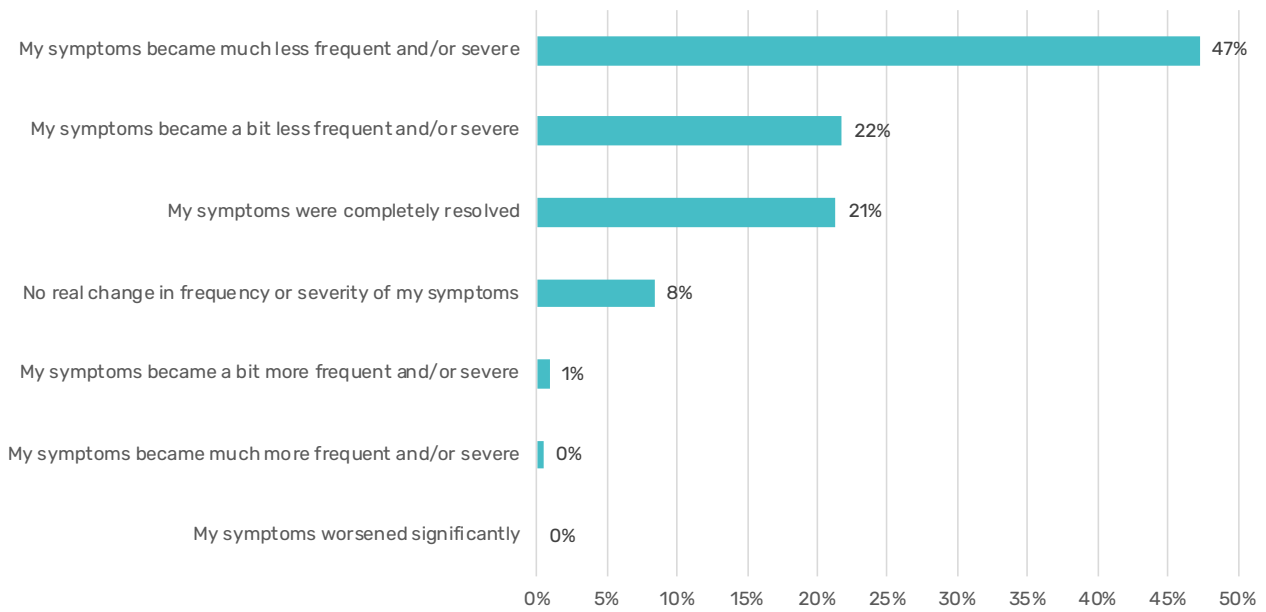


To what extent do you agree with the following statements? *The government should help lower the cost of medicinal cannabis prescribed in private clinics so more people can afford to buy it privately*

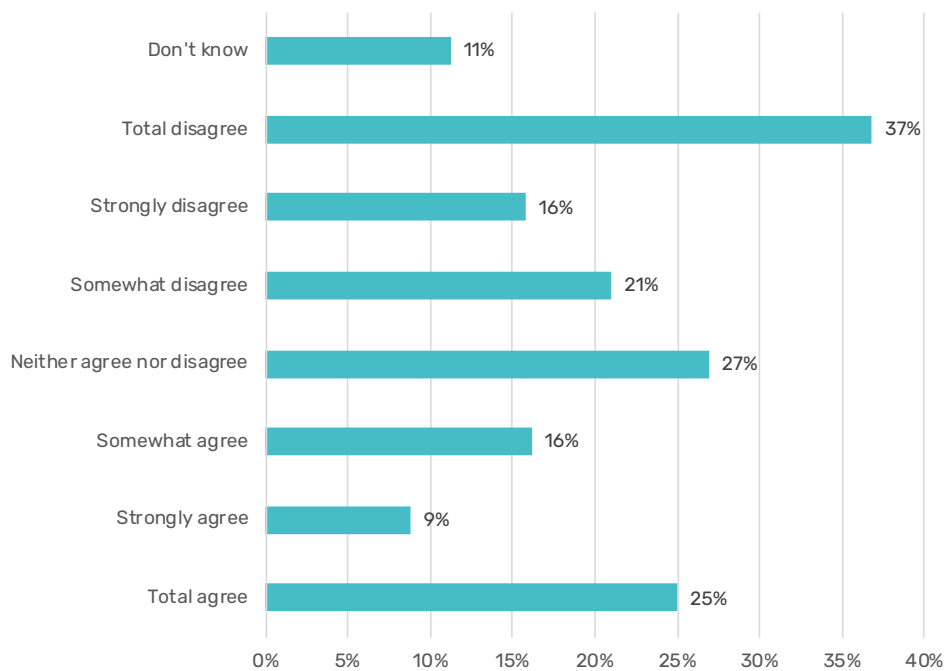


For your particular health issue, what was the effect you experienced from using cannabis?

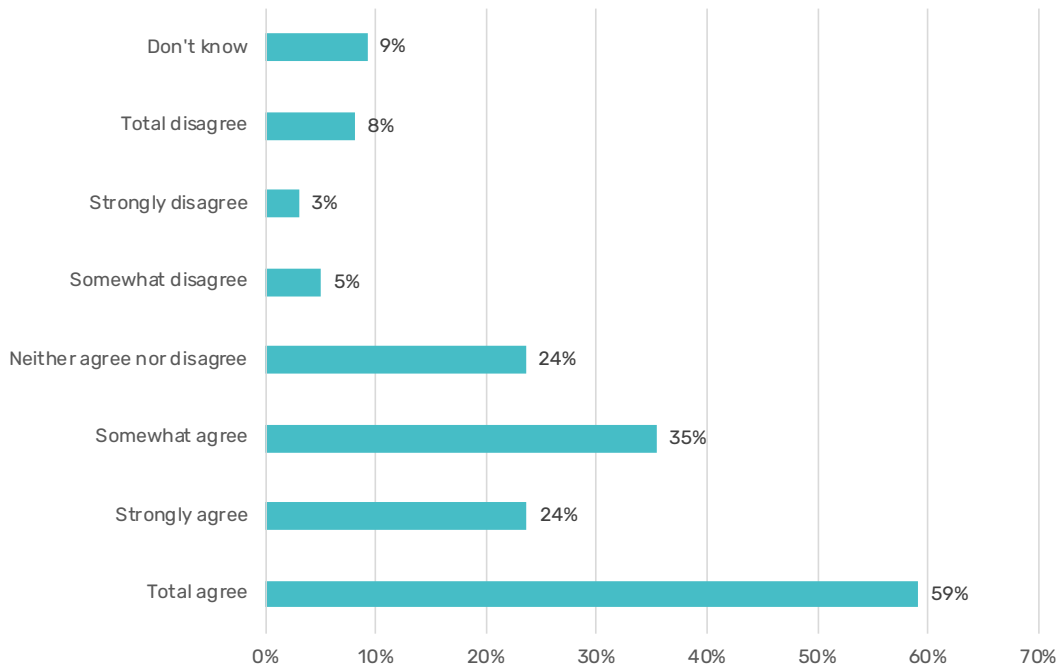
(sample size: 215)



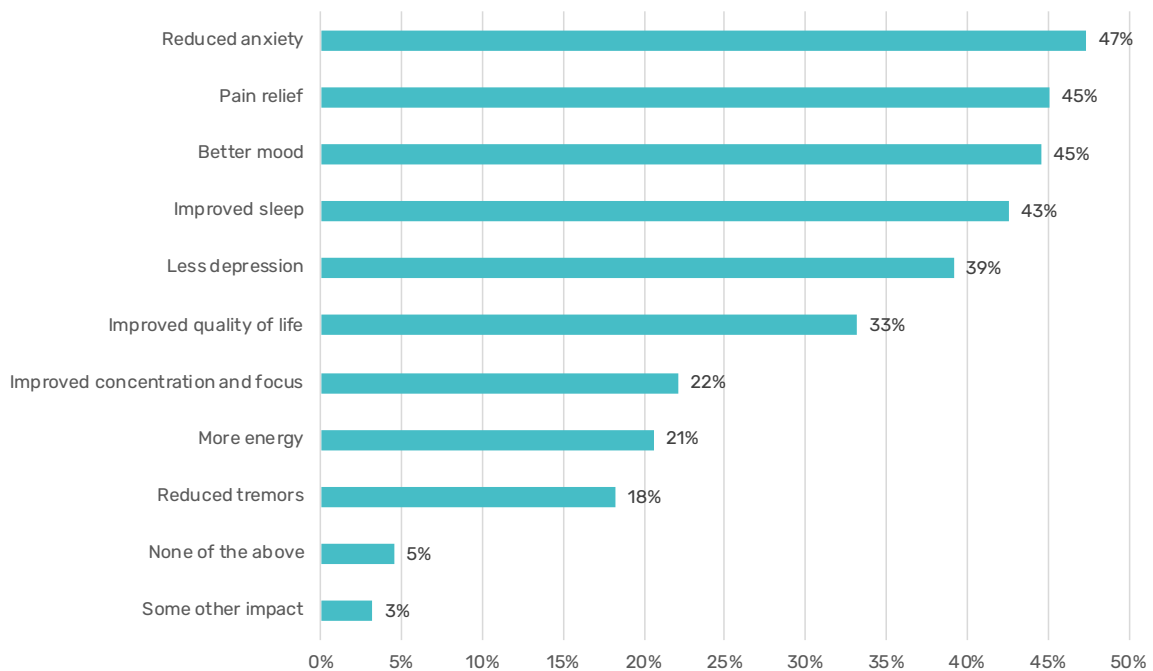
To what extent do you agree with the following statements? Medicinal cannabis is not a serious clinical treatment and is just used by people who want to consumer cannabis legally



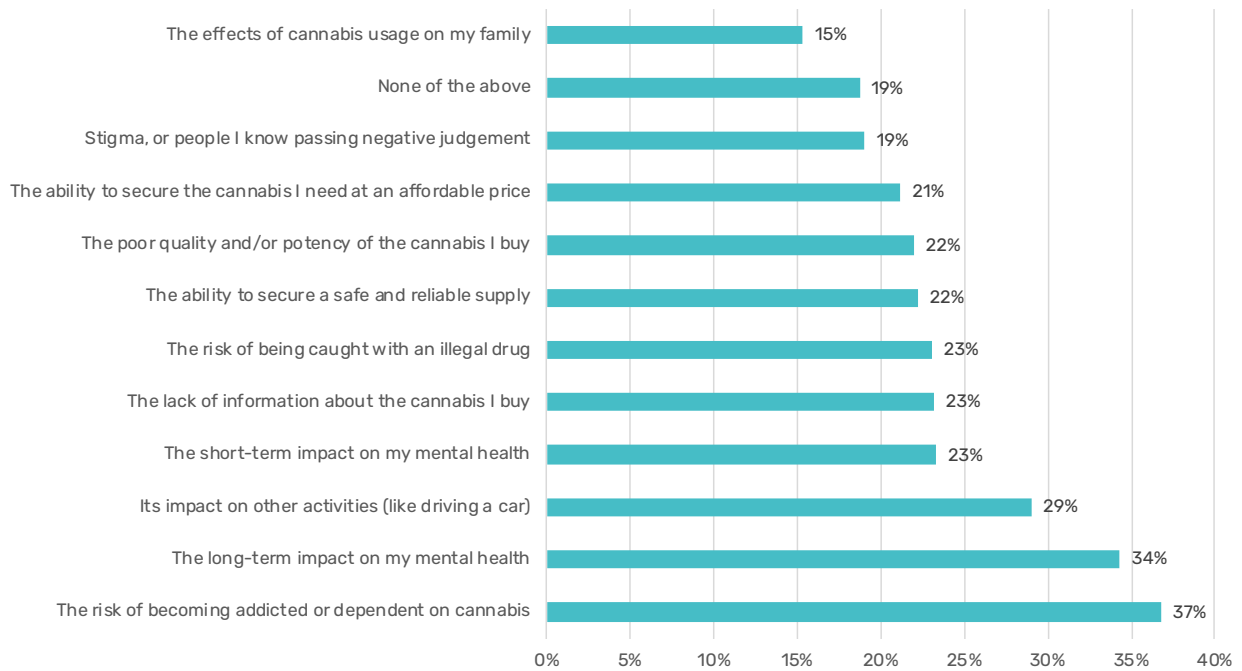
To what extent do you agree with the following statements? In ten years time, there will be widespread understanding and acceptance of the medical benefits of cannabis



In terms of some of the reported health benefits, which of the following have you personally experienced (sample size: 215)



When thinking about using cannabis to address your personal health issues, which of the following do you find concerning?



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