



# Cannabis and MS

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The role of cannabis in treating  
MS symptoms

July 2017

Let's stop MS together

## Foreword

Dealing with pain and spasticity<sup>1</sup> when you have MS is relentless and exhausting - it can make it impossible to manage daily life. Most people with MS will experience these symptoms at some point and, while there are licensed treatments available to help, they don't work for everyone.



But, we know that cannabinoids (compounds that make up the cannabis plant) could help. In the UK, MS is the only condition which has a licensed treatment derived from cannabis ('nabiximols' but also known as Sativex) – used to manage spasticity. Evidence also increasingly indicates that cannabis itself can be effective in treating pain.

Many people in the UK could benefit from taking Sativex. However, it's currently unavailable on the NHS (with the exception of Wales). That means for the most part, only people who can afford to pay for expensive private prescriptions can get it.

This has resulted in many people with MS turning to illegal forms of cannabis as an alternative. It's simply not right that some people are being driven to break the law to relieve their pain and spasticity. It's also really risky when you're not sure about the quality or dosage of what you're buying.

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<sup>1</sup> Spasticity refers to feelings of stiffness and a wide range of involuntary spasticity and is one of the most common symptoms of MS.

We have reviewed our position on cannabis use as a medicinal treatment for people with MS. With the aid of our medical advisers we reassessed the level of evidence. And we've worked with people with MS, both through a UK wide survey and focus groups, to share their perspectives and experiences. Of course the clinical evidence is not exhaustive and cannabis would not be appropriate for all people with MS. However, there is enough evidence to assert that cannabis for medicinal use, if managed properly, could benefit around 10,000 people who suffer from pain and spasticity.

We want to see all licensed treatments derived from cannabis made available to people who need them. But until that happens we're calling on the UK government to legalise cannabis for medicinal use to treat pain and spasticity in MS, when other treatments have not worked.

We believe that people should be able to access objective information about the potential benefits and side effects of using cannabis for medicinal purposes.

And, we believe it's both unfair and against the public interest to prosecute people with MS for using cannabis to treat pain and spasticity, when other treatments have not worked for them.

Countries like Germany and Canada have already made cannabis available for medicinal use, and Ireland is considering it. We hope this review starts a new conversation about cannabis for medicinal use in the UK. One that is based on the latest clinical evidence and which recognises the

extremely difficult situation in which many people with MS find themselves.

For our part, we'll continue to campaign for all people with MS to access the

right treatment at the right time, no matter where they live.

**Genevieve Edwards Director of External Affairs, MS Society**

## About MS

Over 100,000 of us in the UK have MS. It's unpredictable and different for everyone. It's often painful, exhausting and can cause problems with how we walk, move, see, think and feel. But it doesn't have to be this way. We're driving research into more – and better – treatments for everyone.

Together, we are strong enough to stop MS.

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## Executive Summary

In 2016 we revisited our stance on cannabis for medicinal use to better reflect the evidence, opinions and experiences of people with MS.

MS is the only condition which has a medically licensed, cannabis derived, treatment for spasticity, Sativex. However, Sativex is not available on the NHS across the UK (with the exception of Wales) because the pharmaceutical company and the relevant approval bodies have not been able to negotiate a pricing agreement, which is a major concern because many people simply cannot afford to pay for it privately.<sup>2</sup> We are calling for the pharmaceutical company and the NHS to get back around the negotiating table to explore every possible avenue to putting in place a flexible pricing agreement that can make Sativex available for people with MS who could benefit.

While there are a variety of symptom management treatments for pain and spasticity on the NHS,<sup>3</sup> they are not appropriate, available or effective for all people with MS who experience these symptoms.

In an anonymised survey, 22% of people with MS have told us that they have tried illegal forms of cannabis. A number of people who could benefit from Sativex, but cannot access it, feel their only option is to obtain cannabis illegally. Other people may have tried licensed<sup>4</sup> treatments for pain and spasticity, and found that they do not work for them, and so turn to cannabis instead. In either of such cases they cannot be sure of its quality and cannot access medical advice on the most safe and effective way of taking it.

Right now, people who use illegal cannabis risk prosecution with a maximum penalty of five years in prison and an unlimited fine.

We've consulted widely with people with MS and a number of clinicians to come to our revised position. In particular, we have:

- Surveyed 3,994 people with MS about their attitudes and experiences of cannabis<sup>5</sup>
- Conducted an analysis of all cannabis related clinical trials for MS
- Met with MS Society medical advisers to reach a consensus on whether cannabis could provide a benefit to people with MS

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<sup>2</sup> Sativex is technically available in Wales on the NHS, although we have evidence that many people with MS in Wales do not actually receive it. MS Society Cymru is working with the Welsh Government and Local Health Boards and we expect to see a rise in the number of prescriptions for Sativex in Wales.

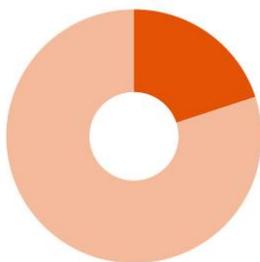
<sup>3</sup> Please see <https://www.mssociety.org.uk/what-is-ms/signs-and-symptoms>

<sup>4</sup> [NICE recommends which licensed treatments should be used in the NHS for pain and spasticity. This includes drugs like baclofen and gabapentin.](#)

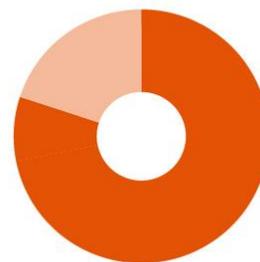
<sup>5</sup> Research conducted by the MS Society. An online survey was promoted between 8 and 22nd December 2014 via the MS Society social media and campaigns community, and the UK MS Register. 3,994 adults with MS, living in the UK responded. Data has not been weighted. For full results please see <https://www.mssociety.org.uk/node/696144>

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- Hosted a series of focus groups across the UK with people with MS to discuss how our position on cannabis for medicinal use should best reflect the evidence gathered in the previous steps.<sup>6</sup> We found that:
- 22% of people surveyed had tried cannabis for medicinal purposes and 7% were still using it
- 26% of people who had stopped taking cannabis, did so largely because of concerns over potential prosecution
- A further 26% of people with MS have considered using cannabis and decided not to – again concerns about legality and safety were often key reasons for this decision
- 72% of people we asked thought cannabis for medicinal use should be legalised
- The level of clinical evidence to support cannabis for medicinal use is not conclusive. But there is sufficient evidence for our medical advisers to say that on the balance of probability, cannabis for medicinal use could benefit many people with MS experiencing pain and muscles spasms, if they have tried other treatments that haven't worked for them. Our advisers estimate that this could be up to 10% of the UK MS population, which would mean approximately 10,000 people.
- People with MS felt there was a strong case to support a change in the law.



**22%** tried cannabis to help with their symptoms



**72%** thought cannabis for medicinal use should be legalised

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<sup>6</sup> Focus groups were carried out in January 2017. People with MS were invited to take part in discussion on 'symptom management treatments' rather than cannabis for medicinal use in order to attract a representative sample of opinions.

## Recommendations

### People with MS

- Other treatments are available to treat pain and spasticity in MS and these treatments should be prescribed and tried first.
- Cannabis derived licensed treatments are the best option and should be available, through the NHS, to all who could benefit. However, at the time of writing this report, this appears unlikely to happen until the price of Sativex is reconsidered or stronger clinical evidence of its effects on MS symptoms are produced.
- Approximately 10% of people with MS could benefit from taking cannabis for medicinal use as a treatment for pain and spasticity where other treatments are ineffective.
- We do not recommend that people smoke cannabis. Smoking is bad for MS.
- Some people, particularly those with previous mental health problems, may experience adverse effects and should not use medicinal cannabis.<sup>7</sup>
- While we understand that people often feel they have no option but to use illegal forms of cannabis, they should be aware of the risks. These include the unknown quantities of different cannabinoids (the compounds found in cannabis) which potentially present additional risks and uncertainties.<sup>8</sup>
- If someone does want to use cannabis, they should be able to consider the strain, formulation and dosage with advice from a health professional.

### The UK government

- The UK government and UK health bodies should develop a system that legalises cannabis for medicinal use to treat pain and spasticity in MS. This system should enable people with MS to access cannabis for medicinal purposes in a safe and legal way with the aid of a medical professional, where there is sufficient evidence that it can treat their symptoms and other treatments have not worked for them.
- Until that system is established people should not face prosecution for using cannabis to treat their MS symptoms.
- Failing this the government should introduce a defence so that, for example, possession of cannabis for medicinal purposes would not be a criminal offence.

### Industry

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<sup>7</sup> For more information on the mental health risks related to cannabis see <http://www.rcpsych.ac.uk/healthadvice/problemsdisorders/cannabis.aspx>

<sup>8</sup> For more information see <http://www.mssociety.org.uk/cannabis>

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- Sativex should be made routinely available on the NHS for people with MS who need it. The pharmaceutical company that makes Sativex need to work with the NHS to find a way of making Sativex widely available to people who need it.
- If further negotiations fail, the pharmaceutical company should consider the pricing of Sativex and/or pursue further research into the benefits to convince the NHS to make it available

## Researchers

- Further research should be undertaken to fully realise the medicinal effect that cannabis has on MS symptoms. As a funder of research, the MS Society, welcome proposals for clinical trials into cannabinoids.
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## What is cannabis?

Cannabis, or marijuana, refers to the dried flowers and leaves of the hemp plant, *Cannabis sativa*. Cannabis contains approximately 60 pharmacologically active compounds, also called cannabinoids. The two main cannabinoids thought to have medicinal value are delta-9-Tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is psychoactive while CBD is non-psychoactive. Psychoactive compounds affect brain functioning, causing changes in behaviour, mood and consciousness.

It is thought that the ratio of THC to CBD determines the level of psychoactive vs therapeutic effects of botanical and pharmaceutical cannabinoid-based drugs.

## What is 'medicinal cannabis'?

Medicinal cannabis is a term applied to a range of products botanical and pharmaceutical, legal and illegal, which are derived from the cannabis plant and are used to treat various symptoms. It can often be confusing as it's used interchangeably for all the various forms in popular media. We've tried to simplify this by unpacking the term into the following categories:

### 1. Licensed medical cannabis

To achieve a medical licence for use in the UK, a treatment has to have undergone clinical trials. These trials compare its effects with a placebo or another treatment which is commonly prescribed for the same purpose. In the UK there are two medically licensed treatments which are regularly referred to as medicinal cannabis:

**Nabilone** is a synthetic THC drug licensed to treat nausea for people undergoing chemotherapy. Some people with MS have been prescribed this 'off label' (meaning outside its licence) to treat pain or spasticity. Access to it varies depending on where in the UK you live and whether your doctor would be willing to prescribe it for you.<sup>9</sup>

**Sativex** is a drug derived from cannabis, containing a 1:1 ratio of THC to CBD. It has a licence to treat spasticity in MS which means it can be prescribed by a doctor.<sup>10</sup> However, as it's not approved to be routinely commissioned on the NHS (with the exception of Wales), it is extremely difficult to get without paying for a private prescription. In 2014 NICE looked at Sativex when updating their guidelines for MS and came to the conclusion that it did not represent a cost effective use of NHS resources. We strongly criticised this decision at the time and have been calling for it to be made available on the NHS ever since. In Wales, the All Wales Medicines Strategy Group (AWMSG) went against the NICE decision and recommended Sativex for use on the NHS [August 2014]. However, we've found that despite the AWMSG's decision people in Wales, many people with MS in Wales do not actually receive it. MS Society Cymru is working with the Welsh Government, clinicians and Local Health Boards to address this, and we expect to see a rise in the number of prescriptions for Sativex in Wales.

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<sup>9</sup> See <https://bnf.nice.org.uk/drug/nabilone.html#indicationsAndDoses> for prescribing recommendations.

<sup>10</sup> For information on Sativex's medical license please see <http://www.mhra.gov.uk/spc-pil/?prodName=SATIVEX%20ROMUCOSAL%20SPRAY&subsName=CANNABIDIOL&pageID=SecondLevel>

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## 2. Unlicensed medicinal cannabis

There are also cannabis products which are not typically used for recreational purposes but do not have a medicinal licence. The most common examples in the UK are products which are advertised as CBD only. These sometimes claim to provide a number of benefits and until recently were legal to buy online in the UK due to not containing THC (the psychoactive THC cannabinoid).

The Medicines and Healthcare products Regulatory Agency (MHRA) decided in 2017 that, as CBD only products are sold and used to treat various symptoms, they should be considered a medicine. That means they need a medical licence to be sold legally in the UK. A licence requires clinical evidence gathered from trials; CBD products do not currently have this, so are likely to be unavailable in the UK for a number of years. You may see them still being sold as 'food supplements'.

## 3. Recreational cannabis

The various forms of recreational (or botanical) cannabis are what most people think of when the term medicinal cannabis is used. Commonly used recreationally, whether grown or bought in any form, all are currently illegal. Cannabis that's grown and sold illegally include hash, weed, skunk and cannabis oil, and the levels of THC to CBD varies depending on the strain and form.

Skunk, which contains high levels of THC, is particularly prevalent in the illegal market. It has been particularly developed to optimise cannabis' psychoactive (rather than for medicinal) properties.<sup>11</sup>

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<sup>11</sup> For more information see <http://www.talktofrank.com/drug/cannabis>

## Experiences and views of the MS Community<sup>12</sup>

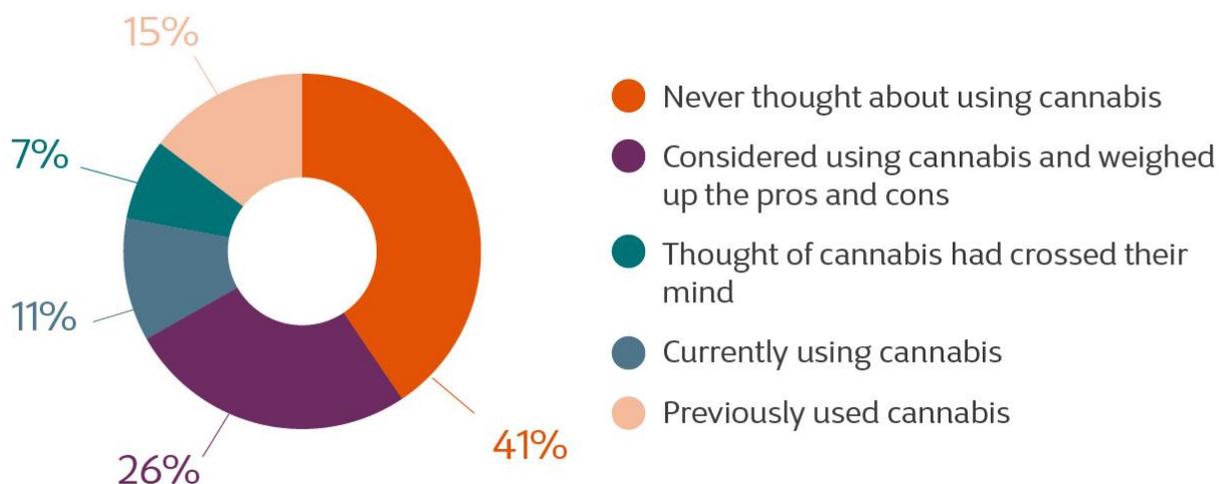
We conducted a survey of 3,994 people with MS from across the UK in September 2014 asking for their attitudes and experiences of cannabis and Sativex. The survey was conducted anonymously through various channels to capture the range of experiences and views that people with MS hold.<sup>13</sup> The respondents were:

- 71% female, 29% male
- 51% aged 35-54, 39% over 55, 10% 18-34
- 49% relapsing remitting MS, 28% secondary progressive, 15% primary progressive

### Using cannabis to manage symptoms

More than 1 in 5 people (22%) reported they had used cannabis to try to manage their MS symptoms and 7% of those surveyed were still using cannabis.

26% had considered using cannabis, weighing up the pros and cons, but had not taken it.



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<sup>12</sup> All quotes included from the survey have been anonymised. For more information on the methodology of the survey, see full report <https://www.mssociety.org.uk/node/696144>

## Why people were using cannabis

The majority of people (56%) currently using cannabis for medicinal purposes felt that the benefits outweighed the side effects. 40% of those currently using cannabis were doing so because they were unable to obtain a prescription for a licensed alternative.

"I am using cannabis because I am unable to obtain Sativex. I would rather use Sativex than be in the position of using a drug dealer"

Cannabis was most commonly used to treat pain, muscle stiffness, spasticity and spasms. Many also commented on cannabis aiding a good night's sleep, which in turn had a positive impact on other MS symptoms.

"if any of my symptoms are severe enough to cause chronic sleep deprivation... then after a week or so of that I'll use cannabis"

## Why people stopped using cannabis

The illegal status of cannabis was a factor in why people stopped using it. 18% no longer used cannabis as they wanted to manage their MS without using illegal drugs and 15% were specifically concerned about being prosecuted. Others commented on the difficulty in continuing to source cannabis.

## Why people don't take cannabis

"My main concerns are prosecution, having to find a 'dealer', the 'high' you get from cannabis and becoming hooked"

78% of people had never used cannabis but 11% had considered it and 26% said they had weighed up the pros and cons. When asked to give a reason for why they hadn't used cannabis many commented that they did not know how to access it. Others were wary of the potential negative impact on family and friends if they were to take an illegal drug.

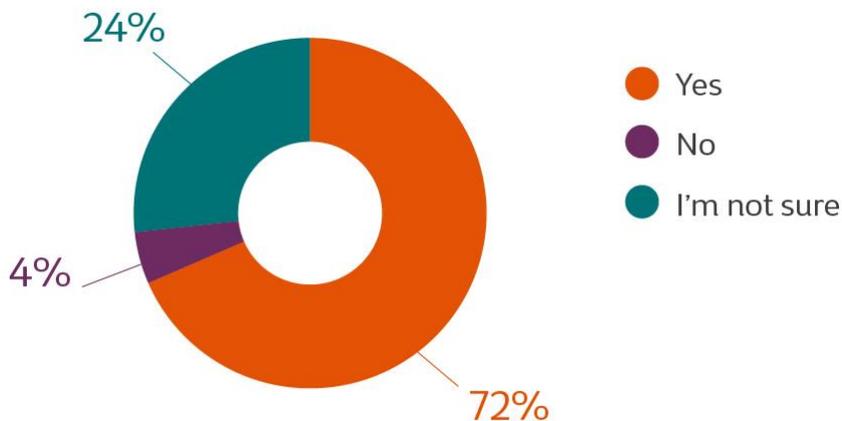
Safety was an issue raised, with people commenting that they 'would like to try it from a safe and legal source'. Others had used cannabis in the past recreationally and had had negative experiences.

"Cannabis... is not regulated, can't be relied upon to be totally safe, is not a route I would wish to go down"

For many, it was down to the fact that they were unwilling to engage in an illegal activity.

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## Thoughts on whether cannabis for medicinal use should be legal



The vast majority favoured legalisation of cannabis for medicinal use (72%), despite many not having tried it. Only 4% of respondents felt strongly against legalisation. Four out of five did not personally consider it to be an issue of high priority.

"I wish that I didn't have to break the law in order to feel more normal but this is definitely better than how life was!"

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## Evidence Review

### What does the clinical evidence say?

In 2016, we reviewed the existing clinical trials that have been conducted into cannabis and cannabis derived drugs for treating MS.

A number of clinical trials have been carried out to investigate how cannabinoids could benefit people with MS, including trials into Sativex.

### Summary of available evidence

The leading research journal *Neurology* and the American Academy of Neurology (AAN) have developed guidelines to assess the quality of different clinical trials and provide recommendations for clinicians regarding the benefits of treatments in clinical trials.<sup>14</sup> Our findings are mainly based on two evidence reviews they carried out in 2014.

Many of the trials recorded both whether people felt a subjective benefit from the treatment as well as testing their symptoms for any improvement using objective clinical measures.



#### Evidence for smoked cannabis

There is currently not enough evidence to suggest that smoking cannabis can treat spasticity or pain in MS and smoking can negatively impact on an individual's MS. However, trials into different forms of cannabis have shown more promising results.<sup>15</sup>



#### Oral cannabis extract

Different cannabinoids have been studied within clinical trials and are referred to here as 'oral cannabis extracts'. This includes various preparations of cannabis extract, dronabinol (2.5 mg THC), and nabilone (100 mg CBD).

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<sup>14</sup> Koppel et al., Efficacy and safety of medical marijuana in selected neurological disorders: Report of the Guideline Development Subcommittee of the American Academy of Neurology, *Neurology*, 2014

<sup>15</sup> Studies have shown that smoking tobacco has a negative effect on a person's MS. For more information see <https://www.mssociety.org.uk/ms-news/2015/09/smoking-and-ms-new-evidence>

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Spasticity	The results showed that people felt that oral cannabis extracts were effective at reducing their symptoms of spasticity but when tested objectively it was less clear whether symptoms were improving.
Pain	The evidence found that oral cannabis extracts were effective at alleviating pain or painful spasms both subjectively and objectively.
Other	Other MS symptoms were studied within the trials such as tremors and bladder symptoms but did result in convincing enough evidence.



### Nabiximols (Sativex)

Spasticity	The trials for Sativex show that people felt it was effectively treating their spasticity, but that is was not clear that it was effective from a clinically objective standpoint.
Pain	In treating central pain or painful spasms, Sativex was found to be probably effective at alleviating pain or painful spasms but the evidence is not as strong as it is for oral cannabis extracts.
Other	The evidence for treating tremors and bladder symptoms is not currently convincing.

### Reported adverse effects

There were common side effects reported across the studies with cannabis derived drugs including: dizziness, drowsiness, memory disturbance, difficulty concentrating, increased appetite, nausea, vomiting and constipation. Less common side-effects were: myalgia, increased spasticity, seizures, lower limb weakness, cystitis, dehydration, temporary psychosis and hallucinations.

## Perspectives of MS Society medical advisers

### Interpreting the evidence 'on the balance of probability'

We convened a meeting of our MS Society medical advisers in December 2016, to consider whether:

*"On the balance of probability could cannabis for medicinal purposes improve the quality of life for people with MS?"*

Five neurologists specialising in MS from across the UK attended and discussed both their own views on cannabis for medicinal use and whether they felt the evidence was strong enough to recommend cannabis as a treatment.

They noted the challenges they have had in prescribing Sativex to people who could benefit, commenting that, while some people respond well to it, it is not appropriate for everyone. They also highlighted that the benefit of Sativex over other forms of cannabis is that the formulation and recommended dosage means that a predictable response is achieved.

In their experience individual requests for funding (the only route to get Sativex on the NHS, with the exception of Wales) were consistently refused.

### Cannabis in treating different symptoms

The medical advisers considered the level of clinical evidence available on cannabis before coming to a consensus on whether it could help treat spasticity, pain and other symptoms (like tremor).

#### *Spasticity*

Our medical advisers felt that cannabis should be considered for people who do not see clinical benefit from current first line treatments.<sup>16</sup> Estimating, from the trial evidence and personal experience, that approximately a quarter of people with spasticity could potentially benefit.

#### *Pain*

Our medical advisers highlighted that there are a variety of treatments available for pain management. But, if these were ineffective, cannabis could potentially provide a benefit for a number of people with MS.

#### *Other symptoms*

In trials people have reported improvement in bladder symptoms and there are anecdotal reports of improvement in tremor. However our advisers felt that, at

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<sup>16</sup> There are a range of treatments available for different symptoms. To see more please go to <https://www.mssociety.org.uk/what-is-ms/signs-and-symptoms>

present, there was insufficient evidence to make a recommendation that cannabis could be useful in treating other symptoms associated with MS.

## Overall Consensus

It was felt that, on the balance of probability, cannabis offers the potential for symptomatic relief for pain and spasticity, and an improvement of quality of life for approximately 10% of the overall MS population, however;

- It should only be factored as part of an overall approach to symptom management (including medications and physical therapies), not in isolation. Cannabis is not recommended over other symptom management treatments available. Our advisers only recommended using it after trying other tried and tested options.
- Smoking cannabis is not recommended as it presents too great a risk<sup>17</sup>
- Some people may experience adverse effects, such as mental health issues, and should not use cannabis for medicinal purposes.<sup>18</sup>
- At present cannabis remains illegal and there is considerable variability in its use. If cannabis were to be used for medicinal purposes, the strain, formulation and dosage would need to be considered and ideally advice should be sought from a health professional.

## Further research

The consensus from our medical advisers based on the 'balance of probability' suggests that cannabis can benefit people with MS. While we strongly feel that the urgency of the situation requires action now, we also want to see the current evidence base improved. For this to happen, more research is needed.

Ultimately, as well as potential further research into the benefits of Sativex, we want to see licensed medical cannabis for MS, including Sativex, routinely available to all people with MS who could benefit.

As a funder of research, we welcome research proposals which wish to further explore the medicinal properties of cannabinoids for MS symptoms.

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<sup>17</sup> For more information on the risks of smoking in MS see <https://www.mssociety.org.uk/ms-news/2015/09/smoking-and-ms-new-evidence>

<sup>18</sup> For more information on the mental health risks related to cannabis see <http://www.rcpsych.ac.uk/healthadvice/problemsdisorders/cannabis.aspx>

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## Focus Groups

In January 2017, we held focus groups in Birmingham, Belfast, Cardiff and Edinburgh to consult people with MS on how our new position on cannabis for medicinal use should best reflect the evidence. To include as representative sample as possible, the participants were invited through the MS Register based on their demographics and were only informed they would be discussing cannabis for medicinal use once they had confirmed their place. Each focus group was given a summary of the findings from the survey, the evidence review and the medical adviser meeting and asked to discuss how they would like to see the MS Society act on these findings.

Every focus group expressed some confusion over what was considered 'medicinal cannabis' as opposed to recreational cannabis, many had been exposed to misinformation from unreliable sources. All participants highlighted that they wanted the MS Society to provide access to objective and trustworthy information.

The consensus was that there was a strong enough evidence base to support a call for legalisation, regardless of whether they personally felt they could benefit from taking cannabis. All groups had a generally relaxed attitude towards cannabis use, though not all participants wanted to use it personally.

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## Conclusion

We feel that the results from our review point to one clear, sensible approach: legalising cannabis for medicinal use for people with MS who are experiencing symptoms of pain and spasticity and where other treatments have not worked. A number of other countries have already taken this step or are considering it, offering the UK examples of different ways this could be conducted.

Each of the four strands of this review has followed robust procedures to ensure our results are objective.

We hope by undertaking such a thorough review, publishing these findings and our recommendations lead to a renewed conversation about cannabis for medicinal use in the UK.

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