NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline

Cannabis-based medicinal products

Draft for consultation, August 2019

This guideline covers prescribing of cannabis-based medicinal products for people with intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy. In this guideline cannabis-based medicinal products include:

- cannabis-based products for medicinal use as set out by the UK Government in the 2018 Regulations
- the licensed products delta-9-tetrahydrocannibinol and cannabidiol (Sativex) and nabilone
- plant-derived cannabinoids such as pure cannabidiol (CBD)
- synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example, dronabinol.

Who is it for?

- Healthcare professionals prescribing cannabis-based medicinal products
- Healthcare professionals providing care for people taking cannabis-based medicinal products
- Commissioners and providers of services for people taking cannabis-based medicinal products
- People taking cannabis-based medicinal products, their families and carers.

This draft guideline contains:

- the draft recommendations
- recommendations for research
- rationale and impact sections that explain why the committee made the recommendations and how they might affect practice
- the guideline context.

Information about how the guideline was developed is on the guideline's page on the NICE website. This includes the evidence reviews, the scope, and details of the committee and any declarations of interest.

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Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.1 Intractable nausea and vomiting

1.1.1 Consider nabilone as an add-on treatment for adults (18 years and over) with chemotherapy-induced nausea and vomiting which persists with optimised conventional antiemetics.

1.1.2 When considering nabilone for adults with chemotherapy-induced nausea and vomiting, take into account potential adverse drug interactions, for example, with central nervous system depressants and other centrally active drugs.

To find out why the committee made the recommendations on intractable nausea and vomiting and how they might affect practice, see rationale and impact.

1.2 Chronic pain

1.2.1 Do not offer the following to manage chronic pain in adults:

- nabilone
- dronabinol
- THC (delta-9-tetrahydrocannabinol)
- a combination of cannabidiol (CBD) with THC.

1.2.2 Do not offer CBD to manage chronic pain in adults unless as part of a clinical trial.

To find out why the committee made the recommendations on chronic pain and how they might affect practice, see rationale and impact.

1.3 Spasticity

1.3.1 Do not offer THC: CBD spray (Sativex) to treat spasticity in people with multiple sclerosis because it is not a cost-effective treatment at its list price.

1.3.2 Do not offer other cannabis-based medicinal products to treat spasticity unless as part of a clinical trial.

To find out why the committee made the recommendations on spasticity and how they might affect practice, see rationale and impact.

1.4 Severe treatment-resistant epilepsy

Because there is no good quality evidence in this population, the committee were unable to make a recommendation on the use of cannabis-based medicinal products for severe treatment-resistant epilepsy. Therefore, they made research recommendations to promote further research and inform future practice

NICE is developing technology appraisal guidance on CBD for adjuvant treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome, with publication expected in December 2019. Therefore, the use of CBD for seizures associated with these syndromes was excluded from the guideline.

To find out why the committee made the research recommendations on CBD, and THC in combination with CBD for severe treatment-resistant epilepsy, see rationale.

1.5 Prescribing

Who should prescribe?

1.5.1 Initial prescription of cannabis-based medicinal products[1] must be made by a clinician on the General Medical Council's Specialist Register who should have a special interest in the condition being treated. For children and young people under 18 years, the initiating prescriber should be a tertiary paediatric specialist.

Shared care

1.5.2 After the initial prescription, subsequent prescriptions of cannabis-based medicinal products may be issued by another prescriber as part of a shared care agreement under the direction of the initiating specialist prescriber.

1.5.3 Efficacy and safety of cannabis-based medicinal products should be monitored and evaluated, and doses should be adjusted by the initiating specialist prescriber as part of the shared care agreement.

1.5.4 A shared care agreement for a person prescribed a cannabis-based medicinal product should include:

- the responsibilities of all parties [the initiating specialist prescriber, the other prescriber(s), the patient, family and carers]
- the nature and frequency of monitoring and how this will be recorded
- when treatment might be stopped, for example, if it is not effective or adverse events are severe

[1] This excludes nabilone which has a marketing authorisation for treating chemotherapy-induced nausea and vomiting in adults (aged 18 years and over). The summary of product characteristics does not specify who should prescribe the product.

- how communication will be managed between the initiating specialist prescriber, the other prescriber, the patient, family and carers
- how the treatment will be funded
- how care will be maintained when either the patient or the initiating specialist prescriber moves location.

To find out why the committee made the recommendations on who should prescribe and how they might affect practice, see rationale and impact.

Factors to think about when prescribing

1.5.5 When prescribing cannabis-based medicinal products, take into account:

- current and past use of cannabis (including any over-the-counter and online products)
- history of substance misuse
- potential for dependence, diversion and misuse (in particular with THC)
- mental health and medical history, in particular, liver impairment, renal impairment, cardiovascular disease
- potential for interaction with other medicines, for example, hypnotics, sedatives and hormonal contraceptives
- pregnancy and breastfeeding.

1.5.6 When prescribing cannabis-based medicinal products for babies, children and young people, pay particular attention to the:

- potential impact on psychological, emotional and cognitive development
- potential impact of sedation
- potential impact on structural and functional brain development.

1.5.7 When prescribing cannabis-based medicinal products, advise people to stop any non-prescribed cannabis, including over-the-counter, online and illicit products.

1.5.8 For more information on safe prescribing and use of cannabis-based medicinal products, see the recommendations in the NICE guideline on controlled drugs.

To find out why the committee made the recommendations on factors to think about when prescribing and how they might affect practice, see rationale and impact.

Supporting shared decision making

1.5.9 Before prescribing cannabis-based medicinal products, advise people about:

- the potential benefits, any potential harms, including any risk of dependence or interaction with other medicines
- the licensed status of products
- how long they are expected to use the medicine
- how long it will take to work
- what it has been prescribed for
- how it may affect their ability to drive (see the advice from the Department of Transport on drug driving and medicine: advice for healthcare professionals)
- not allowing others to use the prescribed medicine.

1.5.10 When discussing cannabis-based medicinal products with patients and their families and carers, follow the recommendations on shared decision making in the NICE guideline on patient experience in adult NHS services.

To find out why the committee made the recommendations on supporting shared decision making and how they might affect practice, see rationale and impact.

Terms used in this guideline

Cannabis-based medicinal products

In this guideline cannabis-based medicinal products include:

- cannabis-based products for medicinal use as set out by the UK Government in the 2018 Regulations
- the licensed products delta-9-tetrahydrocannibinol and cannabidiol (Sativex) and nabilone
- plant-derived cannabinoids such as pure cannabidiol (CBD)
- synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example, dronabinol.

Optimised conventional antiemetics

These are treatments that are commonly used in practice at an optimum tolerated dose to manage nausea and vomiting.

Recommendations for research

The guideline committee has made the following recommendations for research.

Key recommendations for research

1 Fibromyalgia or persistent treatment-resistant neuropathic pain in adults

For adults with fibromyalgia or persistent treatment-resistant neuropathic pain, what is the clinical and cost effectiveness of cannabidiol (CBD) as an add-on to standard treatment? What is the effectiveness of CBD as an add-on treatment compared to standard treatment alone?

To find out why the committee made the research recommendation on fibromyalgia or persistent treatment-resistant neuropathic pain in adults see rationale and impact.

2 Chronic pain in children and young people

In children and young people with intractable cancer-related pain and pain associated with specific diseases (such as epidermolysis bullosa), what is the clinical and cost effectiveness of cannabis-based medicinal products as an add-on to standard treatment to improve symptoms in comparison to treatment with standard care?

To find out why the committee made the research recommendation on chronic pain in children and young people see rationale and impact

3 CBD for severe treatment-resistant epilepsy

What is the clinical and cost effectiveness of CBD in epileptic disorders in children, young people and adults?

To find out why the committee made the research recommendation on CBD for severe treatment-resistant epilepsy see rationale.

4 THC in combination with CBD for severe treatment-resistant epilepsy

Does the addition of delta-9-tetrahydrocannabinol (THC) to CBD have an effect on seizure frequency, brain structure and neurophysiological performance when compared with both CBD alone and placebo in epileptic disorders in children, young people and adults?

To find out why the committee made the research recommendation on THC in combination with CBD for severe treatment-resistant epilepsy see rationale.

5 Spasticity

What is the clinical and cost effectiveness of cannabis-based medicinal products for people with spasticity? In particular, what is the impact of spasticity on improvements in quality of life?

To find out why the committee made the research recommendation on spasticity see rationale and impact.

Other recommendations for research

Chemotherapy-induced intractable nausea and vomiting in adults

What is the clinical and cost effectiveness of cannabis-based medicinal products as an add-on treatment for adults with chemotherapy-induced nausea and vomiting which persists with optimised conventional antiemetics?

Chemotherapy-induced intractable nausea and vomiting in babies, children and young people

What is the clinical and cost effectiveness of cannabis-based medicinal products as an add-on treatment in babies, children and young people with chemotherapy-induced nausea or vomiting which persists with optimised conventional antiemetics?

Intractable nausea and vomiting not caused by chemotherapy

What is the clinical and cost effectiveness of cannabis-based medicinal products as an add-on treatment for people with persistent nausea or vomiting not caused by chemotherapy which hasn't fully responded to optimised conventional antiemetics?

Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect practice. They link to details of the evidence and a full description of the committee's discussion.

Intractable nausea and vomiting

Recommendations 1.1.1. to 1.1.2

Why the committee made the recommendations

Intractable nausea or vomiting can be defined as persistent nausea or vomiting that does not respond fully to optimal antiemetic treatment. Although there are different causes of intractable or persistent nausea and vomiting, evidence was only identified for the use of delta-9-tetrahydrocannabinol (THC), nabilone and dronabinol in people with chemotherapy-induced and radiotherapy-induced nausea and vomiting.

Limited evidence showed that nabilone, which is licensed in the UK for adults, resulted in complete or partial reduction in chemotherapy-induced nausea and vomiting. However, most of the studies were old, of low quality and used outdated antiemetic regimens that do not reflect current practice. Nabilone was also associated with more adverse events (drowsiness, dizziness and dry mouth), particularly in children. The committee noted that although use of cannabis-based medicinal products for intractable chemotherapy-induced nausea and vomiting would

be short term, there was a lack of evidence on longer term adverse events, such as dependence and the development of psychological disorders. They identified this as a concern, particularly when considering repeated use. The committee also noted the limited evidence for children and young people, based on these findings they were unable to make recommendations specifically for this group.

The committee agreed that nabilone may play a role in treating intractable chemotherapy-induced nausea and vomiting in people who have not had a full response to optimal antiemetic therapy. Based on the limited evidence, the committee were unable to make a strong recommendation for its use. Therefore, the committee only recommended that nabilone could be considered as an add-on treatment in adults with intractable chemotherapy-induced nausea and vomiting which persists despite the use of optimised conventional antiemetics.

The committee were aware that people may be taking other medication when using nabilone and were concerned about potential adverse drug interactions. They recommended that adverse drug interactions should be carefully considered when prescribing nabilone. The committee highlighted concerns for the use of nabilone with central nervous system depressants and other centrally active drugs. They recommended that healthcare professionals should think about these when considering nabilone and refer to the summary of product characteristics for further information on dosing, patient monitoring, contraindications and adverse events.

Evidence for the use of other cannabis-based medicinal products was limited and the committee were unable to make any practice recommendations. However, they made a research recommendation to inform future guidance.

Nabilone is not currently licensed in the UK for children and young people under 18 years because its safety and efficacy has not been established. Therefore, the committee made another research recommendation on the effectiveness of cannabis-based medicinal products in babies, children and young people with intractable nausea and vomiting.

Only 1 study was identified which included people with radiotherapy-induced nausea and vomiting. The committee noted that there are other causes of intractable nausea

and vomiting but were unable to make further recommendations due to lack of evidence. Therefore, the committee made an additional research recommendation.

How the recommendations might affect practice

The committee highlighted that the use of nabilone is uncommon in current practice and it is not used as first-line treatment for chemotherapy-induced nausea and vomiting. The recommendations could result in an increase in use of nabilone as an add-on treatment for adults with chemotherapy-induced nausea and vomiting, but the current level of use is uncertain.

Full details of the evidence and the committee's discussion are in evidence review A: Intractable nausea and vomiting

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Chronic pain

Recommendations 1.2.1 and 1.2.2

Why the committee made the recommendations

Some evidence showed that cannabis-based medicinal products reduce chronic pain, but the treatment effect was modest (an average improvement of about 0.4 on a scale ranging from 0 to 10). The evidence did not show a reduction in opioid use in people prescribed medicinal cannabis. Because the number of people who might benefit is large and the cost potentially high, an economic model was developed to compare benefits with the potential costs. The model used data from the trials in the base case analysis but also assumed a larger potential benefit from cannabis-based medicinal products in various sensitivity analyses. In all cases, the potential benefits offered were small compared with the high and ongoing costs, and the products were not an effective use of NHS resources. The evidence included CBD in combination with THC, THC alone, dronabinol and nabilone so the committee named

these products in the recommendation. The committee also agreed that the recommendation should follow the evidence and specify adults.

There was no evidence for the use of CBD alone. Therefore, the committee recommended that CBD should not be offered unless as part of a clinical trial. People who have fibromyalgia or persistent treatment-resistant neuropathic pain are often taking high doses of painkillers over long periods. These can cause nausea, drowsiness, mood disturbance and fatigue. The committee noted that this is a significant population of people with chronic pain (around 15%). Cannabis-based medicinal products might improve safety in this group by either replacing standard care or reducing doses of other medicines (including opioids). Therefore, the committee made a research recommendation for CBD in adults with fibromyalgia or treatment-resistant neuropathic pain.

There was no evidence for intractable cancer-related pain or pain associated with painful childhood diseases. The committee agreed that cannabis-based medicinal products could potentially offer additional benefits for this group, for example, by allowing them to receive their care in an outpatient rather than an inpatient setting. They agreed to make a research recommendation to explore the clinical and cost effectiveness.

How the recommendations might affect practice

Prescriptions of cannabis-based medicinal products for chronic pain are currently rare. GPs refer people with chronic pain to specialist pain services where clinicians on the Specialist Register with expertise in this area decide whether cannabis-based medicinal products should be prescribed. The new recommendation might reduce the number of these prescriptions.

Full details of the evidence and the committee's discussion are in evidence review B: Chronic pain

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Spasticity

Recommendations 1.3.1 to 1.3.2

Why the committee made the recommendations

The committee agreed that the evidence showed benefits of THC:CBD spray (licensed product in UK: Sativex) for treating spasticity in people with multiple sclerosis. There were reductions in some measures of patient-reported spasticity and no difference in adverse events in the treatment or placebo groups although much of the evidence was assessed as low quality. The committee agreed that the longer-term benefits of THC:CBD spray are likely to outweigh any potential harms, although it was not clear how benefits related to improvements in quality of life.

The committee considered the evidence from 2 published economic evaluations but noted that they were contradictory and subject to potentially serious limitations. So they considered results from a new economic model developed specifically for the cannabis guideline. The model included data from all relevant trials, longer-term registry data and data on adverse events. However, the results of the new model showed that it was highly unlikely that THC:CBD spray could be considered a cost-effective treatment. In reflection of the trial evidence, the model predicted that the average person would receive a small quality of life (QALY) gain, equivalent to around 30 days perfect health with THC:CBD spray added to standard care. The acquisition costs of the treatment are offset by some predicted savings in management costs but the model still estimates that THC:CBD spray would cost an additional £3,000 over 5 years. The QALY gains are too small to justify this level of expenditure unless the acquisition cost were reduced from £375 to £188 per pack. Therefore the committee agreed with decisions made for the NICE guideline on multiple sclerosis that they could not recommend THC:CBD spray based on current costs.

The committee agreed that the evidence for the effectiveness and safety of other cannabis-based medicinal products was much more limited. There is also currently no evidence on the cost effectiveness of products other than THC:CBD spray and in other clinical indications (for example, motor neurone disease and spinal cord injury). The committee agreed to include a recommendation that other cannabis-based medicinal products should not be used to treat spasticity unless used in the context of a clinical trial. This recommendation was needed to ensure that other products

were not used as an alternative to THC:CBD spray without sufficient evidence of their effects and associated costs.

Because there is limited evidence from trials on how reductions in spasticity affect quality of life and no evidence was found for conditions such as cerebral palsy, the committee agreed to make a research recommendation to inform future guidance.

How the recommendations might affect practice

The recommendation against the use of THC:CBD spray (Sativex) reflects the recommendation in the NICE guideline on multiple sclerosis and is therefore unlikely to affect current practice. The second recommendation means that other cannabis-based medicinal products will also not be used to treat spasticity outside of a research study.

Full details of the evidence and the committee's discussion are in evidence review C: Spasticity

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Severe treatment-resistant epilepsy

Research recommendations on CBD, and THC in combination with CBD

Why the committee made the research recommendations

Cannabis-based medicinal products are currently unlicensed for the treatment of epilepsy. There are some reports of individual patients having fewer seizures with these products when other treatments have not fully controlled the seizures. But current research is limited and of low quality, making it difficult to assess just how effective these products are for people with epilepsy. Published randomised controlled trials have focused on the use of pure cannabidiol in people with Dravet and Lennox-Gastaut syndrome. People with these epilepsy syndromes also report a very high rate of adverse events. Open-label studies (clinical trials in which the treatment and placebo groups are not disguised) of cannabis-based medicinal products in other types of epilepsy have also shown a very high level of adverse events (in up to 98% of people) but it was not possible to determine how many of these were due to the cannabis-based products.

The committee discussed the limited evidence and agreed that it did not warrant a practice recommendation. However, they also agreed that they should not make a recommendation against the use of cannabis-based medicinal products as this would restrict further research in this area and would prevent people who are currently apparently benefiting from continuing with their treatment. Until there is clear evidence, specialists, people with epilepsy and their carers should continue to make treatment decisions in the best interests of each person with epilepsy. However, people seeking treatment for severe epilepsy should be made aware that currently there is no clear evidence of the safety and effectiveness of cannabis-based medicinal products.

The committee agreed that more evidence is needed on the effectiveness of cannabis-based medicinal products in severe treatment-resistant epilepsy and made a research recommendation to inform future practice. They discussed that some individual funding requests are denied because of lack of evidence of effectiveness. More research across different types of epilepsy may address this evidence gap.

The committee discussed the constituents of cannabis-based medicinal products. Some products contain either purified CBD alone or purified CBD combined with THC. Others contain CBD and THC from whole plant extracts. Most studies of cannabis-based products for severe epilepsy have evaluated pure CBD, but the committee agreed it is important to know whether adding THC to CBD offers benefits or affects the type of adverse events observed. They decided to make a research recommendation on how the constituents of a cannabis-based medicinal product influence its effectiveness.

Full details of the evidence and the committee's discussion are in evidence review D: Epilepsy

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Prescribing: who should prescribe and shared care

Recommendations 1.5.1 to 1.5.4

Why the committee made the recommendations

Based on current legislation, the complexity of the conditions, and the licensed (nabilone and Sativex) and unlicensed status of these medicines, the committee agreed that the initial prescription of unlicensed cannabis-based medicinal products must be made by a clinician on the General Medical Council's Specialist Register who has an interest in the condition being treated. The committee also agreed that in line with the summary of product characteristics of Sativex, this too must only be initiated by a specialist. Although there are no legal requirements for nabilone to be prescribed by a specialist prescriber.

There was limited evidence on who should prescribe and monitor cannabis-based medicinal products. Studies were conducted in Australia and Canada, and 1 study included participants from 8 different European countries. These countries have different healthcare systems, funding streams and legislation, which raised questions about their applicability to the prescribing of cannabis-based medicinal products in England. It was also not clear whether all products could be considered cannabis-based products for medicinal use as defined in the 2018 Regulations.

Guidance from the British Paediatric Neurology Association, based on current UK legislation and policy, advises that for children with intractable epilepsy, cannabis-based products should only be prescribed by a consultant paediatric neurologist. The committee agreed that for children and young people this should be a tertiary paediatric epilepsy specialist.

The committee noted that NICE's guideline on controlled drugs recommends that no more than a 30-day supply of a controlled drug is prescribed at any one time. People taking cannabis-based products are likely to need repeat prescriptions as well as close monitoring of effectiveness and adverse effects, and dose adjustments. The committee agreed that there are potential burdens for patients associated with limiting prescribing and monitoring to tertiary care. They highlighted a clear need for shared care arrangements, which could involve other healthcare professionals such as GPs and non-medical prescribers.

The committee agreed that after the initial assessment and prescription by a specialist, allowing other prescribers to prescribe cannabis-based products under specialist direction would improve access for patients.

The specialist initiating treatment should also be involved in monitoring, evaluation and dose adjustment. This should be part of a shared care plan with a clear division of responsibilities between the initiating specialist prescriber and the prescriber acting under their direction.

The committee noted that a shared care agreement should detail the responsibilities of all parties, including the patient and their family and carers. The committee highlighted that the agreement should include details of how communication between parties would be managed, how funding would be obtained and the frequency and nature of monitoring.

Because some patients may need long-term treatment, the agreement should ensure continuity of care by setting out what should happen when the patient or specialist moves location. This should include handover of responsibilities to other specialists or prescribers.

How the recommendations might affect practice

Currently, prescribing and monitoring cannabis-based medicinal products takes place in tertiary care. The recommendations focus on shared care after the initial prescription with the involvement of other healthcare professionals such as non-medical prescribers and GPs. This will allow a more holistic approach to care. Moving away from tertiary care may be cost saving for the NHS.

Full details of the evidence and the committee's discussion are in evidence review E: Prescribing cannabis-based medicinal products

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Prescribing: factors to think about when prescribing

Recommendations 1.5.5 to 1.5.8

Why the committee made the recommendations

The committee agreed a number of factors that should be considered before prescribing cannabis-based medicinal products, based on study data, summaries of product characteristics and committee experience. They highlighted these in a recommendation along with some of the contraindications from the studies of the effectiveness and safety of cannabis-based medicinal products for nausea and vomiting, chronic pain, epilepsy and spasticity.

The committee also discussed whether there were any particular considerations when prescribing cannabis-based medicinal products for babies, children and young people. Although there was no evidence, the committee agreed that there are some unknown effects, such as the impact on brain development and cognitive development, and the effect of sedation.

Many people use non-prescribed, over-the-counter or over-the-internet, cannabis-based food supplements. The committee agreed that when someone is prescribed cannabis-based medicinal products they should be advised to stop using any non-prescribed cannabis products. This will reduce the risk of any drug interactions and reduce the potential for people taking a higher dose of cannabis than prescribed.

How the recommendations might affect practice

These recommendations will help to guide prescribers on some of the important issues to consider when prescribing cannabis-based medicinal products. This may result in more prescriptions for cannabis-based medicinal products, which may increase costs to the NHS. However, if symptoms are reduced with the use of cannabis-based medicinal products this may ultimately reduce the cost of other treatment for these patients, either through primary care or urgent care services.

Full details of the evidence and the committee's discussion are in evidence review E: Prescribing cannabis-based medicinal products.

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Prescribing: Supporting shared decision making

Recommendations 1.5.9 to 1.5.10

Why the committee made the recommendations

Limited evidence was identified on the support prescribers and people may need when making decisions on cannabis-based medicinal products. Some evidence identified the need for training and further education for prescribers, while international guidelines described the overarching support that people seeking cannabis-based medicinal products may need.

The committee agreed that the key theme was the need for prescribers to discuss the risks, benefits and alternatives to cannabis-based medicinal products with people seeking treatment. The committee noted that with the change in legislation people may require licensed or unlicensed products, which would also be a key area for discussion. This recommendation should encourage shared decision making and allow people to make informed decisions about their care.

The committee also recommended that prescribers follow NICE's guideline on patient experience in adult NHS services (CG138). This has specific recommendations on shared decision making and details the support prescribers can provide when discussing treatment options.

How the recommendations might affect practice

The recommendations promote shared decision making and allow people to make informed decisions about their care. The committee noted that there may be situations in which a multidisciplinary team may help to reach a decision on treatment, such as the care of babies, children or young people. A multidisciplinary team may also need to be involved when decisions need to be made that are in the patient's best interest. This may not be feasible in all specialist care settings because staffing and structure of care provision varies.

Full details of the evidence and the committee's discussion are in evidence review E: Prescribing cannabis-based medicinal products.

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Context

Cannabis-based medicinal products have been suggested for a variety of medical conditions. In line with prescribing for all medicines, the potential for harm must be weighed up against the potential for benefit for individual patients.

Current practice

At the time of developing this guideline, delta-9-tetrahydrocannibinol and cannabidiol (Sativex) and nabilone were the only cannabis-based medicines licensed for use in adults in the UK. Delta-9-tetrahydrocannibinol and cannabidiol (Sativex) has been licensed by the MHRA as a treatment for spasticity in multiple sclerosis and is listed under Schedule 4 of the Misuse of Drugs Regulations 2001 ('2001 Regulations'). Nabilone has been licensed by the MHRA as a control of chemotherapy-induced nausea and vomiting and is listed under Schedule 2 of the 2001 Regulations. Dronabinol is listed under Schedule 2 controlled drugs but does not have a marketing authorisation from the MHRA in the UK.

Until September 2018, in cases of exceptional and unmet clinical need, legislation allowed the prescribing of cannabis-based medicinal products through the granting of an individual licence. As Schedule 1 controlled drugs, prescribing was controlled through the licensing process operated by the Home Office.

In November 2018, the UK Government set out the following requirements for the prescription of a cannabis-based product:

> 'A preparation or other product, other than one to which paragraph 5 of part 1 of schedule 4 applies, which:

- is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers)[2]

[2] 'Cannabis-based products for medicinal use related only to cannabis and cannabis preparations (such as extracts from cannabis as well as cannabinoids isolated from cannabis). It does not include synthetic versions of naturally occurring cannabinoids (for example, dronabinol) or any non-natural cannabinoids obtained by chemical synthesis (nabilone).'

- is produced for medicinal use in humans; and
- is a medicinal product, or
- a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product.'

In this guideline, cannabis-based medicinal products include:

- cannabis-based products for medicinal use as set out by the UK Government in the 2018 Regulations
- the licensed products delta-9-tetrahydrocannibinol and cannabidiol (Sativex) and nabilone
- plant-derived cannabinoids such as pure cannabidiol (CBD)
- synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example, dronabinol.

Finding more information and resources

To find out what NICE has said on topics related to this guideline, see our web page on neurological conditions.