Cannabis-based products for medicinal use

Consultation on draft scope
Stakeholder comments table

13/11/2018 – 04/12/2018

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
The Cure Parkinson's Trust	1	12-19	This is a very confusing area. Not least because of the huge range of chemicals that are known to be potentially present in the Cannabis plant species and extracts thereof. There are claims that some effects on neurological processes do occur with what were commonly considered to be "non psychoactive" components, certainly many of the components may be having physiological effects. Many of these substances are major constituents of products that have been legally available in the UK in the past and their particular composition may be relevant to medicinal use in the future although their means of production and quality control may not. It would help if therefore there were a better explanation of what has been available in the UK especially as unlicensed products sold without making claims that meant they should be subject to the level of regulatory status associated with a licence or marketing authorisation (MA) and the two products that were not on Schedule 1 and why i.e. that at least in the case of Sativex it has gone through the rigorous process required to obtain a licensed use in the UK and other countries. I understand that Schedule 1 was intended to be a list of chemicals of no medicinal use but with other potentially damaging properties thus Prescribers were not permitted to prescribe a product that contained those chemicals in the usual way permitted for substances on Schedule 2 onwards. However the listed chemicals seem to be:	Thank you for your comment and the information submitted. This section of the scope describes the recent changes to the UK policy on cannabis based products. The information you have provided will be considered by the committee when they develop the guideline question review protocols.

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			Cannabinol - *a milder derivative of the psychoactive THC* Cannabinol derivatives not being dronabinol or its stereoisomers *(Nabixomal is not specifically mentioned here but as a licensed product moved to Schedule IV?* Cannabis and cannabis resin – *of course the source for the Cannabidiol(CBD) products containing which were unregulated. Some of these products are produced by GMP compliant manufacturers and have some level of analysis including at least the concentration of CBD and presumably evidence of less than the permitted percentage of THC.* Maybe all this confusing background is not especially relevant here but later in the Guideline there needs to be very clear guidance as to what products are considered to be most suitable for use and what that choice needs to be based on since as they are likely to be sourced widely there is a possibility that some of these earlier unregulated products might be suitable for future medical use. A precise definition of “cannabis-based medicinal products” is essential.	
Plymouth Hospitals NHS Foundation Trust	1	15	Sativex and Nabilone are in use in NHS	Thank you for your comment. This section of the scope describes the recent changes to the UK policy on cannabis based products. We will include that nabilone was also available. Following stakeholder comments

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				Sativex and nabilone will also be included within the guideline.
Multiple Sclerosis Trust	1	16-19	This statement is incorrect. Before the decision to reschedule cannabis-based medicinal products the only cannabis-based medicinal products available were nabiximols and nabilone. A recent letter from the Department of Health & Social Care (20 Nov 2018) https://www.england.nhs.uk/wp-content/uploads/2018/11/letter-additional-guidance-on-cannabis-based-products-for-medicinal-use.pdf provides an update on the licensing status of synthetic and naturally occurring cannabis-based products. It is important that the draft scope accurately reports which cannabis-based products are currently licensed in the UK: Nabiximols (Sativex) – Medicines and Healthcare products Regulatory Agency (MHRA) approved for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.	Thank you for your comment. This section of the scope describes the recent changes to the UK policy on cannabis based products. We will include that nabilone was also available. Following stakeholder comments Sativex and nabilone will also be included within the guideline.

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			Nabilone (Cesamet) – MHRA and FDA approved for intractable nausea and vomiting associated with cancer chemotherapy. Dronabinol (Marinol) – FDA approved for anorexia and weight loss in AIDS and intractable nausea and vomiting associated with cancer chemotherapy. Not licenced by MHRA. Cannabidiol (Epidiolex) – FDA approved for seizures associated with Lennox-Gastaut syndrome or Dravet syndrome. The EMA is currently reviewing a marketing authorisation application with a decision expected first quarter 2019. NICE single technology appraisal currently under way, decision expected November 2019.	
Advisory Council on the Misuse of Drugs	1	20-22	The ACMD's recommendation was for synthetic cannabinoids to remain in Schedule 1 of the MDR *pending the 'longer term' review by the ACMD* (i.e. on its own it reads as though ACMD have given their final recommendation on the scheduling of synthetic cannabinoids).	Thank you for your comment. We will amend the text to reflect the future review.
Senzer Ltd	1 5	21-22 22-24	The term Synthetic Cannabinoids is used in the document to refer to two distinct groups of molecules and Senzer would appreciate if NICE could adopt more distinct names and definitions for clarity. Initially the term is used in the context of illicit street products such as 'Spice' and	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to

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			'Mamba', as per the ACMD advice 'Scheduling of Cannabis-derived medicinal products' (19 July 2018). Later in the document it is used to refer to pharmaceutical cannabinoids (e.g. Dronabinol). Senzer would appreciate if these terms could be made clearer and suggests changing the terms to be more aligned with the definitions used by Dame Sally Davies as follows: Non-naturally occurring cannabinoids (Not included in the review) - Illicit 'synthetic' cannabinoids such as Spice, still contained in schedule 1 - Cannabinoids and related molecules with no known medical benefits Pharmaceutical grade cannabinoids (Not included in the review) Preparations of pure cannabinoids used for pharmaceutical treatments, these may be versions of naturally occurring (e.g. Dronabinol, Cannabidiol, Nabiximols) or obtained by chemical synthesis (e.g. Nabilone)	naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
National Pharmacy Association	1	22	Synthetic cannabinoids should remain…… suggest inserting an example	Thank you for your comment. We haven't included an example here as this is a summary of the advice, we have included a hyperlink to the advice for readers.
NHS England	1	23	Suggest amending to say "In September 2018, in light of the CMO's recommendations and in a response to the ACMD advice…" (LQ)	Thank you for your comment, we have amended this section following your comment.

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Fibromyalgia Action UK	1	26	By restricting prescription of cannabis-based medicinal products to doctors on the Specialist Register of the GMC, this could have significant implications, preventing people eligible to receive such prescriptions from doing so. We recognise the importance of procedures being in place to ensure that prescriptions are given appropriately, but by restricting this to specialist registered doctors, this could mean that those patients eligible for cannabis-based medicinal products could be prevented from accessing such treatment. This also ties in with a lack of awareness among General Practitioners firstly in chronic pain conditions such as fibromyalgia, and the need/requirement for cannabis-based products, prompting for improved understanding among general practitioners.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products. We have amended this section of the scope to include other healthcare professionals under who the guideline might be relevant for.
National Pharmacy Association	10	1	It would be useful to include the community pharmacist in the NICE pathway association with “cannabis-based products for medicinal use”	Thank you for your comment. The guideline committee will include a pharmacist.
Families 4 Access	10	9	The current guidelines are restricted to prescribing cannabis as a last resort, after other medications failed or were discarded. We feel that this may merit reconsideration, especially in view of the opiate epidemic and increasing evidence of reduction of opiate use and abuse that may be attributed to cannabis administration. There appears to be enough evidence to warrant consideration of medicinal cannabis as a first-line treatment option for specific indications in lieu of alternative first-line	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products in line with the GCM's guidance on prescribing unlicensed medicines since all cannabis-based medicinal products (except Sativex and nabilone) are unlicensed in the UK.

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			treatments with evidence of high rates of addiction, abuse, severe adverse events, or known drug-drug interaction risks.	
Fibromyalgia Action UK	10	General	The pathway point labelled 'Shared decision-making' is somewhat contradictory to points raised earlier within the draft scope restricting prescription use from doctors on the Specialist Register of the GMC, since this previous point automatically shifts decision power to clinicians. Therefore, the way in which cannabis-based medicinal products needs to be considered, ensuring appropriate prescribing measures are in place for the benefit of society, while ensuring that those patients in need of such treatment can access it in a timely and appropriate manner.	Thank you for your comment. The guideline will consider individual treatment factors and support for both prescribers and patients (or their family members or carers). NICE is also currently developing a guideline on shared decision making.
Tilray	2	13-19	We urge the committee to obtain data from other countries with national medical cannabis programs to make informed, evidence-based decisions on the potential risks identified in this paragraph. Data from these countries in reference to the risks identified in the present scope are available.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline.
Plymouth Hospitals NHS Foundation Trust	2	14	For chronic pain (adults) potential for CNS side effects is huge. Cochrane review (Mucke, Cochrane 2018) and the Canadian Paper;(Allan et al, Can Fam Physician 2018) points out NNH is 6 compared to 30% relief is 24.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for

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				the guideline. If the evidence you refer to meets the review protocol, this will be considered by the guideline committee during the development of the guideline.
Advisory Council on the Misuse of Drugs	2	17-20	The risks quoted are from the CMO's report but reads as though ACMD identified them. Could this be corrected please?	Thank you for your comment. We have amended this section.
Plymouth Hospitals NHS Foundation Trust	2	18	DVLA stand on road safety issues should be addressed	Thank you for your comment. The DVLA's guidance is outside of NICE's remit.
National Pharmacy Association	2	2	Further explaining may be required as to why "products for medicinal use should not be considered as first-line…..	Thank you for your comment. This section describes the UK Government Ministers response to the ACMD advice.
The Cure Parkinson's Trust	2	21-27	The Guideline does need to recognise the anomaly that Sativex as a licensed product with proven efficacy for its licensed indication in MS but is specifically NOT recommended for use in other NICE guidelines because of what is considered to be lack of cost effectiveness. This current Guideline does need to consider how to handle this situation together with the General Medical Council (GMC). Early guidance from the GMC seemed to discourage any Prescriber from prescribing an off label or unlicensed product if there were a licensed alternative (albeit not licensed for the specific situation) it was also apparent that decisions were not to be made for financial reasons. I note however that the current guidance from the GMC seems	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline. This guideline will consider the use of cannabis-based medicinal products for the following groups in line with the GCM's guidance on prescribing unlicensed medicines since all cannabis-based medicinal products (except Sativex and nabilone) are unlicensed in the UK.

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			more ambiguous and maybe that allows more flexibility? Does the phrase "when no licensed suitable alternative is available" from the GMC guidance linked to this document mean that as the NHS does not pay for Sativex the prescriber can go straight to an alternative albeit the composition may be near identical (i.e. pretty much equal ratio of CBD to THC) ? The Guideline needs to consider this challenge along with the general one of who pays and how cost effectiveness is calculated for those products that are now to be made available.	
Multiple Sclerosis Trust	2	21-27	This paragraph should also reference nabilone which is licensed by the MHRA for intractable nausea and vomiting associated with cancer chemotherapy. We are aware that nabilone has occasionally been prescribed off-label for people with MS.	Thank you for your comment. Following stakeholder comments nabilone will also be included within the guideline.
NHS England	2	3	Should this be clarified by adding "unless the patient has a clinical need that cannot be met by any other licensed treatment"? (LQ)	Thank you for your comment. Following stakeholder consultation this section has been amended to reflect the different comments received at stakeholder consultation.
Tilray	2	4	We suggest that the limitation to prescribe by doctors on the Specialist Register may interfere with the patient-doctor relationship and may have, as a practical implication, consequences on access for patients whose doctors not on the Specialist Register deem cannabis-based medicinal products beneficial. We kindly ask that the ability to	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products.

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			prescribe cannabis-based medicinal products be expanded to include all doctors.	
Plymouth Hospitals NHS Foundation Trust	2	6	Cannabis based medicinal products come in various strengths depending on THC: CBD ratio. The first step will be standardising the product	Thank you for your comment. This guideline will consider the formulation of cannabis-based products.
The Cure Parkinson's Trust	2	8-19	It would be helpful if the Guidance provided sources of relevant facts, reviews of evidence etc in order for Prescribers to better consider what choices they make. Again it needs to be clearer that Cannabis derived products could contain hundreds of different and potentially active and/or interactive compounds, evidence relating to precise analysis of those compounds is scarce but needs to be readily available. Patient collected data from around the world could help here notably evidence collected by patient groups such as United Patient Alliance and Families for Access. There is some clinical data to help determine which active components may best serve a need or have greater potential to cause harm e.g. the high proportion of THC and balance of this against other components in the likelihood of precipitating schizophrenia or similar psychotic episodes. The Guideline needs to address this level of detail.	Thank you for your comment. This guideline will consider the formulation of cannabis-based products and will consider individual treatment factors and support for both prescribers and patients (or their family members or carers). The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline.

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The Cure Parkinson's Trust	3	1-10	This i.e. a “cannabis based product” covered under UK law for prescription needs a much better definition i.e. something along the lines of “ a preparation that derives from the Cannabis plant and does not contain any synthetic version of the chemicals and substances that derive therefrom and is produced to GMP quality assured standards for the purpose of administering to man”. Consider using the term “Medicinal Product” but if so define it but note that it is not defined consistently throughout all the relevant legislation. E.g Medicinal product is a product containing a substance or a combination of substances produced and intended for the treatment or prevention of diseases in humans or in animals, for diagnostic purposes, improvement or modification of physiological functions or for achieving other medically justified objectives.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products.
Multiple Sclerosis Trust	3	1-10	The requirements quoted in the draft scope were drawn up to define products which should be rescheduled under the Misuse of Drugs Act. The footnote goes on to state that it does not include synthetic versions of naturally occurring cannabinoids (eg dronabinol) or any non-natural cannabinoids obtained by chemical synthesis (nabilone). The logic behind this arbitrary separation into “naturally	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will

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			occurring" cannabinoids and "synthetic" cannabinoids is not explained further. The rationale should be stated. The definition drawn up for rescheduling should not be used to limit the scope of cannabis-based medicines to be covered by this guideline. There is already a great deal of confusion and misconceptions about cannabis-based medicines; this guideline represents an opportunity to draw together, in a single document, evidence for the full range of cannabis-based products and provide clarity for health professionals, patients and members of the public. We believe that users of the guideline will expect it to include advice on prescribing the full range of cannabis-based medicinal products, and should include both those derived from extracts of the cannabis plant as well as those manufactured chemically. This would therefore include evidence-based advice on prescribing of nabiximols, dronabinol and nabilone.	also be included in the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
National Pharmacy Association	3	12	The guideline would also be useful for community pharmacists, who may be involved in the supply of such products.	Thank you for your comment. Community pharmacists are included in the groups who the guideline is relevant for.
NHS England	3	13	To include 'prescribers' as a whole. GP's may prescribe under shared care arrangements eventually. (LQ)	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-

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				based medicinal products. We have amended this section of the scope to include other healthcare professionals under who the guideline might be relevant for.
National Pharmacy Association	3	13,14	The guideline should be more specific on which healthcare professionals it is referring to.	Thank you for your comment. Healthcare professionals include all those who are prescribing cannabis-based medicinal products or who are providing care to people taking cannabis-based medicinal products. The scope does not have specific individual roles as it important to include all those involved.
Multiple Sclerosis Trust	3	13-19	In addition to these groups, we wish to stress that the guideline will also be for prescribers who are unable to prescribe cannabis-based medicinal products, for healthcare professionals providing care for people who have been refused access to cannabis-based medicinal products and for people using services who have requested and been refused access cannabis-based medicinal products. It is important that the guideline and supporting resources recognise the needs of these groups. As noted in comment 1, turning down requests for treatment has a damaging effect on relationships between health professionals and patients and takes up valuable clinic time. In addition to the guideline, there is a strong need for resources which clearly explain the decision-making and support discussions between health professionals and patients.	Thank you for your comment. We have amended this section of the scope to include other healthcare professionals.

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The Neurological Alliance	3	14	Worth adding 'specialist' doctors – to make it extra clear who these healthcare professionals are (and that they are not GPs).	Thank you for your comment. This line refers to doctors who are on the Specialist Register of the GMC. We believe this line does not need amending and a link to the Specialist Register of the GMC is provided at the beginning of the scope.
SUDEP Action	3	14	Will these clinicians be Specialist doctors? In which case perhaps adding the work Specialist may be useful here to any non-specialists or patients who read this line	Thank you for your comment. This line refers to doctors who are on the Specialist Register of the GMC. We believe this line does not need amending and a link to the Specialist Register of the GMC is provided at the beginning of the scope.
SUDEP Action	3	15	Does this mean any clinicians who may come into contact with a patient taking Cannabis-based medicines? Eg: GPs, Paramedics, LD specialists. Could this be specified?	Thank you for your comment. Healthcare professionals include all those who are providing care to people taking cannabis-based medicinal products. The scope has not specific individual roles as it important to include all those involved.
The Neurological Alliance	3	19	People using services, their families and carers, and the public, are three very separate stakeholder groups, and as such each should have their own bullet point	Thank you for your comment. This section of the scope has been amended following stakeholder consultation to separate out the public.
The Neurological Alliance	3	19	Will there be an 'information for the public' section as per other guidelines? We hope that stakeholders, particularly patient organisations, will get a chance to consult on the information included in this section.	Thank you for your comment. Yes there will be a section on the NICE guideline webpage titled "information for the public". The "information for the public" section provides an overarching summary of the guideline content and as such we don't have consultation on this section.
SUDEP Action	3	19	Will there be an 'information for the public' section like with other guidelines and if so will stakeholders, particularly organisations who advocate for and support people living	Thank you for your comment. Yes there will be a section on the NICE guideline webpage titled "information for the public". The "information for the public" section provides

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			with long term conditions, get a chance to consult on the information included in this section? This information could prove vital in ensuring balanced and clear information is provided to this group and streamline the implementation of this guidance.	an overarching summary of the guideline content and as such we don't have consultation on this section.
National Pharmacy Association	3	20	Would the guideline have some relevance to the emergency services for example paramedics?	Thank you for your comment. Healthcare professionals include all those who are providing care to people taking cannabis-based medicinal products. The scope has not specific individual roles as it important to include all those involved.
Advisory Council on the Misuse of Drugs	3	22	Publicly rather than publically	Thank you for your comment. The scope will be edited before publication to ensure it meets NICE style.
Psoriasis and Psoriatic Arthritis Alliance	3	25	We accept and agree that it would be difficult to cover all cannabis products, particularly those marketed as food supplements, therefore feel that as part of this guideline process good public education is required to make it very clear what the differences are, and what patients should do when making decisions about self-medicating with any unlicensed product whether prescribed or otherwise.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018.
Epilepsy Action	3	3-10	The draft scope currently refers to the interim definition of a cannabis-based product for medical use. The interim definition excludes synthetic cannabinoids and could act to unduly limit the scope of the consultation. While the interim definition as currently included in the scope has been used	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to

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			as a reference point to date the NICE scoping and guidelines process could and should look to expand and clarify the definition. Recommend revisiting the definition included in the scope to ensure it adequately captures all relevant information and does not act to restrict the scope of the guidelines.	naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
The Cure Parkinson's Trust	3	3-4	Spell this out, no-one is going to look up Schedule 4 and when I do I cannot find a paragraph 5 in Part under Schedule 4!	Thank you for your comment. This section is a summary of current practice in the NHS with this particular section being quote of the requirements set out by the UK Government, as this is a summary we are unable to include all information.
The Cure Parkinson's Trust	3	5	I thought the idea was to exclude any synthetics, “cannabinol” could be a synthetic compound and seems to be a derivative of the more active and arguably more relevant THC. Whilst present in extracts from Cannabis it seems a bit irrelevant as a specific reference herein?	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
Drug Science	3	5-6	It is unclear why ‘cannabinol or cannabinol derivative’ is referred to here, is this a typographical error? Cannabinoid or cannabinoid derivative makes much more sense.	Thank you for your comment. This is a quote describing the UK Government requirements therefore we are unable to amend this text.

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Psoriasis and Psoriatic Arthritis Alliance	3	6	The term unlicensed as per the GMC appears to be for treatments that do not have a product licence or no UK licence, but maybe used at different dose or for a condition where the treatment hasn't been specifically tested OR is available, is this the case in this instance for cannabis products? A concern is the patient may not get adequate information about the products, with no in-pack PIL about the treatment, to allow them to make an informed decision. Perhaps inclusion of the 'Specials' guidance from the Royal Pharmaceutical Society may also be a useful reference to consider.	Thank you for your comment. The guideline will link to national advice about the prescribing of unlicensed and off-label use medicines for example the GMC guidance. The guideline will consider individual treatment factors and support for both prescribers and patients (or their family members or carers).
Psoriasis and Psoriatic Arthritis Alliance	3	7	The reference to other treatments implies that this may be used 'instead of other products', perhaps in the real world setting the use may be as an adjunct, which leads to the concerns of interactions with other medications that the patient may use, which may not be confined to GSL, P or POM products. This may be out of scope but given the nature of cannabis and the misunderstanding of what medicinal cannabis is, some guidance on the dangers of adding other non-traditional products within the self-medication pathway, might be helpful.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018.

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Psoriasis and Psoriatic Arthritis Alliance	3	8	It would be useful to explore the definition of pain, beyond chronic pain as the public may not be aware of this and therefore may consider beyond 12-weeks being too long in some instances, if other medication is not helping. There also maybe an unintended consequence that those where acute intermittent pain is also being inadequately controlled exploring the use of cannabis following this guidance, but not understanding why their situation is different. We would also like to suggest that itch in skin conditions such as psoriasis, can also cause people to use pain relief products to alleviate the symptoms and perhaps there may be some merit in exploring whether this should be considered within the scope of this guideline.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
Epilepsy Action	4	10-11	Specific consideration to potential inequalities relating to learning disabilities and mental health problems is particularly welcome given the increased prevalence of these as comorbidities amongst people with epilepsy.	Thank you for your comment. This population has been added to the section of specific considerations.
NHS England	4	11	Suggest using an alternative word to “problems” – maybe conditions? (LQ)	Thank you for your comment. This is NICE style to say mental health problems.
University of York	4	14	Suggest including people with mental health problems as active ingredients in some cannabis products could trigger mental health problems.	Thank you for your comment. This population has been added to the section of specific considerations.
Epilepsy Action	4	16	We would like to see mental health and learning disabilities included as areas of specific consideration in the scope. This is in recognition of the potential additional harms	Thank you for your comment. This population has been added to the section of specific considerations.

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			cannabis-based products could cause to these patient groups.	
Epilepsy Action	4	18	Welcome the inclusion of pregnant women and women who are breastfeeding in the scope. Ensuring consistency of medication is particularly important in epilepsy given the potential for breakthrough seizures and/or worsening seizure control if medicines are changed.	Thank you for your comment.
Families 4 Access	4	18	We suggest that the scope should include special consideration to populations such as elderly patients and patients having chronic conditions such as diabetics, heart failure, high blood pressure or multiple sclerosis. This is important since such populations may need special care when being treated with medical cannabis.	Thank you for your comment. This population has been added to the section of specific considerations.
National Pharmacy Association	4	20	The storage of these products would need to be considered in all settings, including people's own homes, where publically funded health and social care is delivered.	Thank you for your comment. The guideline includes all settings where publically funded health and social care is delivered.
Families 4 Access	4	20	We feel that use for hospitalized and bedridden patients should also be given special consideration, as these impose special limitations on the appropriate methods of administration	Thank you for your comment. This population has not been added to the scope but the committee will consider if specific recommendations for people in hospital need to be made.
Advisory Council on the Misuse of Drugs	4	21	Publicly rather than publically	Thank you for your comment. The scope will be edited before publication to ensure it meets NICE style.
National Pharmacy Association	4	22	The guideline needs to take all possible settings into consideration including when the patient is being administered to hospital etc.	Thank you for your comment. The guideline includes all settings where publically funded health and social care is delivered.

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Royal College of Paediatrics and Child Health	4	3.1	The focus should specifically include children and young people with neurodisabilities and learning disability. This medication might need to be prescribed for intractable seizures and those children often have complex neurodisabilities/learning difficulty and therefore it should be explored in the key questions as well (section 3.5).	Thank you for your comment. This population has been added to the section of specific considerations.
Drug Science	4	8-11	While the draft scope defines only 4 indications for cannabis-based medicines (C-BMs), there will inevitably be demand by patients with other conditions. Therefore, two questions arise: a) how might this list of 4 indications be extended on the basis of future evidence? b) Will RCTS be facilitated on other indications as well as these 4?	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited. The guideline committee will be able to make research recommendations, where appropriate as described in Developing NICE guidelines: the manual, for the 4 indications being considered within the guideline. However the guideline committee will not able to make recommendations for indications that are outside of the scope of this guideline.
Royal College of Anaesthetists	4	General	We are pleased to see a broad range of ages covered and the inclusion of pregnancy and breastfeeding. Inclusion of safety and potential harm is essential. The inclusion of individual factors such as decision-making and prescribing requirements is helpful.	Thank you for your comment.
Tikun Olam	5	10	General spasticity or spasticity related to specific disease?	Thank you for your comment. The guideline will consider all spasticity not limited by specific conditions.

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HSP Support Group	5	10	Hereditary Spastic Paraplegia (HSP) is a rare disease whose main symptom is spasticity in the lower limbs. The symptoms progress slowly with many patients eventually only being able to move using a wheelchair. In the earlier stages of HSP relief of spasticity gives rise to improvements in the quality of life for patients. The HSP Support Group is pleased to note that the scope of the guidance will include those with spasticity, and is keen to ensure that rare diseases with symptoms including spasticity will be covered by the guideline.	Thank you for your comment. The guideline will consider all spasticity not limited by specific conditions.
Tikun Olam	5	11	Provide definition of severe treatment-resistant epilepsy. Perhaps base this on previous history of number of AEDs? Or will this be based on the clinical judgement of the prescriber?	Thank you for your comment. The scope does not define severe treatment-resistant epilepsy, this will be discussed by the guideline committee.
Parkinson's UK	5	11	We recommend you insert a statement after line 11 to include people with other features of long-term conditions like depression. There is limited evidence that cannabis-derived medicinal products can help people with Parkinson's with depression. (Wen-Juan Huang, Wei-Wei Chen and Xia Zhang. Mol Med Rep. 2016 Oct; 14(4): 2899-2903, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5042796/). We believe it is important to ensure the scope covers the possible range of conditions it could treat.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
Parkinson's UK	5	11	Parkinson's UK is in the final stages of approval for funding for a study into the use of a cannabis-derived medicinal	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline

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			product to treat Parkinson's-related psychosis which is a major unmet need for people affected by the condition. If approved, we hope the study will commence in 2019. We therefore recommend that this scope highlights research that is due to take place/taking place using cannabis-derived medicinal products during the development of the guideline and notes the symptoms they are aimed at. If the scope doesn't reflect this, then other symptoms not defined in the current scope would be missed, which would limit the relevance of the guideline.	and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
Epilepsy Action	5	11	While we agree that people with severe and treatment-resistant epilepsy should be the main focus of the scope in relation to epilepsy, due consideration should also be given to other epilepsies. This could act to broaden the literature review and lead to more thorough and comprehensive guidance. We believe 'severe and treatment-resistant epilepsy' should be changed to 'epilepsy' within the scope.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
SUDEP Action	5	11	It would be important for this document to link to existing guidelines for the conditions mentioned in this section (ie: Epilepsy) to support non-epilepsy specialists who may read this guideline or see patients who use Cannabis-based medicines in being able to access definitions and guidance on this specific cohort of patients/type of epilepsy. This will also help them respond to questions from patients who may	Thank you for your comment. The guideline will link to other relevant NICE guidelines. There will be a section on the NICE guideline webpage "information for the public" which will provide clear information regarding the guideline recommendations for the public in addition to the NICE guideline recommendations.

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			not have this type of epilepsy and therefore not meet the criteria for this medication. http://dx.doi.org/10.1136/practneurol-2018-002058 Related to this, will public communications about this guideline provide clear information to the public (including patients, their families, carers and their clinicians) about its availability currently only being for a small sub-set of those living with epilepsy for example?	
Tikun Olam	5	12	Would also suggest investigating the relative effects of THC and CBD, THC/CBD combinations and the evidence suggesting that CBD ameliorates the deleterious effects of THC.	Thank you for your comment. This guideline will consider the formulation of cannabis-based products.
National Pharmacy Association	5	12	The guideline could also cover any required training or advice to be given to the patient or carer 1. The administration of cannabis based products 2. What side-effects to expect 3. Common interactions 4. Lifestyle advice including smoking cessation advice if appropriate How and where to seek further advice and support.	Thank you for your comment. The guideline will consider the areas described in the draft question which includes administration of cannabis-based products, potential side effects and interactions and support for prescribers and people being prescribed cannabis-based products. NICE has published a guideline on smoking cessation and it may be possible to cross reference to that guideline if appropriate.
International Brain Tumour Alliance (IBTA)	5	12-17	We would strongly suggest that the Guideline also considers quality of life as an additional key area. Quality of life outcomes should be deemed one of the key effectiveness indicators, especially for those who are living	Thank you for your comment. The scope includes quality of life in the list of the main outcomes that the guideline will consider. The guideline committee will define the outcomes that will be considered in the evidence reviews through development of the review protocols. The

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			with brain cancer (and potentially other cancer types) and who, therefore, have a significantly life-limiting disease.	guideline committee will consider your comment when developing the evidence review protocols.
InHealth Pain Management Solutions	5	13	We welcome the inclusion of consideration of potential harms in the review. In relation to persistent pain can we ask that as far as the evidence allows the potential harm of long-term use of cannabis medication is taken into account in the review. Persistent pain is a long-term condition and we have experienced in relation to opioid medication that short-term pain reduction can lead to significant long-term harm for patients. Basing recommendations for long term management of a condition on short term benefits shown in relatively short duration trials can cause potential harm. Can we also urge that the outcome measures that are assessed consider the IMMPACT statements that suggest that outcome measures in relation to pain extend beyond the measurement of pain intensity and that benefits that include functional measures should also be demonstrated before recommendations are considered.	Thank you for your comment. The scope includes a list of the main outcomes that the guideline will consider. The guideline committee will define the outcomes that will be considered in the evidence reviews through development of the review protocols. The guideline committee will consider your comment when developing the evidence review protocols.
Tikun Olam	5	15	Treatment algorithms for each disease and precise role in therapy.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products for the following groups in line with the GCM's guidance on prescribing unlicensed medicines since all cannabis-based medicinal products (except Sativex and nabilone) are unlicensed in the UK.

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The Cure Parkinson's Trust	5	17	It is important to provide clear Guidance on what criteria the "Product" needs to fulfil i.e the definition as above plus a requirement for the Product to comply with other safety and analytic requirements for safe use when prescribed in the UK. It should be noted that most of the Products available will come from outside the UK and indeed outside the EU, most advanced seems to be Canada but the US also has licensed producers who may well provide suitable options however other countries such as India may also offer suitable options if they comply with the Guideline spelt out here. Make it clear how Prescriptions will work. At present it is possible, it seems, to present a Prescription to a licensed producer directly then purchase the product as advertised on line although it is not clear that any will accept a UK prescription as yet. It would be better if prescriptions were sourced though suitably placed Pharmacies in the UK i.e. it needs to be clear what the process will be. Who pays? Prescribers need clear guidance as to what Products are thought most suitable and with what they need to comply	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. This guideline will consider the formulation of cannabis-based products. The guideline will consider prescribing requirements for cannabis-based products. Safety compliance is outside of NICE's remit and therefore will not be considered in the guideline.

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			e,g. Analysis - many GMP producers of what might be suitable products can provide some level of analysis of the components in their product. As an absolute minimum there should be available to Prescribers a breakdown of what are thought to be the most active substances including CBD and THC but review of the literature will probably add many others as a minimal requirement e.g..Cannabinol (CBN) Cannabichromene (CBC) Cannabigerol (CBG) and Tetrahydrocannabivarin (THCV) to name a few but other substances not so closely related to the Cannabinoids might also be very relevant to the overall effectiveness of the preparation so the more information that can be collected about the products the better. Is it clear for instance whether Pharmacies could obtain Cannabis plant preparations and make up a derivative product? Theoretically there is no reason why they might not if they could comply with other safety requirements for producing a product and the analysis of the end result was adequate. For the future consideration will need to be given to allowing patients to grow their own and prepare it – we are not ready yet but the technology could be there. Controlled growing conditions and genetically suitable plants can be used to produce very predictable results	

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Families 4 Access	5	17	The current draft relates to "Prescribing requirements for cannabis-based medicinal products". We think that the different routes of administration should be considered, and guidelines be given regarding the differences between them. This is important as the pharmacokinetics of cannabinoids is significantly different based on the route of administration, and accordingly the effects and side effects differ.	Thank you for your comment. The route of administration will be considered by the guideline committee.
NHS England	5	18	We feel that all cannabis based products should be included in the same guideline to make it easier for prescribers. This could involve a link to any previous guidance issued if it was felt a full review wasn't necessary. It would be useful to include synthetics as well as these are also currently available. The issue of hierarchy of prescribing for unlicensed medicines will also need to be considered.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. This guideline will consider the use of cannabis-based medicinal products for the following groups in line with the GCM's guidance on prescribing unlicensed medicines since all cannabis-based medicinal products (except Sativex and nabilone) are unlicensed in the UK.
Make William Well	5	18	There is more clinical evidence to suggest that specific cannabinoids have individual effects on conditions over and above which product they are derived from or whether they are synthetic or plant based. We believe that the exclusion	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and

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			of synthetic cannabinoids is a reaction to synthetic cannabinoid abuse alone and overlooks the medicinal properties of such cannabinoids. Similarly, we are unable to determine why Sativex should be excluded from the review since we believe that consideration should primarily be given to cannabinoid content and not products.	synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
Bayer PLC	5	18	Areas that will not be covered Whilst we accept that this guideline will not re-visit areas covered in another NICE clinical guideline, given the subject as 'cannabis-based products for medicinal use', we feel it should be made clear in the guideline that nabiximols (Sativex®) is the only cannabis-based medicine licensed for use in the UK as a treatment for spasticity in multiple sclerosis, as acknowledged in this draft scope. In addition, given that nabiximols (Sativex®) is licensed for use in the UK as a treatment for spasticity in multiple sclerosis, and that the draft scope makes it clear that *"the existing prescribing guidance and governance arrangements in place for unlicensed medicines continue to apply",* unlicensed cannabis-based products for medicinal use should not be recommended for this indication where a licensed alternative is available.	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.
Multiple Sclerosis Trust	5	18-24	The draft scope lists areas that will not be covered, specifically nabiximols, dronabinol and nabilone. By excluding these cannabis-based medicinal products, this	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following

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			guideline will exclude the majority of studies which have investigated medicinal cannabis. We note that the CMO report (which has formed the basis for this draft scope) did not make this restriction. The CMO report found that there was conclusive evidence of therapeutic benefit of cannabis-based medicinal products; this was largely based on the conclusions of the review carried out by the National Academies of Sciences, Engineering and Medicine (NASEM) report. Within Chapter 4 (Therapeutic effects of cannabis and cannabinoids) of the NASEM report, there are 80 references to dronabinol, 45 to nabilone, and 31 to nabiximols. There are multiple reasons why the majority of clinical studies have used one of these cannabis-based products; consistent doses of THC/CBD and legal issues being the most obvious. By excluding these drugs the appraisal excludes the evidence used to justify rescheduling of medicinal cannabis.	stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
International Brain Tumour Alliance (IBTA)	5	18-24	We note that currently, the Guideline Scope says that it will not include Sativex and nabilone (Cesamet) which are highlighted in the scoping document as “Areas that will not be covered”. We understand that Cesamet is licensed for use in cancer chemotherapy-induced nausea and vomiting where patients do not respond to standard anti-emetics	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex and nabilone will also be included within the guideline.

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			(https://bnf.nice.org.uk/drug/nabilone.html) and Sativex (currently licensed for multiple sclerosis in adults) is the subject of a clinical trial in glioblastoma brain cancer (https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-sativex-temozolomide-glioblastoma-multiforme-brain-tumour-gwca1208?_ga=2.69177428.417678838.1543929368-791296403.1543929368) Sativex, for example, can be prescribed off-label for people with diseases other than multiple sclerosis for which patient group it is licensed. Therefore, it could be prescribed off-label for people with brain cancer.	
HSP Support Group	5	19	It is noted that Sativex will not covered by the guideline as advice has been prepared covering the use of Sativex in Multiple Sclerosis (MS). The symptoms of HSP overlap significantly with those of MS, such that patients are often mis-diagnosed with MS prior to their HSP diagnosis. The HSP Support Group would be keen to ensure that Sativex as a treatment for conditions other than Multiple Sclerosis is included within the scope of the guideline.	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.
Multiple Sclerosis Society	5	19	Nabiximols (Sativex) was indeed considered by the NICE guideline on MS (CG186). A surveillance consultation on an update of this guideline has just closed and our understanding based on the response is that any re-consideration of Sativex is out of scope of that update. This means that there is currently no vehicle for a possible re-	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.

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			consideration based on new evidence or further negotiations on price. We feel it would make most sense for Sativex to be considered as part of this guideline, along with considering to what extent evidence of clinical benefit may translate to other cannabis-based medicinal products.	
Association of British Neurologists	5	19	The draft scope excludes consideration of Sativex, whilst reviewing the effectiveness of other cannabis-based medicinal products for spasticity. Sativex is licenced for use in MS and provides clinically significant benefit to many patients, is prescribed in some regions of the UK and in some specialist settings. Considering cannabis-based products for spasticity whilst excluding Sativex is an artificial distinction, reducing the overall quality of the evidence considered. Patients and their doctors need a single coherent guideline, taking into account all the available treatment options. The opportunity should be taken to review the Sativex guidance together with the other cannabis related drugs. We commend NICE for responding to this issue in such a timely and prompt manner. Having guidance published will be extremely helpful for practitioners. Of course it is essential the scope is sufficiently focussed to allow the committee in a relatively short time to formulate useful guidance and for this reason we entirely agree in excluding synthetic cannabinoid medications from the	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.

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			review. However we strongly believe it makes no sense to exclude the only licensed cannabis-based medication; Nabiximols (sativex). This is particularly relevant when this drug has a UK license for the management of Multiple Sclerosis related spasticity and spasticity is specifically listed as areas this scope is going to cover. The reason the draft Scope document gives for not including Sativex is that it is covered by the MS guidelines. This guidance was published in 2014 and therefore is at least 5 years old. Sativex was not recommended at that time on cost-effectiveness grounds (not clinical effectiveness). The planned technology appraisal [ID387] that NICE agreed to undertake has unfortunately never come to fruition. We would therefore strongly recommend that Sativex is included in this scope and not only considered in the next update of the MS clinical guidelines CG186 Questions 1.1-1.4 are all relevant but when considering spasticity the results need to be compared to Sativex. How can the committee make recommendations about non-licensed cannabis based products without considering the licensed product first? Question 2.2; how can the committee make recommendations about information to patients and their families if you do not give information about the licensed and safer alternative Sativex?	

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			Essentially this guideline is a matter of patient safety. Sativex is not only licensed for MS related spasticity but is classified by the MRHA as a Schedule 4 drug (medications with low potential for abuse and accepted for medical use). Non-licensed cannabis-based products are classified as Schedule 2 (high potential for abuse, sometimes accepted for medical use with severe restrictions). In our view it would be unethical to consider the use of a schedule 2 unlicensed drug when there is a licensed safer alternative available. For this reason Sativex has to be included in this guideline.	
Epilepsy Action	5	19	The draft scope does not cover nabiximols (Sativex). While we recognise Sativex has previously been considered by NICE in the guideline on multiple sclerosis in adults there is potential that nabiximols may by safe and efficacious for the treatment of other conditions. Similarly, there is a pre-existing evidence base around nabiximols that if covered in the scope could help strengthen the subsequent guidelines. For these reasons, we think nabiximols should be included in the scope.	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.
University College London Hospitals NHS Foundation Trust	5	19- 24	Of course it is essential the scope is sufficiently focussed to allow the committee in a relatively short time to formulate useful guidance and for this reason we entirely agree in excluding synthetic canabinoid medications from the review. However we strongly believe it makes no sense to	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.

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			exclude the only licensed cannabis-based medication; Nabiximols (sativex). This is particularly relevant when this drug has a UK license for the management of Multiple Sclerosis related spasticity and both conditions (MS and spasticity) are specifically listed as areas this scope is going to cover. The reason the draft Scope document gives for not including Sativex is that it is covered by the MS guidelines. This guidance was published in 2014 and therefore is at least 5 years old and further evidence is now available (SAVANT trial Markova et al Int J Neurosci. 2018 Sep 13:1-10). Sativex was not recommended at that time on cost-effectiveness grounds (not clinical effectiveness). The planned technology appraisal [ID387] that NICE agreed to undertake has unfortunately never come to fruition. We would therefore strongly recommend that Sativex is included in this scope and not delayed until the future update of the MS clinical guidelines CG186.	
Royal College of Anaesthetists	5	19-21	We query the exclusion of nabiximols (Sativex) in the broader assessment for indications beyond the NICE guidance. They have only been previously considered in the very narrow context of spasticity in Multiple Sclerosis (NICE CG186). Research in the context of pain has been done, and its inclusion would seem essential.	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.

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Multiple Sclerosis Trust	5	19-21	Nabiximols was assessed in the NICE guideline CG186 and considered not to be cost effective for the NHS in England, Scotland and Northern Ireland (but is consider cost effective in Wales). At the time we criticised the lack of transparency and very limited stakeholder engagement in making this decision. We understand that nabiximols is to be reassessed as part of the review of CG186, but are concerned that this is not an appropriate way to consider evidence around this specific treatment. We would therefore like to see nabiximols assessed in a NICE single technology appraisal which would allow a more detailed and transparent analysis of cost effectiveness and negotiations on price.	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.
Make William Well	5	2	Whilst we acknowledge that there is clinical evidence in relation to the "groups" listed in lines 8 to 11 on page 5, the extent to which these have evidence supporting the efficacy of medicinal cannabis in their treatment over and above conditions such as brain tumours is not clear. We believe that public and patient demand has had more to do with the list of groups which have been named than a proper analysis of the clinical evidence.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
Advisory Council on the Misuse of Drugs	5	22	The draft scope excludes nabiximols, synthetic and non-natural cannabinoids but further clarity is needed on whether they will be considered for the conditions within scope.	Thank you for your comment. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-

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				tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
Royal College of Anaesthetists	5	22-24	Synthetic cannabinoids should be included if there is evidence available and is a licensed drug, as is the case with Nabilone UK, Dronabilone US). By excluding these it is not clear how a comprehensive analysis of the subject can be undertaken.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline.
Epilepsy Action	5	22-24	The draft scope currently excludes synthetic cannabinoids including versions of naturally occurring cannabinoids and non-natural cannabinoids obtained by chemical synthesis. Excluding these areas from the scope is likely to impact on the breadth and quality of available evidence. This is further evidenced by the fact that two prevalent cannabinoid medicines, dronabinol and nabilone, sit in this area. We believe that synthetic versions of naturally occurring cannabinoids and non-natural cannabinoids obtained by chemical synthesis should be included in the scope.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.

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			We believe that synthetic cannabinoid receptor agonists (SCRAs), commonly referred to by their street name 'spice', should not be covered in this scope.	
National Ankylosing Spondylitis Society	5	25	The draft scope does not include products marketed as food supplements. In a recent survey by NASS, 52% of those who had used cannabis-based products medically had used CBD oil for pain relief.	Thank you for your comment. The UK Government definition of cannabis-based products in November 2018 did not include other cannabis-based products such as those marketed as food supplements, therefore the guideline will not consider these products.
The Cure Parkinson's Trust	5	25	These products cannot be ignored in this Guideline and might provide an acceptable GMP compliant option to consider for certain patients e.g. where a substantial CBD component only is desired.	Thank you for your comment. The UK Government definition of cannabis-based products in November 2018 did not include other cannabis-based products such as those marketed as food supplements, therefore the guideline will not consider these products.
Walton Centre NHS Foundation Trust	5	25	Statement as to why 'other cannabis products' such as those marketed bas food supplements are not covered by the guidance.	Thank you for your comment. The UK Government definition of cannabis-based products in November 2018 did not include other cannabis-based products such as those marketed as food supplements, therefore the guideline will not consider these products.
Families 4 Access	5	25	Why exclude Sativex? Guidelines should apply to all cannabis-based medicines and Sativex is one.	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.
Royal College of Anaesthetists	5	25-28	Exclusion of food supplements is unhelpful as many patients already take them and some guidance would be beneficial for patients, professionals and the public. If evidence exists, it should be acknowledged and appropriately scrutinised. If it is of insufficient quality that	Thank you for your comment. The UK Government definition of cannabis-based products in November 2018 did not include other cannabis-based products such as those marketed as food supplements, therefore the guideline will not consider these products.

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			can be assessed and suggestions for further, high quality studies encouraged. If no evidence exists that can be made explicit. Food supplements is a broad term, and many are used in medicine (e.g. Vitamins, Mineral supplements, etc) when they are the specific therapeutic intervention.	
Plymouth Hospitals NHS Foundation Trust	5	27	Many high Street shops are selling these non-standardised products – should NICE have some caution about them?	Thank you for your comment. The UK Government definition of cannabis-based products in November 2018 did not include other cannabis-based products such as those marketed as food supplements, therefore the guideline will not consider these products.
Families 4 Access	5	3.3	There are other conditions with “GOOD” evidence that should be included such as Anxiety and PTSD.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
Families 4 Access	5	3.3	Why not nausea and vomiting as a symptom? Why limit to “chemo-induced”?	Thank you for your comment. The scope includes people with intractable nausea and vomiting.
Families 4 Access	5	3.3	“Not been successful” implies that other options must be tried. This is NOT the case as they only have to have been considered and rejected. This should be reworded.	Thank you for your comment. This section of the scope was re-worded prior to consultation to say “This guideline will consider use of unlicensed medicines and off-label use of cannabis-based medicinal products in line with the GMC's guidance on prescribing unlicensed medicines and off-label use of licensed use of licensed medicines, that is, when other licensed medicines haven't helped or have been discounted”.

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Families 4 Access	5	3.3	Why limit Spasticity to only MS? Why limit MS to Spasticity, especially given that Sativex is already "really" used for pain relief?	Thank you for your comment. The scope includes people with spasticity not only those with spasticity due to MS.
Families 4 Access	5	3.3	There are other conditions for which there is "SOME" evidence that should be considered: sleep disorders appetite stimulation Fibromyalgia some symptoms of Parkinson's disease management of agitation in dementia bladder dysfunction Glaucoma Tourette's syndrome	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
InHealth Pain Management Solutions	5	4	We welcome the inclusion of chronic/persistent pain as one of the areas for the guideline. There has been considerable public and press speculation about the use of cannabis for chronic pain and there is a need for a comprehensive appraisal of the evidence to guide clinicians and commissioners about the use of cannabis in this area. While we welcome this review, we urge caution in the light of experiences associated with the use of opioid medication in chronic pai and the potential for considerable harm to individuals and society.	Thank you for your comment.
Tilray	5	5-11	The draft scope considers establishing guidelines for the use of cannabis-based medicinal products for four indications – chronic pain, intractable nausea and vomiting,	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being

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			spasticity and severe treatment-resistant epilepsy. Due to the nature of national medical cannabis programs in other countries, there are records of tens of thousands of patients using cannabis-based medicinal products over the past 4 years. We kindly ask that the scope consider additional indications based on the recorded, validated historical data on the use of cannabis-based medicinal products for indications beyond the four listed in this scope.	considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
Families 4 Access	5	5-11	The guidelines list 4 indications for the administration of medical cannabis. We feel that additional indications warrant consideration, since there is increasing evidence of success to the extent that such indications are already recognized by other countries. The guidelines can define the specific indications and possibly limitations for such indications. Examples for such indications include oncological pain and vomiting, AIDS patients suffering from severe weight loss due to loss of appetite or vomiting, post-traumatic stress disorder (PTSD), inflammatory bowel diseases (e.g. Crohn's disease and ulcerative colitis), multiple sclerosis, Parkinson's disease, Turette's syndrome, epilepsy and as palliative care for terminally ill patients.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
The Brain Tumour Charity	5	5-7	The draft scope currently explains the guidelines will consider the use of cannabis-based medicinal products for people with chronic pain, intractable nausea and vomiting, spasticity, and severe treatment-resistant epilepsy, in line with GMC's guidance on prescribing unlicensed medicines	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a

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			which advises the use of cannabis-based medicinal products as a treatment only when other treatments haven't helped or have been discounted. Whilst The Charity recognises the importance of GMC's guidance, we recommend the scope of NICE's consultation on cannabis-based medicinal products to go wider so to consider products not just when other treatments have not helped or have been discounted, but when administration of the product is in the best interest of the patient, clinically and medically.	timely fashion the number of indications being considered has had to be limited. This guideline will consider the use of cannabis-based medicinal products for the following groups in line with the GCM's guidance on prescribing unlicensed medicines since all cannabis-based medicinal products (except Sativex and nabilone) are unlicensed in the UK.
NHS England	5	6	Typo? GMC rather than GCM?	Thank you for your comment. This has been amended.
General Medical Council	5	6	We welcome the signposting to our guidance, however, we believe the link should be corrected to "GMC's guidance".	Thank you for your comment. This has been amended.
Tilray	5	6	We kindly ask that the guidelines explore the applicability of cannabis-based medicinal products outside of the context of the GMC's guidance on unlicensed medicines, particularly since tens of thousands of patients have used cannabis-based medicinal products for a variety of indications. The active ingredients found in cannabis-based medicinal products are not novel chemical entities (NCEs); data on dosing and safety exist. We suggest that the scope include a risk/benefit assessment specific to cannabis-based medicinal products, based on all available data, including patient registries, industry data on patient use and	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products for the following groups in line with the GCM's guidance on prescribing unlicensed medicines since all cannabis-based medicinal products (except Sativex and nabilone) are unlicensed in the UK.

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			adverse event reporting in countries with national medical cannabis programs.	
Royal College of Anaesthetists	5	6	GMC is written incorrectly as GCM.	Thank you for your comment. This has been amended.
Drug Science	5	6	Older people are being excluded. This is unacceptable as many of the conditions covered by the guidelines, e.g. chronic pain, intractable nausea and vomiting, are as relevant and prevalent, if not more so, in older people. Older people should not be denied effective treatment and practitioners should be provided with effective guidelines to provide this.	Thank you for your comment. Older people are included in the scope of this guideline.
Advisory Council on the Misuse of Drugs	5	6	GMC rather than GCM	Thank you for your comment. This has been amended.
NHS England	5	7	Suggest amending sentence to say “i.e. when all other licensed treatment haven’t helped or been discounted:”	Thank you for your comment. Following stakeholder consultation this section of the scope has been amended.
General Medical Council	5	7	We are pleased that the draft scope of the guideline references GMC guidance on prescribing unlicensed medicines. It is important to acknowledge that doctors may prescribe an unlicensed medicine where they conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient. Reasons that may account for this include when other treatments haven’t helped or have been discounted.	Thank you for your comment.

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The Neurological Alliance	5	7	Concerned as to whether this list is definitive enough, in terms of the groups of people the guideline should cover. Suggest further work may be needed to ensure a definitive list, according to available research about the symptoms cannabis based products alleviate. It is essential to ensure as wide a list of groups as possible – there is high expectation amongst stakeholder groups for this guideline. Clinicians could be put in a difficult situation if presented with patients currently smoking cannabis, who have intractable symptoms for which there is evidence for the use of medicinal cannabis, if they are not on the list presented here.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
The Neurological Alliance	5	7	How long do patients have to have been on other treatments for them to be considered eligible for treatment for cannabis-based products? Is this on a case by case basis? Whatever is in the GCM guidance perhaps ought to be quoted here for ease of reference.	Thank you for your comment. A link to the GMC's guidance is included in the scope.
British Association for the Study of Headache	5	8	There are no data for, so no role for, cannabis or cannabinoids in any form of primary headache disorder, specifically migraine and cluster headache headache.	Thank you for your comment.
CSF Leak Association	5	8	The CSF Leak Association welcomes the addition of consideration of use of cannabis-based medicinal products for patients with chronic pain. (CSF = cerebrospinal fluid)	Thank you for your comment.

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National Ankylosing Spondylitis Society	5	8	The draft scope lists people with chronic pain. We feel that people with fluctuating pain should also be included as many conditions including axial spondyloarthritis / ankylosing spondylitis can include periods of flare and times when it is more settled.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
Fibromyalgia Action UK	5	8	The draft scope currently indicates that people with chronic pain will be included; however, this could be taken and interpreted differently by healthcare professionals in the future. Therefore, it may be beneficial to be more explicit (as a sub point), about the chronic pain conditions included under the guidelines, such as fibromyalgia, since the lack of explicit detail could impact on the way in which these guidelines are potentially used in the future.	Thank you for your comment. The scope does not define chronic pain, this will be discussed by the guideline committee.
St Luke's Hospice	5	8-11	To specifically identify within the scope the use of cannabis products for cancer pain in the palliative setting. We feel that the long terms effects of cannabis products may be less relevant in this group. Furthermore, patients with complex cancer pain may have tried and failed to respond to conventional treatments and may be willing to try alternative products to provide symptomatic relief.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
Multiple Sclerosis Trust	5	8-11	The groups listed here were identified in the CMO report as showing conclusive evidence of therapeutic benefit of cannabis-based medicinal products. This conclusive evidence was drawn from studies evaluating, almost exclusively, nabiximols, dronabinol and nabilone. It is	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone and dronabinol will also be included within the guideline. The guideline

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			therefore perverse to exclude these drugs from the guideline (see also comment 10). It is important to note that the patient groups listed here may overlap – for example, people with spasticity may also have chronic pain resulting from their spasticity. Cannabis-based medicinal products could be expected to have an additional benefit through managing multiple symptoms.	committee will consider the overlap of indications people may have when making recommendations.
International Brain Tumour Alliance (IBTA)	5	8-11	The IBTA welcomes NICE's plans to issue a Guideline on cannabis-based products for medicinal use. The categories listed in this section, however, are quite broad so it would be helpful to have further clarification and confirmation that the Guideline will definitely cover, for example, people with brain cancer who experience chronic pain, intractable nausea and vomiting or who suffer from severe treatment-resistant epilepsy. Furthermore, brain cancer presents with a spectrum of symptoms unlike other conditions and cannabis-related products may have therapeutic benefit for this varied symptom profile where individual symptoms do not necessarily meet the specific criteria listed (i.e. 'severe', 'intractable').	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited. The guideline committee will consider the overlap of indications people may have when making recommendations.
Advisory Council on the Misuse of Drugs	5	8-11	It may be helpful for NICE to provide specific advice on other conditions where there is expected to be patient demand.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a

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				timely fashion the number of indications being considered has had to be limited.
NHS England	5	9	Should this be clarified to say “Chemotherapy induced intractable nausea and vomiting”?	Thank you for your comment. NICE has included intractable nausea and vomiting in the scope to enable the guideline to consider all intractable nausea and vomiting not only associated with chemotherapy.
The Neurological Alliance	5	9, 11	On what basis is someone considered to have ‘intractable’ nausea or ‘treatment-resistant’ epilepsy? Again, make explicit or insert a reference to where this info can be found. This is particularly important in relation to polypharmacy. Can a cannabis-based product be used as a second line drug? In epilepsy in children, will the ketogenic diet be used at the same time as/prior to/in place of cannabis-based medicinal products? Link to children’s epilepsy guideline.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited. This guideline will consider the use of cannabis-based medicinal products for the following groups in line with the GCM's guidance on prescribing unlicensed medicines since all cannabis-based medicinal products (except Sativex and nabilone) are unlicensed in the UK. Where appropriate this guideline will cross refer to other relevant guidelines. Other guidelines will also cross refer to this guideline as appropriate.
Department of Health - Northern Ireland	5	General	I would suggest that the conditions to be covered in the scope of the NICE guidance (section 3.3) should also include:	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a

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			• Improving short-term sleep outcomes in individuals with sleep disturbance associated with obstructive sleep apnoea syndrome, fibromyalgia, chronic pain, and multiple sclerosis • Increasing appetite and decreasing weight loss associated with HIV/AIDS • Improving symptoms of Tourette syndrome • Improving anxiety symptoms, as assessed by a public speaking test, in individuals with social anxiety disorders These conditions were highlighted as having at least moderate or limited evidence in Dame Sally's initial review of the evidence for CBMPs and so it would seem sensible to avoid any potential accusations of the scope being too narrow by including these in the NICE analysis.	timely fashion the number of indications being considered has had to be limited.
Royal College of Anaesthetists	5	General	It is encouraging to see pain covered in a broad sense, although this is offset by the narrow remit of products to be included in the review.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.

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Royal College of Anaesthetists	5-6	General	There is considerable risk to the clinical conclusions of this review by excluding a large body of material, simply because it falls outside the current remit of acceptable use, or because it refers to already licensed materials. The focus will be too narrow to provide a robust assessment of all the evidence and clear guidance for future areas of research and clinical activity.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline.
University of York	6	1	Although you have ruled out smoking products it would be useful to include products which can be vaped	Thank you for your comment. Vaped products will be considered in the guideline. The scope has been amended to make this clear.
Tikun Olam	6	1	Please clarify position of vaped medicinal cannabis	Thank you for your comment. Vaped products will be considered in the guideline. The scope has been amended to make this clear.
Spectrum Cannabis	6	1	Suggest clarity regarding “smoking” products, provided that it is possible to inhale cannabis via a medical vaporizer without combusting the product.	Thank you for your comment. Vaped products will be considered in the guideline. The scope has been amended to make this clear.
Families 4 Access	6	1	Why are synthetic cannabinoids excluded? Guidelines should apply to all cannabis-based medicines including Dronabinol and Nabilone.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic

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				cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
NHS England	6	1-3	Does “smoked” cannabis-based products include vaping, or does this need to be mentioned separately?	Thank you for your comment. Vaped products will be considered in the guideline. The scope has been amended to make this clear.
Royal College of Anaesthetists	6	1-3	Although smoking for medicinal use is excluded by the current government legislation, it would be appropriate to review the published evidence. Where this is weak this can be explicitly commented on.	Thank you for your comment. Smoked products have not been included in the scope as set out by the Government on the 21 September 2018, the administration of cannabis-based products for medicinal use by smoking is prohibited. It would therefore not be relevant to assess any effectiveness data for this route of administration.
Multiple Sclerosis Trust	6	1-3	While we acknowledge that smoked cannabis-based products are prohibited, we would point out that the majority of studies on the harms of long-term cannabis use, particularly in adolescents, is based on the effects of smoked cannabis.	Thank you for your comment. Smoked products have not been included in the scope as set out by the Government on the 21 September 2018, the administration of cannabis-based products for medicinal use by smoking is prohibited.
Multiple Sclerosis Trust	6	20	Multiple sclerosis in adults: management NICE guideline CG186 is currently being updated. As noted in comment 11, we understand that this will include a review of the evidence for the cost effectiveness of nabiximols for spasticity. The proposed surveillance decision for CG186 states: Recommendation 1.5.23 recommends that Sativex is not used as a treatment for spasticity as it was found to be not	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.

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			cost effective, however there is new cost-effectiveness evidence which indicates that it may be cost effective. Evidence was also identified that supports the use of botulinum toxin in treating spasticity; botulinum is not currently recommended, but is within scope. However, we would like to see nabiximols assessed in a NICE single technology appraisal which would allow a more detailed and transparent analysis of cost effectiveness as well as negotiations on price.	
Association of British Neurologists	6	20	There is a proposal to update this guidance	Thank you for your comment.
Brain Tumour Research	6	4	Why have the NICE guidelines on brain tumours (July 2018) not been included in this list?	Thank you for your comment. This guideline is included under the link to the NICE cancer guideline webpage.
Families 4 Access	6	4	Can we reword “Over-The-Counter” as this has a medical prescribing definition and may lead to confusion. Perhaps “Retail Products currently sold as food supplements?	Thank you for your comment. This section has been re-worded to say “Other cannabis products such as those marketed as food supplements”
Families 4 Access	6	6	Cannabis based products for smoking are precisely the same as products for vaping. This can be reworded or removed to be placed in another section?	Thank you for your comment. Vaped products will be considered in the guideline. The scope has been amended to make this clear.
Parkinson's UK	6	7	We are pleased to see that NICE have included the Parkinson’s NICE guideline (NG71) in the list of related guidance to this scope. There is limited evidence about the effect of cannabis on controlling Parkinson’s symptoms, however anecdotally people with the condition state that it	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a

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			does help to control their symptoms, where other medications fail. We will be conducting research on this early next year and would be happy to share this with NICE when it is completed.	timely fashion the number of indications being considered has had to be limited.
Fibromyalgia Action UK	6	General	A link to the chronic pain pathway would be applicable here.	Thank you for your comment. There is a link to the NICE chronic pain guideline which is currently being developed.
Epilepsy Action	7	13-15	'Cannabidiol for adjuvant treatment of seziures associated with Dravet syndrome and Lennox-Gastaut syndrome' NICE Technology appraisal guidance referenced in the draft scope have now been separated by condition. Now Dravet syndrome [ID1211] and Lennox-Gastaut syndrome [ID1308]. Suggest clarifying in the scope.	Thank you for your comment. We have updated this section to show there are 2 separate technology appraisals.
Tikun Olam	7	26	• Value of information analysis should also be considered. • It is not clear if and when the economic evaluation plan will be developed and if/when this plan will be put out for consultation. Given the nature of the evidence available and potential role in therapy, cost-consequence and/or budget impact may be more relevant that cost-utility analysis. Wider societal benefit highly relevant and should be considered, particularly productivity and carer time	Thank you for your comment. The economic evaluations produced for NICE guideline committees typically consider only the Health Related Quality of Life of relevant patients and costs accruing to the NHS and publically funded Personal Social Services. This is necessary because taking consistent and transparent decisions about cost-effectiveness relies on an accurate representation of the opportunity cost to these services. When developing economic analyses for this guideline it may be appropriate to widen this perspective in sensitivity analyses. The choice of outcomes and costs that may be included in these analyses will be informed by the evidence base and the committee's discussions. Different types of analysis may be used to inform the committee's consideration of

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				the evidence if appropriate (e.g. cost-utility analysis, cost-consequences analysis, value-of-information analysis). The economic plan will not be consulted on, however the economic analysis will be included in the guideline consultation and stakeholders will be able to comment on the economic analysis.
Plymouth Hospitals NHS Foundation Trust	7	27	Cost Implications are around £2,500 per patient per 3 months. Our CCG (New Devon CCG) have already worried about it. If many patients need Independent Financing Applications –how a busy pain department will cope with it.	Thank you for your comment. The economic evaluations produced for NICE guideline committees typically consider only the Health Related Quality of Life of relevant patients and costs accruing to the NHS and publically funded Personal Social Services. This is necessary because taking consistent and transparent decisions about cost-effectiveness relies on an accurate representation of the opportunity cost to these services. When developing economic analyses for this guideline it may be appropriate to widen this perspective in sensitivity analyses. The choice of outcomes and costs that may be included in these analyses will be informed by the evidence base and the committee's discussions. Different types of analysis may be used to inform the committee's consideration of the evidence if appropriate (e.g. cost-utility analysis, cost-consequences analysis, value-of-information analysis).
The Cure Parkinson's Trust	7	27 onwards	A review of the bigger picture is essential alongside further scientific research but for the immediate Guidance to prescribers there needs to be clarity on who pays for what	Thank you for your comment. The economic evaluations produced for NICE guideline committees typically consider only the Health Related Quality of Life of relevant patients and costs accruing to the NHS and publically funded

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			and how the acceptability of price of products is determined.	Personal Social Services. This is necessary because taking consistent and transparent decisions about cost-effectiveness relies on an accurate representation of the opportunity cost to these services. When developing economic analyses for this guideline it may be appropriate to widen this perspective in sensitivity analyses. The choice of outcomes and costs that may be included in these analyses will be informed by the evidence base and the committee's discussions. Different types of analysis may be used to inform the committee's consideration of the evidence if appropriate (e.g. cost-utility analysis, cost-consequences analysis, value-of-information analysis).
Tilray	7	27-30	Economic data on cost savings for Medicaid in states in the US in which cannabis-based medicinal products are available to patients exist. In considering the economic impact of a medicinal cannabis program in the UK, we urge the scope to consider that if cannabis-based medicinal products can be trialled before they become a last resort for treatment, this could result in significant cost savings to the NHS.	Thank you for your comment. The economic evaluations produced for NICE guideline committees typically consider only the Health Related Quality of Life of relevant patients and costs accruing to the NHS and publically funded Personal Social Services. This is necessary because taking consistent and transparent decisions about cost-effectiveness relies on an accurate representation of the opportunity cost to these services. When developing economic analyses for this guideline it may be appropriate to widen this perspective in sensitivity analyses. The choice of outcomes and costs that may be included in these analyses will be informed by the evidence base and the committee's discussions. Different types of analysis may be used to inform the committee's consideration of

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				the evidence if appropriate (e.g. cost-utility analysis, cost-consequences analysis, value-of-information analysis).
Tikun Olam	7	6/8	NICE guideline on Epilepsies is currently in scoping phase. Please clarify how the MC guideline will related to the specific epilepsy guideline as presumably MC should be considered as a comparator in the epilepsy guideline.	Thank you for your comment. Where appropriate this guideline will cross refer to other relevant guidelines. Other guidelines will also cross refer to this guideline as appropriate.
PresQUIPP	8	11	The cost impact of the use of cannabis based medicines has the potential to be considerable e.g. the US list price for Epidiolex has been quoted of $32,500 per patient per year, equating to approximately £25k per patient per year. A robust cost effectiveness analysis is required based on the actual UK cost of the specific product(s) to be used for each indication, which takes into account any additional costs around importing and handling the medicines, and associated activity costs.	Thank you for your comment. The economic evaluations produced for NICE guideline committees typically consider only the Health Related Quality of Life of relevant patients and costs accruing to the NHS and publically funded Personal Social Services. This is necessary because taking consistent and transparent decisions about cost-effectiveness relies on an accurate representation of the opportunity cost to these services. When developing economic analyses for this guideline it may be appropriate to widen this perspective in sensitivity analyses. The choice of outcomes and costs that may be included in these analyses will be informed by the evidence base and the committee's discussions. Different types of analysis may be used to inform the committee's consideration of the evidence if appropriate (e.g. cost-utility analysis, cost-consequences analysis, value-of-information analysis).
Multiple Sclerosis Society	8	11	It is important to note that the patient groups outlined here are not mutually exclusive. For example, it is common for people with spasticity due to MS to also experience chronic pain (although exact quantification is difficult). Cannabis-	Thank you for your comment. The guideline committee will consider the overlap of indications people may have when making recommendations.

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			based medicinal products could be expected to have an additional benefit for such groups in helping to manage multiple symptoms and these groups should be considered as part of the development of the guideline.	
Multiple Sclerosis Society	8	11	Part 1 of the 2018 Home Office review, into the scheduling of cannabis and cannabis-based products for medicinal purposes from Professor Dame Sally Davies, Chief Medical Officer (CMO) for England and Chief Medical Advisor to the UK Government, assessed the therapeutic and medicinal benefits of cannabis-based products for medicinal use in humans on prescription. That report identified 'conclusive or substantial evidence that cannabis or cannabinoids are effective for the treatment of chronic pain in adults (cannabis)'. In addition the CMO identified the same level of evidence for 'improving patient-reported multiple sclerosis spasticity symptoms'. MS Society evidence review 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. <u>Summary of available evidence:</u>	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. If the evidence you refer to meets the review protocol, this will be considered by the guideline committee during the development of the guideline.

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			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 (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). 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. <u>Evidence for smoked cannabis</u> There is currently not enough evidence to suggest that smoking cannabis can treat spasticity or pain in MS and in general smoking also has the potential to negatively impact on an individual's MS. However, trials into different forms of cannabis have shown more promising results. <u>Oral cannabis extract</u> 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). Results:	

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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. <u>Nabiximols (Sativex) Results</u> *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 the clinical 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 again is not currently great. <u>Cannabis in treating different symptoms:</u> Our 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*	

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			Our medical advisers felt that cannabis should be considered for people who do not see clinical benefit from current first line treatments. Estimating, from the trial evidence and personal experience, 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 present, there was insufficient evidence to make a recommendation. <u>Overall Consensus</u> It was felt that, on the balance of probability, cannabis offers the potential for symptomatic relief 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.	

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			- 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 smoking it presents too great a risk. - Some people may experience adverse effects, such as mental health issues, and should not use cannabis for medicinal purposes. 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.	
Multiple Sclerosis Society	8	11	We are aware that the cost and efficacy of cannabis-based medicinal products can vary widely. It will be particularly important for NICE to consider a range of treatments and their efficacy rather than a single “average” price and benefit, as the incremental cost effectiveness ratio of given products are likely to vary widely.	Thank you for your comment. The economic evaluations produced for NICE guideline committees typically consider only the Health Related Quality of Life of relevant patients and costs accruing to the NHS and publically funded Personal Social Services. This is necessary because taking consistent and transparent decisions about cost-effectiveness relies on an accurate representation of the opportunity cost to these services. When developing economic analyses for this guideline it may be appropriate to widen this perspective in sensitivity analyses. The

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				choice of outcomes and costs that may be included in these analyses will be informed by the evidence base and the committee's discussions. Different types of analysis may be used to inform the committee's consideration of the evidence if appropriate (e.g. cost-utility analysis, cost-consequences analysis, value-of-information analysis).
International Brain Tumour Alliance (IBTA)	8	11-32	See comment number 1 above.	Thank you for your comment.
Plymouth Hospitals NHS Foundation Trust	8	13	My Scope is limited to adults in chronic pain only. Will patient be monitored for objective measurements by fMRI or return to work to prevent diversion	Thank you for your comment. The guideline will consider people with chronic pain, it will not be limited to only adults with chronic pain.
Fibromyalgia Action UK	8	13	Comment number 2 applies to this point with reference to the key issue and draft question of explicitly discussing the chronic pain conditions included under the scope of these guidelines.	Thank you for your comment.
InHealth Pain Management Solutions	8	13	When considering persistent pain it is important to recognise that there are different pain conditions with different mechanisms that need to be taken into account. The effect of cannabis medication may be quite different for example in neuropathic and nociceptive pain or in functional pain such as fibromyalgia. It is important that the review considers this as a generic recommendation for use in persistent pain, based on an undifferentiated review may	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.

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			lead to patients receiving medication inappropriately for particular pain conditions.	
Multiple Sclerosis Trust	8	13-16	This list of symptoms has been selected from those considered to show conclusive evidence of therapeutic benefit in the CMO report, based on clinical trials which have mostly investigated nabiximols, dronabinol and nabilone. See comment 10.	Thank you for your comment. Following stakeholder comments Sativex, nabilone and dronabinol will also be included within the guideline.
HSP Support Group	8	15	The guidelines seek to examine the clinical effectiveness of cannabis based products. For rare diseases such as HSP there is little published evidence to support many of the treatments that are commonly prescribed for HSP symptoms, with many prescriptions made on the basis of the similarity of symptoms with other conditions. The HSP Support Group would be keen to ensure that the guideline does not prevent the prescription of cannabis based medical products for rare diseases with spasticity if a treatment is shown to successfully reduce similar symptoms in an alternative condition.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the evidence which meets the review protocols to inform the recommendations.
Multiple Sclerosis Society	8	17	Our review of the evidence, referenced above, identified the following reported adverse effects: There were common side effects reported across the studies we looked at in our evidence review (see above) with cannabis-derived drugs including, considered above: dizziness, drowsiness, memory disturbance, difficulty concentrating, increased appetite, nausea, vomiting and constipation. Less common side-effects were: myalgia,	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the

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			increased spasticity, seizures, lower limb weakness, cystitis, dehydration, temporary psychosis and hallucinations	evidence which meets the review protocols to inform the recommendations.
Families 4 Access	8	17	The draft refers to side effects from the point of view of their indication. We feel that methods and capabilities to control or diminish side effects should also be considered as a specific topic, since this may reduce the need to treat side effects.	Thank you for your comment. The guideline will consider the clinical and cost effectiveness of cannabis-based medicinal products as well the side effects.
Association of British Neurologists	8	19	Sleepiness, dizziness and mental problems (including confusion) are reported, plus there may be other anticipated risks such as dependence or psychosis .	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the evidence which meets the review protocols to inform the recommendations.
University of York	8	23	It is encouraging to see the inclusion of potential interactions between cannabis products and medication, it would be useful to broaden this to include potential interactions with tobacco, alcohol and other drugs.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the evidence which meets the review protocols to inform the recommendations.

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Multiple Sclerosis Society	8	23	We agree that these issues should be in scope of the guideline. Some people may experience adverse effects, such as mental health issues, and we would recommend they should not use cannabis for medicinal purposes.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the evidence which meets the review protocols to inform the recommendations.
National Ankylosing Spondylitis Society	8	24	Interactions with other medicines eg opioids, biologics, anti inflammatories should be considered	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the evidence which meets the review protocols to inform the recommendations.
Association of British Neurologists	8	25	Contraindications may include history of psychosis and cautions history of substance abuse.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the

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				evidence which meets the review protocols to inform the recommendations.
SUDEP Action	8	28	Will research considered as part of the methodology for producing this guideline also consider not only the side-effects from cannabis-based medicines but also the wider epilepsy risks associated with epilepsy mortality (including SUDEP)? This may prove relevant in considering issues of non-adherence in people taking this medication due to side-effects, the need for polytherapy, or during periods of mediation changes for example. It would also be important to consider any available evidence of epilepsy-related deaths during clinical trials using cannabis-based medication.	Thank you for your comment. The guideline will consider the effectiveness, safety and potential harms of cannabis-based medicinal products. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline.
NHS England	8	29	May be useful to include any information (if available) on switching of products. For example for patients taking a product privately being switched onto a GMP product on the NHS if felt to be appropriate.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline.
Multiple Sclerosis Society	8	29	We agree that these issues should be in scope of the guideline.	Thank you for your comment. This guideline will consider the formulation of cannabis-based products and will consider individual monitoring requirements for cannabis-

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			We would like to see cannabis for medicinal use clearly monitored. That would include a registry of people accessing cannabis to collect info on type, dose and outcomes. It would also involve limiting the range of THC/CBD preparations available to support easier collection of data and comparison of results in different indications. These measures would enable the clinical and research community to continue to gather evidence on the effectiveness of medicinal cannabis in 'real time'. As noted above, this approach could inform a managed access scheme for some indications of medicinal cannabis where NICE may feel additional evidence is required.	based medicinal products and the guideline committee will consider recommendations in this area.
Families 4 Access	8	29	The draft scope considers "monitoring requirements". We feel that monitoring capabilities are also relevant; specifically – how accurately can a doctor ensure actual use and accurate dosage taken by a prescribed patient. This may reduce the hazard of intentional and unintentional abuse, improve patient and public safety and improve treatment success and efficacy. In addition, we recommend that the guidelines cover in this context the effect of monitoring patient adherence to a prescribed dosing regimen, including how to monitor and maintain patient adherence, prevent misuse and abuse.	Thank you for your comment. The guideline will consider individual treatment factors and support for both prescribers and patients (or their family members or carers) and individual monitoring requirements for cannabis-based medicinal products and the guideline committee will consider recommendations in this area.
HSP Support Group	8	4	Many people with HSP end up on PIP as the severity of their symptoms progresses. The use of medication to	Thank you for your comment. The economic evaluations produced for NICE guideline committees typically consider

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			relieve symptoms, including spasticity, is likely to delay the point at which a person with HSP will need to apply for PIP. The relief of symptoms also delays the need for an array of crutches, walking frames, wheelchairs, ramps, walk-in bathroom conversions and other building works as symptoms change, and has the potential to delay moving into a care home or reduce the level of care needed in a care home. The HSP Support Group is keen to ensure that the economic assessment will consider the financial impacts of delaying the need for mobility aids, delaying applications for PIP, and delaying moving into a care home.	only the Health Related Quality of Life of relevant patients and costs accruing to the NHS and publically funded Personal Social Services. This is necessary because taking consistent and transparent decisions about cost-effectiveness relies on an accurate representation of the opportunity cost to these services. When developing economic analyses for this guideline it may be appropriate to widen this perspective in sensitivity analyses. The choice of outcomes and costs that may be included in these analyses will be informed by the evidence base and the committee's discussions. Different types of analysis may be used to inform the committee's consideration of the evidence if appropriate (e.g. cost-utility analysis, cost-consequences analysis, value-of-information analysis).
Pfizer UK	8	4	It is unlikely that economic effects are sufficiently captured using the NHS+PSS perspective and the draft scope acknowledge that a broader perspective may need to be explored in sensitivity analyses. Pfizer suggest changing the sentence to comprehensively reflect the high unmet need and potential societal opportunity costs, which currently are underestimated using a strict NHS+PSS perspective. Please change the sentence to: "*We will review the economic evidence and carry out economic analyses, using a NHS and personal social services (PSS) perspective. If appropriate, a broader perspective may be used in sensitivity analyses (for*	Thank you for your comment. The economic evaluations produced for NICE guideline committees typically consider only the Health Related Quality of Life of relevant patients and costs accruing to the NHS and publically funded Personal Social Services. This is necessary because taking consistent and transparent decisions about cost-effectiveness relies on an accurate representation of the opportunity cost to these services. When developing economic analyses for this guideline it may be appropriate to widen this perspective in sensitivity analyses. The choice of outcomes and costs that may be included in these analyses will be informed by the evidence base and

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			example, including non-NHS costs, consequences and societal aspects, such as work presenteeism, absenteeism and productivity*).*"	the committee's discussions. Different types of analysis may be used to inform the committee's consideration of the evidence if appropriate (e.g. cost-utility analysis, cost-consequences analysis, value-of-information analysis).
Royal College of Nursing	8	6	There are a number of challenges, which the guideline development committee might be aware of which are needed to establish a system that would allow people to access medicinal cannabis. The first challenge is establishing what is classed as medicinal cannabis? Also, there could potentially be challenges in how to access the treatment across the existing landscapes and structures, many services are already stretched and would struggle to manage the demand from patients to access this treatment.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018.
The Neurological Alliance	8	9	Will the risks associated with not treating with cannabis-based medicinal products be considered alongside the risks of such treatment? This is not explicit. In the case of many neurological patients, there are potential harms of not treating, which also merit consideration alongside the potential harms of doing so.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the evidence which meets the review protocols to inform the recommendations.
Families 4 Access	8	9	We feel that special consideration should be given to absorption precision, accuracy and consistency, which in	Thank you for your comment. The development of the guideline will follow the processes and methods described

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			turn affects safety and tolerance build-up, side effects and other factors that have a significant effect on the success and effectiveness of treatment.	in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the evidence which meets the review protocols to inform the recommendations.
University College London Hospitals NHS Foundation Trust	8	9- 32	Questions 1.1-1.4 are all relevant but when considering spasticity the results need to be compared to Sativex. How can the committee make recommendations about non-licensed cannabis based products without considering the licensed product first? This would render such a guideline worthless.	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.
Royal College of Anaesthetists	8	General	It would be helpful if one of the questions looked at dose effect relationships to guide dosing in the conditions mentioned. It needs to be established if there are thresholds where dose has an increased risk of side effects.	Thank you for your comment. The dose of cannabis-based products will be considered by the guideline committee.
Association of British Neurologists	9	1	A trial for a period set by a pain physician with subsequent review of benefits, ideally with appropriate outcome measures, and ongoing review to ensure benefit is sustained without significant evolving side effects.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the

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				evidence which meets the review protocols to inform the recommendations.
Multiple Sclerosis Society	9	10	We agree that this should be in scope of the guideline. It is vital that prescribers have confidence to prescribe to patients who could benefit, as argued above. It is also important patients have access to accurate information and advice. We recently shared the news with our community about the legalisation of cannabis for medicinal use. In response, a number of people with MS shared their recent experiences of speaking to their GP or neurologist about cannabis. Their responses reflect issues around misinformation and confusion. These include confusion between the change in the law and the availability of Sativex, and professionals providing incorrect information such as 'cannabis isn't legal for people with MS' or 'neurologists are not able to prescribe it', or simply not having clarity themselves in order provide patients with the information they want. Prescribers and patients must also be made fully aware of the challenges in accessing Sativex. 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	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.

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			MS from across the UK attended. They noted the challenges they have had in prescribing Sativex to people who could benefit. In their experience individual requests for funding (the only route to get Sativex on the NHS outside of Wales) were consistently refused. In addition, 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. 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. 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. We strongly urge the manufacturer of Sativex and NICE to get back around the table and explore every possible option for securing patient access to it on the NHS. However, with the vast majority of patients in England unable to access Sativex it would be wrong to withhold other treatment	

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			options simply in the hopes that such a compromise will one day be found.	
National Pharmacy Association	9	10	2.2 What support is needed to help prescribers and patients…. ought to include community pharmacists as the healthcare professionals who would be supplying this medication, and could be asked for some further advice from the patient/carer.	Thank you for your comment. Healthcare professionals include all those who are prescribing cannabis-based medicinal products or who are providing care to people taking cannabis-based medicinal products, include community pharmacists. The scope has not specified individual roles as it important to include all those involved.
Association of British Neurologists	9	10	Advice from a pain physician, with written information about risks of short and long term use. Patients should be counselled that even if a trial of cannabinoids seems helpful, benefits may not be sustained and dependence may occur, with risk of other side effects such as sleepiness, dizziness or mental problems.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the evidence which meets the review protocols to inform the recommendations.
SUDEP Action	9	10	It is vital given the risk to people with epilepsy, particularly those with difficult to treat epilepsy, that any information given to prescribers, clinicians who support patients on this medication, the patients themselves and their families/carers, is provided in the context of understanding and considering wider epilepsy risks (associated with epilepsy mortality) to enable them to make informed	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the

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			decisions about their treatment options and lifestyle choices. This messaging and information must be balanced to help mitigate risks of epilepsy-related deaths due to non-adherence issues (ie: stopping medication due to side-effects or to take publicly available cannabis products).	evidence which meets the review protocols to inform the recommendations.
SUDEP Action	9	10	Does information also need to be provided for clinicians who may these patients (perhaps in-between appointments with the prescribing clinician) and those who may be the first point of contact for patients wishing to consider this treatment option?	Thank you for your comment. Following stakeholder consultation the scope has been amended to include all healthcare professionals in the section who the guideline may be relevant for.
Advisory Council on the Misuse of Drugs	9	10	There needs to be clarity on what support prescribers can expect to receive to aid decision making on specific products and which frameworks prescribers can follow.	Thank you for your comment. The guideline will consider individual treatment factors and support for both prescribers and patients (or their family members or carers). Cross reference to other NICE guidelines which support evidence-informed decision making will be made where appropriate.
University College London Hospitals NHS Foundation Trust	9	10- 12	Question 2.2; how can the committee make recommendations about information to patients and their families if you do not give information about the licensed and safer alternative Sativex?	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.
Parkinson's UK	9	10-12	Clear information in plain English about the products would be needed for both people with Parkinson's, their carers	Thank you for your comment. The guideline will consider individual treatment factors and support for both

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			and families and also for prescribers. It should include the standard information contained in most patient information including what the medication is used to treat, how to take the medication, what to do if taking other medicines, common side effects, how to report side effects and how to store the product.	prescribers and patients (or their family members or carers).
Multiple Sclerosis Trust	9	10-12	Support may also be needed for others involved in the care of people seeking cannabis-based medicinal products to treat symptoms such as specialist nurses, physiotherapists and GPs.	Thank you for your comment. Following stakeholder consultation the scope has been amended to include all healthcare professionals in the section who the guideline may be relevant for.
SUDEP Action	9	13	Will there be guidance included as to whether Cannabis-based medications are to be used as monotherapy or can be used as polytherapy (either as first or second line medication)? This could prove important in educating patients and non-specialist clinicians on how this medication could be prescribed to them and the impact it could have on seizure control.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products for the following groups in line with the GCM's guidance on prescribing unlicensed medicines since all cannabis-based medicinal products (except Sativex and nabilone) are unlicensed in the UK.
Families 4 Access	9	13	With regards to prescribing requirements we think that dosing capabilities of cannabis based medicinal products may be included.	Thank you for your comment. Dosing of cannabis-based products will be considered by the guideline committee.
NHS England	9	14	Typo (prescribe) – not sure if this should be “who should be prescribed” or “who should be prescribing”?	Thank you for your comment. This has been amended.
PresQUIPP	9	14	3.1 Who should be prescribe cannabis-based medicinal products?	Thank you for your comment. We recognise that obtaining unit costs in this area will be more challenging than is usually the case in economic evaluations conducted for NICE guidelines. We will endeavour to obtain costs that

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			Prescribing responsibility should be clearly addressed by the guideline. The guideline should also consider the supply route for these products including their suitability for FP10 prescribing and supply by community Pharmacy. There is currently considerable variation in the cost to the NHS for unlicensed “specials”, from both the basic cost of the drug and associated on costs. This needs to be considered as part of the economic evaluation and cost effectiveness assessment.	most appropriately reflect the acquisition cost and various cost-consequences associated with cannabis based products.
Multiple Sclerosis Society	9	14	We believe initially it should be specialist prescribers only (at least until greater evidence is collected). These should be specialists in pain or consultant level clinicians. In order for clinicians to have confidence to prescribe however, this guideline should define what is meant by a cannabis derived product (see above).	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products. The guideline will consider who within this guidance should prescribe.
Parkinson's UK	9	14	Parkinson’s UK believe that all relevant clinicians with an expertise in Parkinson’s, who are allowed to prescribe medication (Parkinson’s nurses, grade 7 and above, consultants and specialist pharmacists) should be able to prescribe cannabis-derived medicinal products. Although they will need further guidance and education from NHS England, Health Education England and from relevant	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products. The guideline will consider who within this guidance should prescribe.

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			professional bodies to enable them to confidently prescribe these products to their patients.	
Parkinson's UK	9	14	We believe that GPs could also prescribe cannabis-derived medicinal products with clear guidance from a Parkinson's specialist, like a consultant, Parkinson's nurse or specialist pharmacist.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products. The guideline will consider who within this guidance should prescribe.
Fibromyalgia Action UK	9	14	This should state 'who should be prescribed...'	Thank you for your comment. This has been amended.
Association of British Neurologists	9	14	Specialist pain physicians.	Thank you for your comment.
Young Epilepsy	9	14	There is an error on this line: '*Who should be prescribe cannabis-based medicinal products?'*.	Thank you for your comment. This has been amended.
Epilepsy Action	9	14-17	In the draft scope formulation is currently only mentioned in reference to other relevant guidance. There are a multitude of active compounds in cannabis and the combinations and ratios of such compounds in specific cannabis-based medicinal products is an important point for the purpose of the scope. Suggest that formulations should be a separate stand-alone question and potential to include clarification of specific compounds and formulations within the scope.	Thank you for your comment. This guideline will consider the formulation of cannabis-based products.

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Advisory Council on the Misuse of Drugs	9	15	The current structure for quality assurance mechanisms around the variability of products needs to be refined.	Thank you for your comment. The regulation of drugs is outside NICE's remit.
Tikun Olam	9	23	Please also consider productivity, activities of daily living, carer time,	Thank you for your comment. These outcomes could be considered under service user and carer satisfaction. Your comment will be considered by the committee when developing the evidence review protocols.
Pfizer UK	9	23	Please include mortality and hospitalisation due to use of cannabis-based products as a main outcome.	Thank you for your comment. These outcomes could be considered under clinical outcomes and effectiveness. Your comment will be considered by the committee when developing the evidence review protocols.
Pfizer UK	9	23	The draft scope includes young people, children and babies, pregnant women and women who are breastfeeding to be considered for the assessments of risks and benefits in the use of cannabis-based products for medicinal use. Given the vulnerability of these potential patient populations Pfizer strongly recommends to include cognitive function and psychological symptoms (intellectual capacity) as additional outcomes in section 3.6 (page 9) of the draft scope. Various references, such as Rabin et al, 2017, highlight the potential effects of cannabis-based products for medicinal use during the critical neurodevelopmental processes that occur up to the age of 18. (*Rabin RA, George TP. Understanding the link between cannabinoids and psychosis. Clinical Pharmacology & Therapeutics. 2017 Feb;101(2):197-9.*)	Thank you for your comment. These outcomes could be considered under clinical outcomes and effectiveness. Your comment will be considered by the committee when developing the evidence review protocols.

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			Pfizer suggest adding cognitive function and psychological symptoms (intellectual capacity) as additional outcomes in section 3.6 (page 9) of the draft scope.	
Pfizer UK	9	23	Pfizer acknowledges the important of assessing the service use satisfaction (line 28) and carer satisfaction (line 29) as separate outcomes in section 3.6 (page 9). Affiliated and equally important outcomes to be considered alongside service use satisfaction and carer satisfaction are service utilisation and health system costs. Pfizer suggest adding service utilisation and health system costs to section 3.6 (page 9) as additional outcomes to the draft scope.	Thank you for your comment. The economic evaluations produced for NICE guideline committees typically consider only the Health Related Quality of Life of relevant patients and costs accruing to the NHS and publically funded Personal Social Services. This is necessary because taking consistent and transparent decisions about cost-effectiveness relies on an accurate representation of the opportunity cost to these services. When developing economic analyses for this guideline it may be appropriate to widen this perspective in sensitivity analyses. The choice of outcomes and costs that may be included in these analyses will be informed by the evidence base and the committee's discussions. Different types of analysis may be used to inform the committee's consideration of the evidence if appropriate (e.g. cost-utility analysis, cost-consequences analysis, value-of-information analysis).
Pfizer UK	9	23	Although the NICE guidelines manual stipulates the information required in the economic reference case, the likely costs associated with acquisition and sourcing of cannabis-based products for medicinal use may not necessarily be adequately captured.	Thank you for your comment. We recognise that obtaining unit costs in this area will be more challenging than is usually the case in economic evaluations conducted for NICE guidelines. We will endeavour to obtain costs that most appropriately reflect the acquisition cost and various cost-consequences associated with cannabis based products.

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			Pfizer therefore suggests adding acquisition and sourcing costs as additional outcomes in section 3.6 (page 9) of the draft scope.	
Spectrum Cannabis	9	23	Add - Reduction of other medications – under "Main outcomes.." This would be in an effort to track the improvements to patients through the reduction of previously prescribed medicines, limiting their varied adverse effects. There are significant learning to be had by looking at the Canadian experience over the last 5 years.	Thank you for your comment. These outcomes could be considered under clinical outcomes and effectiveness. Your comment will be considered by the committee when developing the evidence review protocols.
International Brain Tumour Alliance (IBTA)	9	23-30	We believe that "addressing unmet need" should also be a main outcome. We would suggest that "service user satisfaction" be amended to read "service user satisfaction and improved outcomes". Similarly for the wording regarding carer satisfaction.	Thank you for your comment. These outcomes could be considered under clinical outcomes and effectiveness or service user satisfaction. Your comment will be considered by the committee when developing the evidence review protocols.
The Neurological Alliance	9	24	The main outcomes that may be considered…' – this is very unclear. Far greater clarity is needed about how these outcomes will be considered, their order of priority etc. Otherwise there is a lack of transparency.	Thank you for your comment. The committee will further refine the outcomes to be considered when developing the evidence review protocols.
Tikun Olam	9	26	Will the specific clinical outcomes be specified and open to consultation prior to the literature review being conducted.	Thank you for your comment. The evidence review protocols will be published as described in section 4 of Developing NICE guidelines: the manual.
HSP Support Group	9	26	As HSP is a rare disease there is not much published evidence to support the use of treatments. The HSP Support Group would be keen to ensure that the guideline	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence

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			does not prevent the prescription of cannabis based medical products for rare diseases with spasticity if a treatment is shown to successfully reduce similar symptoms in an alternative condition.	reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the evidence which meets the review protocols to inform the recommendations. The guideline committee will consider your comment when considering the evidence.
Association of British Neurologists	9	26	Clinician rated scales for spasticity are unreliable as there may be significant variability of symptoms during the day and from day-to-day. Patient reported scores are essential to capture this variability.	Thank you for your comment. These outcomes could be considered under clinical outcomes and effectiveness. Your comment will be considered by the committee when developing the evidence review protocols.
InHealth Pain Management Solutions	9	26	We would urge that the guidelines, when considering chronic pain, ensure that they reflect that medications even if shown to be effective, are only of value as part of a comprehensive biopsychosocial approach to pain and that medication while having an important place in this area not the only approach to managing pain and that medication used out with such an approach can have significant negative consequences on the individual's quality of life and wellbeing.	Thank you for your comment. These outcomes could be considered under clinical outcomes and effectiveness. Your comment will be considered by the committee when developing the evidence review protocols.
Multiple Sclerosis Trust	9	26-30	Clinical outcomes and effectiveness should take account of prevention of complications as a result of taking a cannabis-based medicinal product. Users of medicinal cannabis report reduced use of other conventional medicines; where reported, this outcome should also be considered.	Thank you for your comment. These outcomes could be considered under clinical outcomes and effectiveness. Your comment will be considered by the committee when developing the evidence review protocols.

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			Impact on services should also be considered. For example, nabiximols is indicated for people who respond to an initial trial of therapy. The cost and impact on MS services of carrying out this initial trial should be taken into account.	
Tikun Olam	9	27	Health-related quality of life	Thank you for your comment. This outcome could be considered under quality of life. Your comment will be considered by the committee when developing the evidence review protocols.
Plymouth Hospitals NHS Foundation Trust	9	27	Will the patients be followed up by questionnaires and who will follow them and how frequently. If the patients do not get an optimum benefit, how long it should be tried for. If people are drop outs, how they will be managed. Will there be a central register to put in all the patients, indications for use, side effects and outcomes at certain periods, so we can have a robust data in the future to recommend the therapy for potential candidates.	Thank you for your comment. The guideline will consider the individual patient monitoring requirements, treatment durations, reviewing and stopping criteria for cannabis-based medicinal products. The guideline committee will consider the evidence in these areas to inform the guideline recommendations.
SUDEP Action	9	27	Alongside quality of life as an outcome, it is worth considering risk management / risk mitigation as an outcome? For those who may be considered at a higher risk to people with epilepsy, being able to reduce risks associated with epilepsy mortality due to improved seizure control (from cannabis-based medications as part of a wider plan to reduce risks) would be a positive outcome to assess.	Thank you for your comment. These outcomes could be considered under clinical outcomes and effectiveness. Your comment will be considered by the committee when developing the evidence review protocols.

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Tikun Olam	9	30	Tolerability	Thank you for your comment. This outcome could be considered under clinical outcomes and effectiveness. Your comment will be considered by the committee when developing the evidence review protocols.
Pfizer UK	9	30	Please include dependence and withdrawal alongside adverse effects and safety as it is potentially a cannabis specific outcome (Curran HV, Wiffen P, Nutt DJ. 2016 Cannabis and Cannabis Resin), which may not be captured in the typical adverse event and safety search during the systematic literature review stage, but is acknowledged in section 3.5 (page 8) point 1.4 (line 29) of the draft scope. Pfizer suggest changing line 30 in section 3.6 (page 9) of the draft scope to "adverse effects, safety, dependence and withdrawal".	Thank you for your comment. These outcomes could be considered under clinical outcomes and effectiveness. Your comment will be considered by the committee when developing the evidence review protocols.
Multiple Sclerosis Society	9	5	We agree that this should be in scope of the guideline. Decisions about treatment should be genuinely shared decisions between patients and prescribers. Different treatments will work well for different people, depending on their MS and lifestyle. People with MS will want to consider how a treatment, its side effects and any monitoring/ongoing management will impact on their quality of life, and prescribers should respect their choices.	Thank you for your comment.
Advisory Council on the Misuse of Drugs	9	5	There is a need for more information on the range of products available to be prescribed by clinicians. There is a lack of published data on such products, particularly on the	Thank you for your comment. This guideline will consider the formulation of cannabis-based products and how to safely prescribe them. We will work with other government

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			characterisation, bioavailability, pharmacokinetics and pharmacodynamics of products, how they are to be used and the impact of the route of administration, including the effect of heat on producing the major active agents from their acid forms. Unless the clinician knows the dose, the route of administration and the suggested dosing frequency then it is difficult to see how CBMPs could be used effectively.	agencies such as the MHRA to inform these recommendations.
HSP Support Group	9	7	As HSP is a rare disease, patients are often willing to try alternative medicines and treatments to relieve their symptoms, including treatments for conditions with similar symptoms. Similarity of symptoms and reported relief by others may be sufficient for some patients to wish to try new treatments as their symptoms and the severity of their symptoms change. The HSP Support Group is keen to ensure that the guideline does not prevent open discussions around potential treatment options with relevant health professionals.	Thank you for your comment. The guideline will consider individual treatment factors and support for both prescribers and patients (or their family members or carers). NICE is also currently developing a guideline on shared decision making.
Association of British Neurologists	9	7	Individual factors: previous psychiatric history; obtaining consent: patient capacity.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the

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				evidence which meets the review protocols to inform the recommendations.
Association of British Neurologists	9	7	Many patients with MS have a combination of pain and spasticity and would benefit from a drug that treats symptoms. Patients potentially may not reach the treatment threshold for either symptom individually, whilst having a significant cumulative benefit. Considering pain and spasticity as 2 separate entities may exclude a significant number of patients who would benefit	Thank you for your comment. The guideline committee will consider the overlap of indications people may have when making recommendations.
InHealth Pain Management Solutions	9	7	When considering individual treatment factors that need to be taken into account when considering prescribing and obtaining patient consent for cannabis-based medicinal products it would be helpful if specific risks are identified that would allow appropriate risk assessment before any recommended prescribing takes place. The use of opioid risk assessment tools for example has helped to reduce potential harms in opioid prescribing.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The guideline committee will consider all the evidence which meets the review protocols to inform the recommendations.
National Ankylosing Spondylitis Society	9	7 - 9	At what stage will cannabis-based medicines be offered – eg when other treatments have failed, to complement other medications already prescribed. It appears it is as a last resort only at present?	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products for the following groups in line with the GCM's guidance on prescribing unlicensed medicines since all cannabis-based medicinal products (except Sativex and nabilone) are unlicensed in the UK.
National Ankylosing	9	7-9	Consider social, work and religious / ethnic stigma and discrimination.	Thank you for your comment. The scope includes a list of the main outcomes that the guideline will consider. The

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Spondylitis Society				guideline committee will define the outcomes that will be considered in the evidence reviews through development of the review protocols. The guideline committee will consider your comment when developing the evidence review protocols.
Parkinson's UK	9	7-9	We believe that the impact of Parkinson's medications and specific timings need to be taken into account when prescribing cannabis-derived medicinal products. An individual's medication regime can be complex and is usually developed after detailed discussions with their consultant or Parkinson's nurse so there would need to be close contact to ensure any introduction of a new medication doesn't interact or impact other Parkinson's medications already being taken.	Thank you for your comment. The scope includes a list of the main outcomes that the guideline will consider. The guideline committee will define the outcomes that will be considered in the evidence reviews through development of the review protocols. The guideline committee will consider your comment when developing the evidence review protocols.
National Pharmacy Association	Equality impact assessment	1.1	People would be concerned "regarding effects on the brain" regardless of religion or beliefs. The NPA suggests that this concern be addressed in the guidelines for healthcare professionals including community pharmacists who may be asked these questions from concerned patients/carers.	Thank you for your comment. The scope includes a list of the main outcomes that the guideline will consider. The guideline committee will define the outcomes that will be considered in the evidence reviews through development of the review protocols. The guideline committee will consider your comment when developing the evidence review protocols.
Walton Centre NHS Foundation Trust	General		The draft scope should consider use in glioblastoma tumours	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being

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				considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
Royal Pharmaceutical Society	General	"Areas that will not be covered"	The usefulness of this guideline to prescribers will be limited by synthetic cannabinoids being outside of scope. This will mean the need for clinicians to refer to multiple guidelines when supporting the patient which will undermine the value of this guideline for decision-making and safe and effective prescribing. The guideline will be more useful if medicinal products with marketing authorisations were included in pathways together with cannabis based medicinal products without marketing authorisations.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
Families 4 Access	General	Clinical Guidelines Committee	Psychiatrist: Why specialising in addiction? With 30% of patients consuming to treat a mental health condition, would we not be better with one who specialises in areas where there is good evidence that cannabis can be of benefit, Eg: Anxiety and PTSD?	Thank you for your comment. The guideline committee recruitment advert included a role for a consultant psychiatrist specialising in addiction as it was felt that having this expertise on the guideline committee was important. The guideline will not be considering the use of cannabis-based medicinal products for anxiety or PTSD but will be considering the 4 indications listed in the scope
Families 4 Access	General	Clinical Guidelines	Patients Representatives: Should there not be one patient per condition for which guidelines are to be produced?	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a

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		Committee		timely fashion the number of indications being considered has had to be limited. The guideline committee will consider the overlap of indications people may have when making recommendations.
Families 4 Access	General	Clinical Guidelines Committee	Palliative care requires a specific paediatric specialist too	Thank you for your comment. The guideline committee recruitment advert included a role for a paediatrician specialising in palliative care.
University of York	General	General	It will be important to distinguish between human and animal studies when reviewing and reporting evidence.	Thank you for your comment. Animal studies will be excluded when searching the literature for the guideline.
UKMSSNA (United Kingdom Multiple Sclerosis Specialist Nurse Association)	General	General	We would like to ensure that cannabis is accessed in a way that is safe, responsible, equitable and assessed by a multidisciplinary team approach to ensure that the right people can access its benefits at the right time. This would ensure further research into its effects could continue.	Thank you for your comment.
UKMSSNA (United Kingdom Multiple Sclerosis	General	General	There are a number of challenges, of which I am sure you are aware, that are needed to establish a system that would allow people to access medicinal cannabis. The first challenge is establishing what is classed as medicinal cannabis? There will also be challenges in how to access the treatment across the existing landscapes and	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products.

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Specialist Nurse Association)			structures, many services are already stretched and would struggle to manage the demand from patients to access this treatment.	
UKMSSNA (United Kingdom Multiple Sclerosis Specialist Nurse Association)	General	General	We need to ensure that all treatment is research led and not as a result of the enhanced media exposure and work towards a framework that provides safe, effective and fair access to medicinal cannabis.	Thank you for your comment.
Royal College of Nursing	General	General	The Royal College of Nursing (RCN) welcomes proposals to develop NICE guidelines on cannabis based products for medicinal use. The need for a guideline is topical. The RCN invited members who care for people who may benefit from the use of cannabis based products for the management of their conditions, to review the draft document on RCN's behalf. The comments below reflect the views of our reviewers.	Thank you for your comment.
Royal College of Nursing	General	General	The draft scope seems comprehensive and seems to demonstrate equality of opportunity in identifying the target audience of those who might benefit from the use of cannabis based products to manage their conditions.	Thank you for your comment.

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Royal College of Nursing	General	General	There is a need to ensure that cannabis products for medicine use are accessed in a way that is safe, responsible, equitable and assessed by a multidisciplinary team approach to ensure that the right people can access its benefits at the right time. This would ensure that further research into its effects could continue. .	Thank you for your comment.
Royal College of Nursing	General	General	We need to ensure that all treatment is evidenced based and not as a result of the enhanced media exposure and all work towards a framework that provides safe, effective and fair access to medicinal cannabis.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline.
Royal College of Nursing	General	General	It would be helpful if a flow chart/protocol is included in the final guideline	Thank you for your comment. The guideline committee may choose to include an algorithm in the guideline is appropriate as described in Developing NICE guidelines: the manual. NICE will also produce a pathway for this guideline as described in the scope.
Cochrane Pain, Palliative and Supportive Care Review Group	General	General	This position paper, endorsed by the Occupational and Environmental Medical Association of Canada, may be of interest for the guideline: https://oemac.org/wp-content/uploads/2018/09/Position-Statement-on-the-Implications-of-cannabis-use.pdf	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. If the evidence you refer to meets the

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				review protocol, this will be considered by the guideline committee during the development of the guideline.
Cochrane Pain, Palliative and Supportive Care Review Group	General	General	This position paper of the European Pain Federation may be of interest for the guideline: https://onlinelibrary.wiley.com/doi/full/10.1002/ejp.1297	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. If the evidence you refer to meets the review protocol, this will be considered by the guideline committee during the development of the guideline.
Neonatal & Paediatric Pharmacists Group	General	General	NPPG welcome the development of this guideline and are in agreement with the proposed scope.	Thank you for your comment.
NHS England	General	General	The guidance ought to be strengthened on who can and cannot prescribe cannabis based products. The GMC has 65 specialities (and 32 subspecialties) covered within their specialist register. Consideration should be given to restricting the prescribing of these products to a small number of specialties who may prescribe. There may be specialties that might identify that they should not be prescribing these products.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products. The guideline will consider who within this guidance should prescribe.

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			The guidance should be explicit that GPs should not prescribe these products and the prescribing should be the responsibility of specialist secondary or tertiary care services.(RP)	
General Medical Council	General	General	We are pleased that NICE is developing guidance on prescribing of cannabis-based products for medicinal use. In particular we welcome that the guideline will be in line with our guidance on prescribing unlicensed medicines in *Good practice in prescribing and managing medicines and devices.*	Thank you for your comment.
General Medical Council	General	General	We believe the draft scope should be clear that, as per the legislation, cannabis-based products for medicinal use (where they are a special medicinal product) are restricted to *use in accordance with a prescription or direction of a specialist medical practitioner.*	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products. The guideline will consider who within this guidance should prescribe.
The Brain Tumour Charity	General	General	There are several issues that it is unclear will be resolved by the current NICE scope consultation. Particularly, the definition of “cannabis-derived medicinal product” is unclear and abstract, and how this relates to the consideration of unlicensed treatment options. For patients to make an informed choice about treatment options and to have satisfactory access routes to medicinal products, clinicians need to have confidence in the first	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018.

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			instance to prescribe these medicinal products. This will only ensue if both patients and clinicians can easily understand what products are available.	
The Brain Tumour Charity	General	General	Related to Comment 2, if clinicians are to be confident in prescribing certain cannabis-derived medicinal products then this necessitates a potential need for significant support for prescribers. Since there is projected difficulty around the definitions of these products as well as licensing these products, clinicians may benefit from peer support or educational products that would help assist them in having the confidence to prescribe appropriate medicines for the appropriate conditions. Whilst NICE have noted the issue in the scope of this guideline, we believe it may be in the interests of NICE to make concerted efforts to provide this support and education in coalition with NHS England, other professionals bodies and patient groups.	Thank you for your comment. The guideline will consider individual treatment factors and support for both prescribers and patients (or their family members or carers). NICE does not provide educational tools to clinicians, however it is hoped that the recommendations will inform practice.
The Brain Tumour Charity	General	General	As reported by the Chief Medical Officer for England and the Chief Medical Officer to the UK Government in their report, there is a stronger evidence base for some indications in comparison to others. In addition to this, there exists a relatively small market share of any one product	Thank you for your comment.

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			meaning the financial incentives for full-randomised clinical trials for such products simply does not exist. Therefore, this presents a potential for a form of managed access schemes for cannabis-based medicinal products. This would gather evidence of the benefits and effectiveness of cannabis-based medicinal products in such an environment of controlled circumstances and confounding variables with strong data outcomes. We are glad that policy and regulation surrounding medical cannabis has mirrored that of public and patient demand. However, so quickly this policy development has arisen that there is not a solid evidence base behind it. We thus welcome an increase of research into cannabis-based medicinal products and NICE should take advantage of this opportunity by promoting some forms of managed access schemes in order to undertake this endeavour.	
Imperial College - International Association for the Study of Pain	General	General	• IASP is pleased to note that the scope will include assessment of safety and effectiveness in people with chronic pain and that it covers a broad age range.	Thank you for your comment.
Imperial College -	General	General	IASP is pleased to note that the potential for harm will be weighed up against the potential for benefit for individual patients and that the ACMD has identified several potential	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence

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International Association for the Study of Pain			risks relating to inappropriate prescribing and diversion of cannabis-based medicinal products, including increased risk of schizophrenia, respiratory symptoms, increased risk of road traffic accidents and heightened probability of substance abuse. It would be important to know how NICE propose to access and synthesise such evidence- since much of it relates to published evidence outside of the randomised controlled trial literature eg epidemiology.	reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline.
PresQUIPP	General	General	At present there is no pharmacopoeial standard for either a finished medicinal product containing a cannabis substance or substances, nor are there any pharmacopoeial standards for any of the active ingredients of cannabis such as cannabidiol (CBD). This could be seen as a fundamental flaw to providing evidence based guidance for what at present are mostly unregulated herbal products with unknown batch to batch variability. Therefore it is of utmost importance to provide clarity about the medicinal products that are or will be assessed for each indication. The guideline needs to specify where a pure CBD product such as Epidiolex is indicated/recommended and where a product containing a mixture of CBD and tetrahydrocannabinol (THC) is indicated/recommended. In the case of the latter, the guideline needs to specify the	Thank you for your comment. This guideline will consider the formulation of cannabis-based products.

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			purity of the product and the ratio of CBD to THC for each indication. NB Once pharmacopoeial standards become available, NICE guidelines may need to be reviewed in light of this and in light of any changes that may occur to previously assessed products if the specifications of those products changes to meet any new pharmacopoeial standard that comes in to force.	
Tilray	General	General	Broadly, we feel that the scope, and the NICE Pathway, should not restrict the guidelines to patients for whom other treatments have not been successful. From both a patient care and economic impact perspective, if cannabis-based medicines are beneficial to patients, they should be considered based on an evidence-based risk/benefit analysis to the patient. In its current form, the scope for the guidelines may not meet the government's objectives, as set out by the Home Secretary, that patients should have access to medicinal cannabis as deemed appropriate by their doctor. Such a restricted approach has been taken by those at the Royal College of Physicians and British Paediatric Neurology Association when developing interim guidance for cannabis-based medicinal products, which, in fact, resulted in very few patients being able to access cannabis-based medicinal products that have been shown to improve outcomes.	Thank you for your comment. As most cannabis-based medicinal products (except Sativex and nabilone) are unlicensed in the UK, this guideline will consider the use of cannabis-based medicinal products for the specified groups in line with the GCM's guidance on prescribing unlicensed medicines which states this is when other licensed medicines haven't helped or have been discounted.

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Tilray	General	General	We feel that the scope should indicate that NICE will take into consideration the full range of internationally available data, including patient outcome data not produced through randomised control trials.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline.
British Academy of Childhood Disability	General	General	BACD welcomes this guideline and are pleased that children are being given special consideration within it.	Thank you for your comment.
Make William Well	General	General	Given the extent to which NICE believes in clinical evidence, could not the prescription of cannabinoids for paediatric brain tumours, where all else has failed, form the basis for an adaptive clinical trial whereby the efficacy of cannabinoids could start to be determined and children, for once, aren't left languishing behind adults when it comes to the availability of treatment options…	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
NHS Surrey Downs CCG	General	General	Referring to medicinal cannabis by different nomenclature. It is important that the wording matches and is super clear, so everyone who refers to the guidelines knows exactly which drug is being referred to. For example; Sativex® is referred to as:	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will

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			• delta-9-tetrahydrocannabinol and cannabidiol in the manufacturer's Summary of Product Characteristics (SPC) - accessed 30/11/2018 • cannabidiol, dronabinol by the British National Formulary (BNF), but under the drug name of "Cannabis extract" -accessed 30/11/2018 • nabiximols (which is the United States Adopted Name (USAN), and not (Recommended) International Nonproprietary Name (rINN) - by the NICE scope document It would be best if the NICE guidelines used the rINN (if one is available) throughout the document when indicating Sativex. We understand that the GW Pharmaceuticals product expected for licensed use in 2019 will be licensed as Cannabidiol, although brand name is currently unknown.	also be included within the guideline. The scope has been amended to ensure consistency in the wording.
Nottinghamshire Healthcare NHS Foundation Trust	General	General	What are the grounds for not considering cancer treatment?	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
Nottinghamshire Healthcare NHS	General	General	Why aren't Sativex or synthetic cannabinoids being considered?	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out

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Foundation Trust				by the UK Government from November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
Multiple Sclerosis Society	General	General	There are issues of critical relevance to the use of cannabis-based medicinal products but where the responsibility for resolving them are not clear (i.e. whether they are in scope of the guideline, or if not, how they will be resolved). These include: 1. The definition of "cannabis-derived medicinal product" and how this relates to consideration of unlicensed treatment options. A recent letter from NHS England to clinicians (see here) specified the legal definition adopted by the Government and summarised the current licensing situation (no licensed options other than Sativex). In order for clinicians to have the necessary confidence to prescribe cannabis based products, and for patients to make an informed choice about	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline. We will not be considering illegal forms of cannabis or the issues associated with them.

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			treatment options, they need to understand what products are available. 2. The potential need for significant support for prescribers. Related to the above difficulty around definitions and licensing, many clinicians may feel that they would benefit from educational products and/or peer support in order to gain confidence in prescribing appropriately. As noted below we are pleased to see this issue in the scope of the guideline. However, there could be a strong case for a concerted educational and support effort from NICE, NHS England, relevant professional bodies and patient groups – of a scale and complexity that would not normally be required on the back of a NICE guideline. 3. The potential for a form of managed access scheme for cannabis-based medicinal products. We are aware that the evidence base for medicinal cannabis is stronger for some indications than for others, as indicated in the Chief Medical Officer for England and Chief Medical Advisor to the UK Government's report on the therapeutic and medicinal benefits of Cannabis based products. In addition, the financial incentives for full randomised	The guideline will consider individual treatment factors and support for both prescribers and patients (or their family members or carers). The guideline will consider individual monitoring requirements for cannabis-based medicinal products and the guideline committee will consider recommendations in this area. This guideline will consider the formulation and dosing of cannabis-based products. It is outside of the guideline's remit to define a managed access scheme for cannabis-based medicinal products.

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			clinical trials for such products do not exist due to the relatively small market share of any one product. One potential solution for some indications could be a managed access scheme to gather real-world evidence of the benefits of key cannabis-based medicinal products in controlled circumstances with strong data infrastructure. 4. The prevalence of illegal alternatives, including for recreational use. Unlike most other medicines, there is evidence that patients are accessing illegal forms of cannabis relatively often, often with significant risk as dosage, formulation and general safety of such products cannot be guaranteed. We also know there is misunderstanding among people with MS as to what is considered 'medicinal cannabis' as opposed to recreational cannabis, which compounds the issue. This means that there are law enforcement and patient safety considerations not present in a normal NICE guideline process. We believe that the NICE guideline would appropriately be developed in the context of a broader working group on patient access to cannabis-based medicinal products - comprising NICE, NHS England, MHRA, Home Office,	

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			Department of Health and Social Care, plus relevant patient and professional groups (for MS these would be at a minimum the MS Society and the Association of British Neurologists). This guideline will of course be of central importance to ensuring appropriate patient access, but it will only be successful if the issues outlined above are resolved in parallel.	
Multiple Sclerosis Society	General	General	As mentioned above, we are concerned that the interim clinical guidance commissioned by NHS England and produced by the Royal College of Physicians and the British Paediatric Neurology Association is very restrictive, effectively rolling back the progress made by the Home office, MHRA, ACMD and Dame Sally Davies, Chief Medical Officer for England. That is why it is important that this guideline considers the breadth of existing evidence on the effectiveness of cannabinoids for medicinal use.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline.
Royal College of Physicians	General	General	The RCP is grateful for the opportunity to respond to the above consultation. In doing so we would like to draw your attention to the RCP guidance on this subject . https://www.rcplondon.ac.uk/projects/outputs/recommendations-cannabis-based-products-medicinal-use . We have also liaised with experts in pain research, Rheumatology, Palliative Care, and with our Joint Speciality Committee for Clinical Pharmacology and Therapeutics and would like to make the following comments.	Thank you for your comment.

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Royal College of Physicians	General	General	Our experts note that this guidance will be important because the demand for these products is already high, even though they are not available in the usual way.	Thank you for your comment.
Royal College of Physicians	General	General	Our experts are pleased to note that the scope will include assessment of safety and effectiveness in people with chronic pain and that it covers a broad age range.	Thank you for your comment.
Royal College of Physicians	General	General	Our experts are pleased to note that the potential for harm will be weighed up against the potential for benefit for individual patients and that the ACMD has identified several potential risks relating to inappropriate prescribing and diversion of cannabis-based medicinal products, including increased risk of schizophrenia, respiratory symptoms, increased risk of road traffic accidents and heightened probability of substance abuse. It would be important to know how NICE propose to access and synthesise such evidence- since much of it relates to published evidence outside of the randomised controlled trial literature eg epidemiology.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline.
Royal College of Physicians	General	General	A guideline on Sativex®, in which NICE's 'Recommendation: Do not offer Sativex to treat spasticity in people with MS because it is not a cost effective treatment' [[Page 5/11, line 21] should not preclude the assessment of other cannabis-based products in the treatment or palliation	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.

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			of multiple sclerosis. However, MS is omitted from the list of 'Key areas that will be covered' in Section 3.3 [Page 5/11].	
Royal College of Physicians	General	General	The GMC guidance [Page 5/11, line 6] on the prescribing of unlicensed and off-label products is unclear and possibly wrong. [Br J Clin Pharmacol. 2017 Dec;83(12):2615-2625.] The NICE scoping document refers earlier to the authoritative guidance from MHRA [Page 1/11, line 27]. It would be prudent to use this source of guidance, especially since it may be in future that not all prescribers will be registered medical practitioners.	Thank you for your comment. The guideline will link to national advice about the prescribing of unlicensed and off-label use medicines.
Royal College of Physicians	General	General	Experts in rheumatology are concerned about the clarity and evidence for cannabis product use. Many patients have pain as a major element of their condition and analgesics are of limited use and effect. One of the things our rheumatology experts are concerned about is the major problem of patients with chronic pain syndromes, e.g. fibromyalgia. Most of these patients are managed in primary care and there are such huge numbers of these patients that any move to make such prescribing based in secondary care would be likely to overwhelm services. Our experts note that this will be difficult balance and is something which they are already being asked about frequently.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products.
Royal College of Physicians	General	General	Our experts in Palliative Care support the RCP position in relation to chemotherapy induced nausea and vomiting, as	Thank you for your comment.

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			an exceptional reserve option where people have failed standard anti emetics. Our experts in Palliative Care would not use in chronic pain post cancer treatment.	
Drug Science	General	General	Older people are being excluded throughout the whole document.	Thank you for your comment. Older people are included in the scope of this guideline.
Drug Science	General	General	It is concerning that the medical indications are limited to just 4 indications, although there is data on the clinical value of many more. Please see the recent report by the American Academy of Sciences: http://www.nationalacademies.org/hmd/Reports/2017/health-effects-of-cannabis-and-cannabinoids.aspx	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
Drug Science	General	General	It is important to expand the evidence base on C-BM at the same time as evaluating side-effects (p.8 lines 23-32) and monitoring their effectiveness and safety (p. 9 lines 1-12). RCTs and monitoring of ongoing clinical practise are necessary. Will other forms of research also be facilitated? For instance, experimental medicine studies of C-BMs in pain? Being comprehensive in the forms of research carried out will enhance future C-BM development.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline.
Drug Science	General	General	The draft scope refers to C-BM as a whole. Cannabis contains around 100 unique ingredients (i.e. cannabinoids) so there could theoretically be a plethora of different types of C-BMs. Currently only THC and CBD (cannabidiol) are used in cannabinoid medicines, such as Sativex, Epidiolex	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to

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			and Dronabinol. How will the prescription of C-BMs take account of the many different varieties of cannabis?	naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline. This guideline will consider the formulation of cannabis-based products.
Drug Science	General	General	How will the varieties that can be prescribed be selected so as to minimise side effects and risks of tolerance to and dependence on cannabis? For example, will THC be limited to a maximum percentages (e.g. 12%)in chronic pain? In spasticity, what ration range of CBD:THC will be recommended? In epilepsy, CBD is indicated- what dose range will be recommended of CBD and what maximum level of THC (e.g. 1% or 2%) in these C-BMs?	Thank you for your comment. This guideline will consider the formulation and dosing of cannabis-based products.
Drug Science	General	General	NICE needs to find a way to acknowledge that CBMs may not work for everyone but that in some cases they do work well. This was a failure in the review of Sativex. In real life, a clinician should not prescribe C-BMs (or any other medicines) if they were ineffective. So the appropriate cost-effectiveness calculation is to compare the cost of C-BMs in cases where they are clinically effective with the cost of the alternative in those cases where it is clinically effective.	Thank you for your comment. The guideline committee will consider the effectiveness of cannabis-based products for the indications included within the scope when making recommendations.

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Pfizer UK	General	General	We recognise that the clinical areas identified for focused consideration within this guideline are areas of known unmet need for patients where additional medicinal products and/or therapies have the potential to significantly enhance patients' care and quality of life. We support the development of this guidance using the methods and processes outlined in developing NICE guidelines manual as a way to support considered use of cannabis-based products for medicinal use within the NHS and fully agree that close alignment to related NICE guidance, published or in development, should be maintained.	Thank you for your comment.
The Cure Parkinson's Trust	General	General	If the evidence of the efficacy and safety of these Products is to be collected thought is needed on the requirements for monitoring and reporting outcomes.	The guideline will consider individual monitoring requirements for cannabis-based medicinal products and the guideline committee will consider recommendations in this area.
The Cure Parkinson's Trust	General	General	Patience advocacy groups have a wealth of relevant observational data that could help to inform the more evidence based use of cannabis derived products.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline.
The Cure Parkinson's Trust	General	General	It might be worthwhile considering the introduction of a database register for prescribers in collaboration with a charity already set up to facilitate it and add to current knowledge.	The guideline will consider individual monitoring requirements for cannabis-based medicinal products and the guideline committee will consider recommendations in this area.

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The Cure Parkinson's Trust	General	General	This Guidance needs to be developed in conjunction with the British National Formulary as this will be the source to which Prescribers will wish to turn in selecting defined products.	Thank you for your comment. We will contact the British National Formulary if the guideline is intending to recommend any off-label treatments.
The Cure Parkinson's Trust	General	General	Scope of conditions – whilst the symptoms listed are totally appropriate and should remain general and not necessarily linked to any one diagnosed condition (e.g. MS) thus allowing suitable flexibility for Prescribers we would like to add a few points specific to Parkinson's disease: Although the evidence is as yet equivocal, cannabis-based products might be of benefit for motor and non-motor symptoms of Parkinson's and some of these represent an unmet treatment need – particularly tremor, pain, sleep and anxiety. The Guideline should direct Prescribers to appropriate sources of evidence and encourage further investigation in this field, the collection of outcomes when such products are prescribed and the conduct of more patient surveys to enhance the knowledge base.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
British Pain Society	General	General	The BPS agrees with the need for a guideline for the clinical use of cannabis medications and that this should include the treatment of chronic pain. This is because our members are aware of the uncertainty and pressure from their	Thank you for your comment. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-

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			patients, politicians and the media regarding the use of cannabis for chronic pain. Clear guidance from NICE will assist in avoiding a similar situation as currently exists with opioids and avoid unnecessary cost pressures and adverse clinical and societal consequences of more widespread use. However, we are concerned that the scope specifically excludes the clinical use of Nabiximols (Sativex) and other clinically available cannabinioids eg dronabinol and nabilone because there is considerable and often quoted literature covering the use of these medications for chronic pain, which needs to be explored and analysed. (The fact that Sativex was included for consideration in the NICE guidelines on multiple sclerosis should not exclude its consideration in the current guideline for chronic pain).	tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline.
Spectrum Cannabis	General	General	Canada's experience can offer a five-year view of what cannabis access looks like in a social healthcare system and should be taken into consideration while developing your guidelines. Spectrum Cannabis would encourage a thorough examination of data from Canada, or present the Canadian data as a reference for the development of these guidelines.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline.
The Neurological Alliance	General	General	The evidence base for medicinal cannabis is stronger for some indications than for others. There is a significant need for further research into cannabis-based medicinal products, and their use to alleviate different	Thank you for your comment. The guideline committee will be able to make research recommendations where appropriate as described in Developing NICE guidelines: the manual.

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			conditions/symptoms. This guideline should take the opportunity to recommend further research is undertaken. Whether a managed access scheme, to gather real-world evidence of the benefits of key cannabis-based medicinal products in controlled circumstances with strong data infrastructure, would be appropriate should be considered.	
The Neurological Alliance	General	General	The publicity relating to the Home Office's decision to deregulate cannabis for medicinal use has been such that it is likely there will be a significant public expectation that people with be able to take these products going forward. Moreover anecdotal evidence suggests both that misunderstanding among people with neurological conditions as to what is considered 'medicinal cannabis' as opposed to recreational cannabis, We are aware of reports of people with neurological conditions approaching their GP or neurologist about cannabis, which indicates misinformation and confusion about what the change in the law means. Therefore, there is a need for communications relating to this guideline to be strategic and carefully considered. If it is expected that the group who will be eligible to be prescribed these products is actually rather small, as is suggested y the current guideline scope, there is a significant need for careful management of patient and public expectations.	Thank you for your comment

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The Neurological Alliance	General	General	Unlike other medicines, we know that patients are accessing illegal forms of cannabis relatively often. Obviously, the safety of such products cannot be guaranteed. And as already mentioned, there is anecdotal evidence of misunderstanding amongst people with neurological conditions as to what is considered 'medicinal cannabis' as opposed to recreational cannabis. So, there are both legal issues and patient safety issues not present in a typical NICE guideline process. For this reason we suggest that this guideline merits an addition to the normal processes – namely, a broader working group on patient access to cannabis-based medicinal products, to provide expert input to help develop the guideline. This group should include patients/patient organisations.	Thank you for your comment. We believe there is sufficient expertise within the guideline committee to consider the areas within the scope of the guideline. The guideline will consider the use of cannabis-based products as set out by the UK Government from November 2018, we will not be considering illegal forms of cannabis or the issues associated with them.
University College London Hospitals NHS Foundation Trust	General	General	Firstly we commend NICE for responding to this issue in such a timely and prompt manner. Having guidance published will be extremely helpful for practitioners.	Thank you for your comment.
University College London Hospitals NHS Foundation Trust	General	General	Essentially this guideline is a matter of patient safety. Sativex is not only licensed for MS related spasticity but is classified by the MRHA as a Schedule 4 drug (medications with low potential for abuse and accepted for medical use). Non-licensed cannabis-based products are classified as Schedule 2 (high potential for abuse, sometimes accepted for medical use with severe restrictions). In our view it	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.

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			would be unethical to consider the use of a schedule 2 unlicensed drug when there is a licensed safer alternative available. For this reason Sativex has to be included in this guideline, not only for MS related spasticity but also for chronic pain.	
Fibromyalgia Action UK	General	General	We have a general comment about definitions and terms used within the draft scope. We feel there is a clear distinction between "cannabis-based medicinal products" (which is what the guidance will be about) vs "synthetic cannabinoids" and "cannabis-based products" (which are "out of scope"). We suspect there are reasons for this (which should be explained), but it strikes us as important to firstly very clearly clarify what the differences are in the document. The inclusion of a glossary that clearly states how each of these are defined would be favourable and then it would be advantageous to include a section where the reason why synthetic cannabinoids and cannabis-based products are not "in scope" are explained fully. We feel this is important to be covered partly in terms of completion, but also because there's a huge potential for confusion on the side of patients - particularly between "cannabis-based medicinal products" and "cannabis-based products", the latter of which refers to so called food supplements, vitamins and so on. Ultimately, we can see	Thank you for your comment. The guideline will consider the use of cannabis-based products as set out by the UK Government from November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.

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			this confusion being a potential source of exploitation by manufacturers of cannabis-based products like these.	
Fibromyalgia Action UK	General	General	During our consultation with some members of the fibromyalgia community, it was observed that the guidelines do not necessarily acknowledge potential future use of cannabis-based products within society (for example, in the workplace), since prescribed use may contradict policies enforced by employers, hence why some clarification and guidance for other relevant stakeholders could be useful.	Thank you for your comment. The focus of this guideline is on the effectiveness of cannabis-based medicinal products, therefore it would not be appropriate for NICE to advise about workplace policies with respect to the use of cannabis-based medicinal products.
Fibromyalgia Action UK	General	General	During our consultation with some members of the fibromyalgia community, misconceptions/myths about cannabis-based products within the scope were commented on, with some people feeling it was unclear who may be excluded from being prescribed cannabis-based products. It was felt as though the 'who, what, where, when and why' were not adequately covered in an explicit manner.	Thank you for your comment. This guideline will consider the use of cannabis-based products for people, regardless of the condition, with chronic pain, intractable nausea and vomiting, spasticity and severe treatment-resistant epilepsy.
Fibromyalgia Action UK	General	General	During our consultation with some members of the fibromyalgia community, people felt that the scope should include some reference to patient-centred shared decision making. For example, reserving cannabis-based treatments as a late line approach contradicts statements about compelling evidence of the benefits of cannabis-based products. Individuals felt that patients should have an active say in which treatments they would prefer, based on the	Thank you for your comment. The guideline will consider individual treatment factors and support for both prescribers and patients (or their family members or carers). NICE is also currently developing a guideline on shared decision making.

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			risk/benefit analysis of each, which these scope guidelines don't necessarily emphasise.	
Multiple Sclerosis Trust	General	General	The Multiple Sclerosis Trust welcomes the development of this guideline. Access to cannabis-based medicines is a frequent subject of enquiries taken by the information team at the MS Trust; feedback from MS specialist nurses and neurologists confirms that access to cannabis-based medicines is also a regular topic of discussion in clinics. Turning down requests for treatment has a damaging effect on relationships between health professionals and patients and takes up valuable clinic time. This guideline provides an excellent opportunity to equip health professionals with objective, evidence-based resources to help them communicate eligibility for access to these treatments. As the leading provider of education and training to MS specialist health professionals, we would welcome the opportunity to support the development of such resources.	Thank you for your comments.
Multiple Sclerosis Trust	General	General	The definition drawn up for rescheduling of cannabis-based medicinal products should not be used to limit the scope of cannabis-based medicines to be covered by this guideline. There is already a great deal of confusion and misconceptions about cannabis-based medicines; this guideline represents an opportunity to draw together, in a single document, evidence for the full range of cannabis-	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-

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			based products and provide clarity for health professionals, patients and members of the public. We cover this in more detail in comment 7.	tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline.
Multiple Sclerosis Trust	General	General	Nabiximols (Sativex) is a cannabis-based product licensed for treatment-resistant spasticity for people with multiple sclerosis (MS). For reasons of cost effectiveness, it is not approved for NHS use in England, Scotland and Northern Ireland, although it is considered cost effective and approved for prescribing by the NHS in Wales. While it is possible to be prescribed nabiximols privately, in practice the cost of the treatment makes this impossible for the vast majority of people with MS, particularly those on limited income or who are unable to work. We hear from people who are facing real economic hardship in order to fund the cost of nabiximols for themselves or a member of their family. These are the issues that people are facing in order to access a licensed cannabis-based treatment. In contrast to almost all other medicines, those who are unable to access licenced cannabis-based medicinal products may resort to sourcing illegal cannabis, with all the associated risks. We know that limited access to nabiximols has influenced some people with MS to source cannabis in other ways and this is what troubles us most.	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.

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Multiple Sclerosis Trust	General	General	We recognise that there is a limited body of evidence for the medicinal use of cannabis and cannabis-based medicinal products. As part of the bigger project around medicinal cannabis, which is being developed by the Department for Health & Social Care, the National Institute for Health Research is co-ordinating and supporting a programme of clinical trials to establish a credible evidence base for short and long-term safety and clinical indications. We welcome further research in this area and anticipate that the guideline will highlight areas where additional clinical trials are needed.	Thank you for your comment.
Barts Health NHS Trust	General	General	Sativex needs to be included in this review as the only licensed cannabis based medicinal product for spasticity	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.
Barts Health NHS Trust	General	General	The cost of the many unlicensed medication is unknown or difficult to ascertain for consistency and so different methodology than normally used by NICE should be considered including listing recommendations for audits and research to allow review in the near future once licenses may be gained.	Thank you for your comment. We recognise that obtaining unit costs in this area will be more challenging than is usually the case in economic evaluations conducted for NICE guidelines. We will endeavour to obtain costs that most appropriately reflect the acquisition cost and various cost-consequences associated with cannabis based products.
Barts Health NHS Trust	General	General	Discussions without patients groups must be had to ensure that the illegal use of non-medicinal marijuana is not seen as an the only option for patients	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which

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				included guidance on who is able to prescribe cannabis-based medicinal products.
Brain Tumour Research	General	General	In its current form, the draft scope is unclear as to whether cannabis-based products will be made available to people experiencing chronic pain and/or intractable nausea and vomiting as a result of cancer symptoms or treatment (including and excluding chemotherapy). The symptoms of a brain tumour can be debilitating and incredibly painful and the effects of treatment can be severe and difficult to manage. With so few treatment options available for brain tumours (temozolomide, the chemotherapy drug used to treat high grade gliomas, was approved in 2007 and there have been no brain tumour treatment approved since), patients are eager to explore alternative options and many do so, seeking out cannabis-based products often via unofficial routes. In view of this, cannabis-based products should be considered an option when established treatment options have been exhausted. There is limited research available on the effect of cannabis-based products to treat brain tumours, although there are related trials taking place, for example two of Brain Tumour Research's Member Charities (Astro Brain Tumour Fund and Children's Brain Tumour Research Centre at the University of Nottingham) have combined forces to launch a study into the clinical effects of	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited. The guideline will consider the use of cannabis-based medicinal products in chronic pain and intractable nausea and vomiting including when those are symptoms of cancer. However we will not be looking at cannabis-based medicinal products specifically for the treatment of brain tumours.

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			cannabidiol (CBD) on child brain tumours. As such, as the only UK charity dedicated to funding continuous and sustainable scientific research into brain tumours, we believe that by including explicit reference to use of cannabis-based products for cancer symptoms and effects, this would provide the basis for further research into cannabis-based products for the treatment of brain tumours, especially within adaptive clinical trials – thus reducing the appeal for patients to seek out unauthorised cannabis-based products, which are not then used in a controlled and prescribed manner. Our advisors say there is evidence that the use of cannabis-based products does benefit brain tumour patients who are suffering with headaches and in the control of seizures. Furthermore, for some brain tumour patients who are taking a cocktail of drugs, which can have problematic side effects, they would be able to reduce their intake of those drugs and use cannabis-based products instead, which are less toxic. This could result in a better quality of life and allow brain tumour patients to live well with cancer.	
Brain Tumour Research	General	General	We feel there needs to be clarity about who will be allowed to prescribe and how individual trusts will make that decision.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which

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				included guidance on who is able to prescribe cannabis-based medicinal products. The guideline will consider who within this guidance should prescribe.
Royal College of Paediatrics and Child Health	General	General	Cannabis based derivatives have a wide scope of use. Further evaluation and developments of related products should be encouraged.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
Royal College of Paediatrics and Child Health	General	General	The CBD products should be used under circumstances where routine medications have not achieved the desired benefit/relief e.g. spasticity related with MS, attentional problem e.g. related with ADHD in adults, and for chronic pain. CBD products should remain schedule 2 drugs for now, so only specialist registered clinicians should be able to prescribe so that supervision may be possible.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products. The guideline will consider who within this guidance should prescribe.
Neurology Academy Ltd	General	General	A published NICE guidance on this topic will be helpful for healthcare professionals and the general public.It is important the scope is sufficiently focussed to allow the committee in a relatively short time to formulate useful guidance. However, excluding synthetic cannabinoidsmedications (eg Nabilone) from the reviewmay be short-sighted given their increasing abuse potential. We would also urge you to include the only licensed cannabis-based medicationSativex as part of the scope. Sativex has a UKlicense for the treatment of	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018, this includes who is able to prescribe cannabis-based medicinal products. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline.

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			multiple sclerosis-relatedspasticity, which is an indication that thisscope will cover.Questions 1.1-1.4 are relevant to spasticity. However, surelythe results need to be compared to Sativex, the only licensed nabixol? How can NICE potentially recommendnon-licensed cannabis-basedformulationswithout considering alicensed product first? Surely, all cannabis-based formulations need to held to the same standards as licensed medicinal products? The latter has relevance to Question 2.2.; making recommendations about cannabis-based formulations should include information about Sativex? If not healthcare professionals, patient groups, patients and their families will raise queries.	
Association of British Neurologists	General	General	The neurorehabilitation community main concern is that NICE will only consider the schedule 2 products and not review Sativex or other agents., given that Sativex is available in Wales. The NICE consultation should also review Sativex if possible.	Thank you for your comment. Following stakeholder comments Sativex will also be included within the guideline.
Association of British Neurologists	General	General	There is very limited evidence (ie. only a few small studies) reporting the use of cannabis-based products in movement disorders. The inclusion of movement disorders in the NICE review of cannabis-based products, might be helpful (both to discourage open label use, and to encourage clinical trial evaluation).	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.

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Association of British Neurologists	General	General	Re epilepsy - Published evidence for efficacy is currently only in Dravet Syndrome and Lennox-Gastaut Syndromes. Cases need to be carefully diagnosed in specialist centres. For these conditions prescriptions should only be for cannabidiol. Use in these syndromes is subject to several requirements, as helpfully summarised by the BPNA interim guidelines which the ABN would strongly advise consulting. The ABN anticipate that there is likely to be pressure for prescription of cannabis-based products for other severe epilepsies. However, there is either no or very little evidence for benefit in other forms of epilepsies. In view of this the ABN would advise extreme caution if these products are being considered for any other form of epilepsy at this time, but support the NICE process to review this in case any other evidence comes to light.	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline.
Association of British Neurologists	General	General	The use of cannabis based products for neuropathic pain should be under the remit of a specialist pain clinic, not a general neurology clinic	Thank you for your comment. The guideline will consider the prescribing requirements for cannabis-based medicinal products.
Association of British Neurologists	General	General	There is no evidence that cannabis should be used for primary headache conditions	Thank you for your comment.
Association of British Neurologists	General	General	Comments on use in chronic pain - As the benefits, especially long term, are not established, then in view of known risks, use of cannabinoids should only be where non-opioid strategies have failed and opioids are otherwise being considered. Evidence cited in recent (October 2018)	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published

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			Royal College of Physicians guidance shows that while weak evidence of benefit exists, it is balanced by risks, and long-term risk/benefit ratio is unknown and may be unfavourable. As the long term risks of serious adverse events with opioids is probably greater than for cannabinoids, their use could be justified in the above setting with appropriate monitoring by a pain physician.	evidence which meet the review protocols developed for the guideline.
InHealth Pain Management Solutions	General	General	We welcome the development of this guideline. As an NHS community pain service provider we have already been experiencing patient demand for access to cannabis medication from chronic pain patients and we would welcome a review of the evidence for the use of cannabis in Persistent pain management.	Thank you for your comment.
International Brain Tumour Alliance (IBTA)	General	General	GENERAL COMMENTS: As mentioned, we would like to see confirmation in the Guideline Scope regarding the specific types of diseases, such as cancer, which are being considered as relevant to potential cannabis-based treatment, and which would specifically include brain cancer. We are aware that there are already established routes for patients to access cannabis-based medicinal products. We note that this access is overseen by specialist medical practitioners who are required to be on the General Medical Council's register and that decisions to supply patients with cannabis-based products are made on a case-by-case basis to help meet unmet need when there are no suitable licensed products available. We believe it would	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited. The scope includes a link to the GMC's guidance on prescribing off label medicines. The guideline will consider individual monitoring requirements for cannabis-based medicinal products and

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			be useful for the Guideline Scope to include this information. Brain cancer patients – particularly those who have exhausted all other treatment possibilities – should be allowed to make informed choices from all of the options which might be available. In consultation with their specialist and fully aware of potential side effects, brain cancer patients should have as wide a field of treatments as possible from which to receive potential benefit. Wider access to cannabis-based products for medicinal use, carefully controlled and monitored by specialist healthcare professionals, duly registered at the GMC, could also provide real world evidence of the efficacy (or not) of cannabis-based products to better inform future use. We would also strongly support national data collection on prescribing of cannabis-based products for medicinal use, both in the NHS and private sector. Such a registry could greatly support future research into this treatment approach as well as providing a detailed assessment of patient outcomes which will assist with issues of patient safety and better understanding of the use of cannabis-based medicinal products in the future. Side effects from the use of cannabis-based medicinal products as an off-label	the guideline committee will consider recommendations in this area.

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			therapy should also be reported to the MHRA's Yellow Card Scheme.	
Young Epilepsy	General	General	The draft scope appears to cover the key issues related to the prescribing of cannabis-based medicinal products for the treatment of severe treatment-resistant epilepsy.	Thank you for your comment.
SUDEP Action	General	General	There is available evidence from other countries (in particular Australia and the US) where cannabis-based medication has been made available to patients with epilepsy, showing significant lessons could be learned, particularly regarding the implementation of guidelines. doi: 10.5694/mja17.01247 http://dx.doi.org/10.1016/j.yebeh.2017.02.005 http://dx.doi.org/10.1136/bmjopen-2018-022101 It may also prove important to consider what lessons could be learnt from previous medication scandals such as Soduim Valporate for epilepsy and how this could inform guidance and information produced for this medication. It is also worth considering how to mitigate risks of patients already taking illicitly accessed cannabis, and where information regarding this will be acknowledged in the guideline and public information. Patients may be reluctant to discuss this usage for fear it will be stopped, however	Thank you for your comment. The development of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. If the evidence you refer to meets the review protocol, this will be considered by the guideline committee during the development of the guideline.

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			substance misuse is a risk factor for epilepsy mortality, as flagged in the SUDEP and Seizure Safety Checklist, so should be something taken into account: https://doi.org/10.1016/j.seizure.2014.02.005 ; https://doi.org/10.1111/ene.13651 and doi: [10.3399/bjgp11X572463]	
Advisory Council on the Misuse of Drugs	General	General	Thank you for your e-mail of 13 November 2018 which offered the opportunity to comment on the draft scope for the NICE guideline on cannabis-based medicinal products (CBMPs).1 As referred to in Section 1 of the draft, the Advisory Council on the Misuse of Drugs (ACMD) recently published advice on CBMPs.2 The ACMD expect to receive a further ministerial commission shortly, setting out the scope of the ACMD's longer term review of CBMPs. We would like to offer comments on some of the gaps and challenges which seem relevant to the development of the NICE guideline.	Thank you for your comments.
Families 4 Access	General	General	We recommend adding a chapter dealing with means to control or prevent the hazard of abuse or trafficking of the products.	Thank you for your comment. This is outside of NICE's remit to make recommendations in this area.
Families 4 Access	General	General	We feel that guidelines should also be provided with regards to packaging or shipping methodologies. These are relevant both in order to preserve product quality and avoid misuse by children or minors.	Thank you for your comment. This is outside of NICE's remit to make recommendations in this area.

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Families 4 Access	General	General	The means of administration, bioavailability and efficacy is known to directly affect the amount of cannabis required to achieve a given clinical effect. Monitoring using advanced technologies & a metered dose delivery system can also increase adherence and reduce the hazard of intentional and unintentional abuse, thereby reducing costs of adverse events and policing.	Thank you for your comment. The route of administration, dosing and individual monitoring requirements will be considered by the guideline committee.
Families 4 Access	General	General	Any means of administration should be delivered in such a way that physicians and patients can clearly understand and measure what is being prescribed and delivered and guaranty precise absorption.	Thank you for your comment.
Thames Hospice	Gerera l	General	No mention of use of cannabis products for management of pain or other symptms in chronic malignant pain – consider use in palliative care	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
Families 4 Access	Gerera l	General	We still need to better define what CBMP's are and how do we classify/group them? By THC/CBD ratio? By condition? By strength? What? UPA Propose that all CBMPs up to a predetermined THC/CBD ratio/strength be subject to the same "safety profile" with CBMPs of a higher ratio/strength an alternative safety profile? Our proposal would come into	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. This guideline will consider the formulation of cannabis-based products.

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			line with latest UK research being done currently by UCL under Professor Val Curran. THC > 15% and/or CBD < 4%.	
Families 4 Access	Gererа l	Gener al	Would it be better to not limit the labelling to just CBD/THC? Whilst we lack the evidence, we already know that other cannabinoids are clinically important and we may benefit from their inclusion. Patients already do benefit from this information. (CBN/CBG/CBC/THCa/THCV/etc.…)	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. This guideline will consider the formulation of cannabis-based products.
Families 4 Access	Gererа l	Gener al	In most cases of “specials” prescribing, after the consultant or specialist does the first prescription, GPs can then supervise and repeat? Why should this be any different? Can we look at this?	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products. The guideline will consider who within this guidance should prescribe.
Families 4 Access	Gererа l	Gener al	UPA believe that whilst it is right and appropriate best practices, the introduction of this new classification of medicines should be done with specialists first, we have also never introduced a medicine that has been used by many 100s of 1000s of patients for many decades already and as such, patients have the expertise in the consumption, methods, forms, dosing and titration of cannabis and allowing GPs to prescribe at the earliest possibility would encourage a better therapeutic relationship between patients and doctors and help to share knowledge	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products. The guideline will consider who within this guidance should prescribe.

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			more efficiently, ultimately leading to much better outcomes for patients and doctors alike.	
Families 4 Access	Gerera l	Gener al	The scope suggests that these guidelines are for specialists only. Since the policy restricts prescribing already, this is unnecessary and since it is envisaged that prescribing authority will be broadened on due course, should they not be generic guidelines and not defined as limited to specialists?	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products. The guideline will consider who within this guidance should prescribe.
Families 4 Access	Gerera l	Gener al	Where (in public) can someone consume/vape their CBPM?	Thank you for your comment. It is outside NICE's remit to state where cannabis-based products can be consumed.
Families 4 Access	Gerera l	Gener al	There are Ethnic and Cultural aspects of stigma and attitudes towards cannabis that maybe helpful to highlight in order to help address them - Especially with regards to prescribers?	Thank you for your comment religion and belief has been considered in the guideline equality impact assessment form and specific recommendations to support people who have concerns about taking cannabis-based products due to their religion or belief may need to be made to address this.
Families 4 Access	Gerera l	Gener al	We believe that it would be of benefit to write some "guidance" around this "Guidance" both to help set some context which is unique to CBMPs and also to highlight that they should be used to inform only and that the final decision to prescribe is a clinical one. "It is possible/likely that any patient presenting as someone who currently consumes black market cannabis to return directly to this	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. This guideline will consider the formulation of cannabis-based products, we will not be considering illegal forms of cannabis or the issues associated with them.

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			market for their substandard medicine if they cannot be prescribed a standardised, quality controlled CBMP under the supervision of their medical team. This should be considered as part of any clinical decision.	
Families 4 Access	General	General	A private prescription has already been written relating to the symptom of “Pain” where the primary condition is Fibromyalgia. Can this “utilisation” be noted within the guidelines and expand to all "rheumatic diseases"? Fibromyalgia is a common one but lupus and other autoimmune diseases also are common and especially in other less common demographics.	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited.
British Association for Psychopharmacology	General	General	It is clear that only specialists on the GMC Specialist Register can prescribe it. Though, being a specialist on the GMC specialist register does not guarantee the necessary knowledge for issuing an adequate and safe prescription. It is important to explain who takes responsibility for the training of the possible prescribers of cannabis-based products.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as set out by the UK Government from November 2018 which included guidance on who is able to prescribe cannabis-based medicinal products. The guideline will consider who within this guidance should prescribe. The guideline will also consider individual treatment factors and support for both prescribers and patients (or their family members or carers).
British Association for	General	General	The Royal College of Physician recently gave that statement that there are not enough evidence for the efficacy of cannabis based product for pain relief. This	Thank you for your comment. NICE is aware of the recent statement from the RCP. The NICE guideline will consider the clinical and cost effectiveness of cannabis-based

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Psychopharmacology			followed from a review on the topic by Professor Andrew Rice, Professor of Pain Research, Department of Surgery and Cancer, Imperial College and lead of the IASP Cannabinoid Task Force.	products for medicinal use for people with chronic pain. The guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. If the evidence you refer to meets the review protocol, this will be considered by the guideline committee during development of the guideline. The committee will use its judgement to decide what the evidence means in the context of the guideline referral and decide what recommendations can be made to practitioners, commissioners of services and others.
British Association for Psychopharmacology	General	General	I am concerned about the lack of clear data/evidence on the exact composition, proportion of cannabinoids, that each possible medicinal preparation should contained. Therefore I am not clear how safety and efficacy are going to be determined as both depend greatly from this.	Thank you for your comment. This guideline will consider the formulation of cannabis-based products. The guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The committee will use its judgement to decide what the evidence means in the context of the guideline referral and decide what recommendations can be made to practitioners, commissioners of services and others.

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British Association for Psychopharmacology	General	General	I wonder if a clearer reference should be made to any possible restrictions or caution when prescribing to: a) Individuals that also declare recreational cannabis use or if this should be take into account anyway when recommending doses; b) individuals with a diagnosis and/or family history of schizophrenia spectrum disorders ; c) individuals with pre-existing respiratory conditions though not clear about the evidence for the latter.	Thank you for your comment. The guideline will consider the areas described in the draft question which includes potential side effects and interactions and support for prescribers and people being prescribed cannabis-based products.
British Association for Psychopharmacology	4	15	I am not clear why the elderly are excluded from the potential beneficiary group of patients as likely to also suffer from the conditions these compounds are indicated for. Moreover, the evidence for instance on the potential harm to Mental Health are stronger for younger people rather than the elderly.	Thank you for your comment. Following stakeholder comments the scope has been amended to include specific consideration for older people.
British Association for Psychopharmacology	1	27	The text refers in the context of cannabis based product to the marketing authorisation or product licence and its regulations, which redefines a medicine's terms of use: its summary of product characteristics outlines, among other things, the indication(s), recommended dose(s), contraindications, and special warnings and precautions for use on which the licence is based. My concerns, are the existing lack of data and clarity on the "recommended dose(s), contraindications, and special warnings and	Thank you for your comment. This guideline will consider the formulation of cannabis-based products and the dose of cannabis-based products. It will address particular questions looking at the individual patient monitoring requirements, treatment durations, reviewing and stopping criteria, and also the support needed to help prescribers

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			precautions for use" of cannabis based medicines which makes it difficult for doctors to consistently and safely prescribe them. Before issuing NICE guidelines, shouldn't be clarify these potentially wide range of cannabis products "terms of use"	and patients (or their family members or carers) make decisions about cannabis-based medicinal products. The guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The committee will use its judgement to decide what the evidence means in the context of the guideline referral and decide what recommendations can be made to practitioners, commissioners of services and others.
British Association for Psychopharmacology	9	23	It would be useful to identify key evidence gaps and make recommendations for research	Thank you for your comment. The guideline committee will be able to make research recommendations, where appropriate as described in Developing NICE guidelines: the manual, for the 4 indications being considered within the guideline.
British Association for Psychopharmacology	General	General	My major concern is why they have limited the medical indications to just 4 – when there is data on clinical value in many more – see the American Academy of Sciences report	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a

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			http://www.nationalacademies.org/hmd/Reports/2017/health-effects-of-cannabis-and-cannabinoids.aspx	timely fashion the number of indications being considered has had to be limited.
British Association for Psychopharmacology	5	8-11	The draft scope defines 4 indications for cannabis-based medicines (C-BM) throughout this document. There will inevitably be demand from patients with other conditions. Two questions therefore: How might this list of 4 be extended on the basis of future evidence? Will RCTS be facilitated on other indications as well as these 4?	Thank you for your comment. NICE acknowledges that only 4 indications are being considered in the guideline and therefore there are other indications that are not being considered. To ensure the guideline can be produced in a timely fashion the number of indications being considered has had to be limited. The guideline will be developed following the processes described in Developing NICE guidelines: the manual, for the 4 indications being considered within the guideline. However the guideline committee will not able to make recommendations for indications that are outside of the scope of this guideline.
British Association for Psychopharmacology	general	general	It is important that we expand the evidence base on C-BM at the same time as evaluating side-effects (page 8 lines 23-32) and monitoring their effectiveness and safety (page 9 lines 1-12). RCTs and monitoring of ongoing clinical practice are necessary. Will other forms of research also be facilitated? For example, experimental medicine studies of C-BMs in pain? Being comprehensive in the forms of research carried out will enhance future C-BM development.	Thank you for your comment. The guideline will consider the areas described in the draft question which includes potential side effects and interactions and support for prescribers and people being prescribed cannabis-based products. The guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The committee will

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				use its judgement to decide what the evidence means in the context of the guideline referral and decide what recommendations can be made to practitioners, commissioners of services and others. The guideline committee will be able to make research recommendations, where appropriate as described in Developing NICE guidelines: the manual, for the 4 indications being considered within the guideline.
British Association for Psychopharmacology	general	general	The draft scope refers to C-BMs as a whole. Cannabis contains around 100 unique ingredients we call cannabinoids so there could theoretically be a plethora of different types of C-BMs. Currently only THC and CBD (cannabidiol) are used in current cannabinoid medicines like Sativex, Epidiolex and Dronabinol. How will the prescription of C-BMs take account of the many different varieties of cannabis?	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
British Association for Psychopharmacology	general	general	How will the varieties that can be prescribed be selected so as to minimise side-effects and risks of tolerance to and dependence on cannabis? For example, will THC be limited to a maximum percentage (e.g. 12%) in chronic pain? In spasticity, what ratio range of CBD:THC will be	Thank you for your comment. The guideline will consider the areas described in the draft question which includes potential side effects and interactions and the dose of cannabis-based products.

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			recommended? In epilepsy, CBD is indicated – what dose range will be recommended of CBD and what maximum level of THC (e.g.1 or 2%) in these C-BMs?	
British Association for Psychopharmacology	3	5-6	I was unclear why 'cannabinol or a cannabinol derivative' was referred to here. Is this a typographical error? Cannabinoid or cannabinoid derivative would make much more sense.	Thank you for your comment. This is a quote describing the UK Government requirements therefore we are unable to amend this text.
British Association for Psychopharmacology	General	General	Most specialists on the GMC specialist register do not have any expertise in prescribing cannabis-based products. It will be important to provide training in this so as to avoid inappropriate or dangerous prescription.	Thank you for your comment. The guideline will consider individual treatment factors and support for both prescribers and patients (or their family members or carers).
British Association for Psychopharmacology	General	General	Mention should be made of the importance of the drugs to be prescribed being of known composition, in particular the concentration of THC and the THC/CBD ratio. There should be detailed recommendations on doses to be used, contraindications, and special warnings and precautions. The lack of these will make it difficult for doctors to safely prescribe cannabis-based products.	Thank you for your comment. The guideline will consider the areas described in the draft question which includes potential side effects and interactions and the formulation of cannabis-based products.

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British Association for Psychopharmacology	General	General	It is important that "medicinal cannabis" does not degenerate into a cover for "recreational cannabis", as has happened in a number of US States. The US experience has been that a small proportion of unscrupulous doctors in private practice became widely known as individuals who would prescribe cannabis (for profit) to anyone who stated that cannabis "makes me feel better"; a number of doctors have lost their medical licences in consequence. Therefore, attention should be paid to guidelines for prescription in private practice.	Thank you for your comment. The guideline will make recommendations for all settings where publically funded health and social care is delivered. We are unable to make recommendations regarding private practice.
British Association for Psychopharmacology	4 (Equality Considerations)	17 18	Particular attention should be paid to children and adolescents who appear more prone to develop psychotic reactions to cannabis products especially those with high THC content. Strong warnings should be given against the use of products containing THC during pregnancy in view of the substantial evidence of harm to the foetus.	Thank you for your comment. The guideline will give specific consideration to young people, children and babies and pregnant women and women who are breastfeeding. The guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The committee will use its judgement to decide what the evidence means in the context of the guideline referral and decide what recommendations can be made to practitioners, commissioners of services and others.

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British Association for Psychopharmacology	3.5 (page 8)	12-16	Although the Chief Medical Officer identified several conditions as possible indications for medicinal cannabis, the evidence for these is very different. In particular, the evidence for efficacy in chronic pain is weak while that for certain types of childhood epilepsy is good.	Thank you for your comment. The guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. The committee will use its judgement to decide what the evidence means in the context of the guideline referral and decide what recommendations can be made to practitioners, commissioners of services and others.
British Association for Psychopharmacology	3.5 (page 8)	23	It would be sensible to advice especial caution when prescribing to: a) Individuals who indicate substantial use of smoked cannabis for recreational use or b) individuals with a personal history or family history of psychosis.	Thank you for your comment. The guideline will consider the areas described in the draft question which includes potential side effects and interactions and support for prescribers and people being prescribed cannabis-based products.
British Association for Psychopharmacology	3.5 (page 9)	14	There should be extensive training opportunities for specialists in the prescription of cannabis-based products. There should be some way of identifying those specialists who have received appropriate training in the subject.	Thank you for your comment. The guideline will consider individual treatment factors and support for both prescribers and patients (or their family members or carers).
British Association for Psychopharmacology	1	4	From a pharmacological perspective it is unclear why the guideline scope is restricted to plant-derived cannabinoids. Synthetic cannabinoids should be included too because	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and

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			they are in the same pharmacological class. This is potentially confusing for clinicians and patients alike.	synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
British Association for Psychopharmacology	1	6	It would help clinicians and patients for "cannabis-based products to be described. I suggest "this includes medical cannabis and plant-derived cannabinoids".	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
British Association for Psychopharmacology	1	20	It is not correct that all synthetic cannabinoids remain in schedule 1. Nabilone and Dronabinol are synthetic cannabinoids that were and remain in schedule 2.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic

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				cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
British Association for Psychopharmacology	2	15	There are over 140 plant-derived cannabinoids, which include THC and cannabidiol. The increased risk of psychosis and dependence is thought to be due to THC. The psychopharmacological effects of the other cannabinoids are largely unknown. The potential risks should clearly state that these relate to cannabis-based medicines containing THC.	Thank you for your comment. The guideline will consider potential side effects and interactions and support for prescribers and people being prescribed cannabis-based products.
British Association for Psychopharmacology	2	17	It would be more accurate to describe the increased of risk schizophrenia as “increased risk of psychosis”. This is because THC can cause acute psychotic symptoms and transient psychosis, in addition to increased risk of schizophrenia.	Thank you for your comment. This is a quote from the CMO review, therefore we are unable to amend this text.
British Association for Psychopharmacology	2	18	It would be more accurate to describe the “heightened probability of substance abuse” as “increased risk of cannabis dependence”. This is because (1) “substance abuse” is not a recognised diagnosis whereas cannabis dependence is (WHO ICD-10) and (2) there is consistent evidence that heavy cannabis use can increase the risk of cannabis dependence. However, there is not consistent	Thank you for your comment. This is a quote from the CMO review, therefore we are unable to amend this text.

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			evidence that cannabis use of itself increases risk of other disorders.	
British Association for Psychopharmacology	2	13-19	The potential increased risk of "schizophrenia, respiratory symptoms, road traffic accidents and substance abuse" is based on evidence from studies of heavy non-medical cannabis users. There are very limited data on whether the medical use of cannabis-based products increases the risk of these outcomes. An important factor differentiating this may be the doses used by heavy addicted recreational cannabis users is much higher than medical use, although further research is needed to address this.	Thank you for your comment. This is a quote from the CMO review, therefore we are unable to amend this text.
British Association for Psychopharmacology	4	16	Special consideration should also be given to people with hepatic and renal impairment. This is because most cannabinoids are heavily metabolised by the liver and metabolic products excreted by the kidneys.	Thank you for your comment. We will include hepatic or renal impairment as a particular consideration when developing the protocols for the review questions.
British Association for Psychopharmacology	5	12	Given theoretical risks of increased risk of psychosis and dependence, these guidelines should also include advice on monitoring for psychotic symptoms and dependence.	Thank you for your comment. The guideline will consider the areas described in the draft question which includes potential side effects and interactions and individual patient monitoring requirements, treatment durations,

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			They should also include advice on referral to psychiatric services when appropriate.	reviewing and stopping criteria, including how should treatment be withdrawn or stopped.
British Association for Psychopharmacology	5	18	As stated above, it is unclear from a pharmacological perspective why the guidelines are restricted to plant-derived cannabinoids.	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.
British Association for Psychopharmacology	8	5	This section should also include advice on doses of individual cannabinoids (e.g. THC and CBD) in plant-derived medical preparations. This is to guide clinicians in prescribing.	Thank you for your comment. The dose of cannabis-based products will be considered by the guideline committee.
British Association for Psychopharmacology	4	15	Specific considerations should also be given to older adults (e.g. differences in pharmacokinetics and drug metabolism) and people with mental health (especially psychosis) and substance use disorders	Thank you for your comment. Following stakeholder comments the scope has been amended to include specific consideration for older people and people with mental health problems.

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British Association for Psychopharmacology	20	20	This document refers specifically to 'cannabis-based medicinal products' that were recently rescheduled. It also provides a brief introduction to other products such as Sativex and Dronabinol. It would be helpful to introduce cannabidiol as well. Cannabidiol is not scheduled in the UK. It is widely available on the high street as a 'health food supplement' and is set to be approved by the EMA next year for rare paediatric epilepsy syndromes. The terminology of these products may be confusing for non-specialists. It would be helpful to provide a brief summary of cannabidiol products to help clinicians distinguish between requests for these and recently rescheduled cannabis-based medicinal products	Thank you for your comment. This guideline will consider the use of cannabis-based medicinal products as defined by the UK Government in November 2018. Following stakeholder comments Sativex, nabilone, dronabinol and synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol will also be included within the guideline. Other synthetic cannabinoids are the subject of a further review by the ACMD and are outside the scope of this guideline.

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		of their own fundraising activity		