Cannabis-based medicinal products

NICE National Institute for Health and Care Excellence

Consultation on draft guideline – deadline for comments 17:00 on 05/09/2019 email: CannabisMedUse@nice.org.uk

	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly. We would like to hear your views on the draft recommendations presented in the guideline, and any comments you may have on the rationale and impact sections in the guideline and the evidence presented in the evidence reviews documents. We would also welcome views on the Equality Impact Assessment. In addition to your comments below on our guideline documents, we would like to hear your views on these questions: 1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. 2. Would implementation of any of the draft recommendations have significant cost implications? 3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) See section 3.9 of Developing NICE guidance: how to get involved for suggestions of general points to think about when commenting.
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	British Pharmacological Society
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	None
Name of commentator person completing form:	Natalie Harrison, Policy Officer, British Pharmacological Society

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Type		[office use only]		
Comment number	Document [guideline, evidence review A, B, C etc., methods or other (please specify which)]	Page number Or 'general' for comments on whole document	Line number Or 'general' for comments on whole document	Comments Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
1.	Guideline	General	General	Please refer to cannabis-based products for medicinal use throughout, in-line with legislation and guidance.
2.	Guideline	General	General	There are significant gaps in knowledge of cannabinoids in the following areas, and we feel that these need to be added to the recommendations: · pharmacokinetics of cannabinoids when administered by different routes; · drug-drug interactions with cannabinoids, pharmacokinetic, pharmacodynamic and mixed · long term safety of cannabinoids, in particular on the risk of psychiatric disorders and cognitive function.
3.	Guideline	5	10	We propose that this section should be split into two sections; Lennox-Gastaut and Dravet first (where there is evidence, and it is being appraised separately) and then "other treatment resistant epilepsies" second. We also suggest adding a comment about ongoing clinical trials in these areas (e.g. Retts syndrome). Otherwise it looks like the area where there is evidence is being ignored as it is only included at the end.
4.	Guideline	5	10	Section 1.4 is not as specific as the other sections in terms of bulleted recommendations for when to use it.
5.	Guideline	6	4	Section 1.5.1: it is not clear from reading the indications where it is recommended for use that will relate to individuals younger than 18 years, apart from in clinical trials. It seems that the regulation of prescribing to those under 18 is much more robust and limited than for those

				older than 18 years since any consultant could prescribe and there is only a "should" recommendation on having a specialist interest in the area being treated.
6.	Guideline	6	7-8	We suggest amending the final sentence to read "For Children and Young people under 18 years, the initiating prescriber should be a tertiary paediatric neurologist (or epilepsy specialist)". Further, we suggest amending from just "specialist", as all paediatric consultants in tertiary hospitals will fit this description. This is clarified on p 18, line 21, but it should be in the main section as well
7.		6	17	Section 1.5.4: We are assuming that a primary care or non-specialist doctor can decline to continue prescribing, as with other shared care agreements? The funding requires CCG approval, but they are not mentioned as responsible parties in the first bullet point. This point should be clarified.
8.		7	8	Section 1.5.5: this should specifically refer to "synthetic cannabinoids" in terms of previous substances used. Also, patients may not consider use of a recreational drug as "misuse" and so this is probably not the best term to use.
9.		7	24	Section 1.5.7: again this should refer to "synthetic cannabinoid" use being discontinued. Are other substances (recreational drugs and NPS) okay to continue then? Please clarify
10.		8	5	Section 1.5.9: what about the impact of use in professions where use of cannabis is not allowed (e.g. train drivers, pilots, armed forces personnel); should they not be appropriately counselled about this?
11.		9	12	Recommendations for research: there is no mention about use in chronic pain in adults apart from fibromyalgia or treatment resistant neuropathic pain. Other pain conditions should be considered and mentioned.
12.		18	6	It is now just "an interest" rather than a "specialist interest"; this is much broader as any consultant could have an interest in an area. Generally, we propose that the wording and description of who can prescribe should be tighter and should reference that the individual is not only on the specialist register but that they are on the specialist register for that indication (e.g. oncology, palliative care, neurology).
13.	Guideline	20	10-12	The concerns about effects on brain development are fair, but in the case of poorly treated intractable epilepsy, this also has effects on normal brain development and this overall need is a balance between the two sets of risks and benefits; the text as it currently reads seems to focus on the harms of prescription only. This should be addressed.
14.	Guideline	7	9	Amend to "Over-the-counter CBD oil products for non-medicinal use".
15.	Guideline	7	17	Please add about asking about any allergies (some products are formulated in peanut oil).

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16.	Guideline	7	17	Please add about travelling abroad, as CBPMs are not legal in other countries and patients will need to check the status of the drug with the embassy of the country they are travelling to.
17.	Guideline	8	13	Please consider adding that the CBPMs may affect ability to use tools or machines (i.e. as per standard drug labelling for licensed products that may cause drowsiness).
18.	Guideline	18	5	Specialist doctors on the 'Specialist Register' of the General Medical Council should only prescribe within their own area of practice.
19.	Guideline	23	10	A product can only be described as "pure" if it contains no controlled cannabinoids (i.e. THC). In reality this is very difficult to achieve. In view of this, we recommend the term "pure" is avoided, and simply refer to 'CBD products for medicinal use'.

Insert extra rows as needed

Checklist for submitting comments

- Use this comment form and submit it as a Word document (not a PDF).
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Include page and line number (not section number) of the text each comment is about.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 response from each organisation.
- Do not paste other tables into this table – type directly into the table.
- Mark any confidential information or other material that you do not wish to be made public. Also, ensure you state in your email to NICE that your submission includes confidential comments.
- Do not include medical information about yourself or another person from which you or the person could be identified.
- Spell out any abbreviations you use
- For copyright reasons, comment forms do not include attachments such as research articles, letters or leaflets (for copyright reasons). We return comments forms that have attachments without reading them. The stakeholder may resubmit the form without attachments, but it must be received by the deadline.
- We do not accept comments submitted after the deadline stated for close of consultation.

You can see any guidance that we have produced on topics related to this guideline by checking NICE Pathways.

Note: We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by NICE, its officers or advisory Committees. Further information regarding our privacy information can be found at our privacy notice on our website.