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):	Royal Pharmaceutical Society
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	**N/A**

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Name of commentator person completing form:	Aileen Bryson
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	4	4	We agree that looking at the currently available evidence on long term side effects, nabilone should only be an option when other conventional antiemetics have failed. It should be short term, unless used for palliative care and should not be used in young people. More research into interactions with other medicines and the development of psychological disorders is required.
2	Guideline	4	16	We agree that there is limited high-quality evidence for cannabidiol (CBD) and tetrahydrocannabinol (THC), or combinations of both, in chronic pain and these products should not be prescribed for chronic pain unless part of a clinical trial. However, we question the criteria used to measure quality-adjusted life years (QALYs) in this area as products are not expected to extend life or be fundamentally disease modifying and so pain products appear to be scored unfairly.
3	Guideline	5	1	We agree CBD should not be used for chronic pain unless part of a clinical trial. More research is required in areas such as fibromyalgia where Cannabis-based medicinal products (CBMPs) have the potential to improve safety by replacing or reducing doses of standard treatments.
4	Guideline	5	4	Sativex is a licensed product and patients using it have reported improvements in spasticity. Prescribing Sativex should be a clinical decision between a consultant and a patient and only used in an individual in whom other treatments have failed. The product should be trialled on short term basis to assess outcomes. This treatment should not be withheld to patients already finding improvement purely on the basis of cost. As with other products we advocate for more research and prescribing to be part of a clinical trial.

5	Guideline	5	7	There is limited evidence for other CBMPs so they should only be prescribed within a clinical trial. More research is required to build an evidence base.
6	Guideline	5	10	We agree that further research is required to ascertain the potential of CBMPs in severe treatment resistant epilepsy. We called for the rescheduling of Cannabis to encourage and enable more research projects and trials. Since the rescheduling of Cannabis, it should be easier to access products licensed in other countries. Making no recommendation on the use of CBMPs will detract from consultants considering prescribing for patients who have already shown improvement in severe epilepsy. These products are usually only used as a last resort when traditional treatments have failed and there are concerns that the severity and frequency of the epilepsy seizures could be life threatening. The decision to prescribe should be a clinical one between patient/guardians and the prescriber with usual best practice around discussion of the unlicensed nature of the product and the lack of long term data on developmental complications.
7	Guideline	6	4	We agree that prescribing should be the remit of specialists and for under 18s then a tertiary specialist as appropriate.
8	Guideline	6	10	While every effort should be made to minimise visits to hospital for patients and their families and to support care closer to home to reduce the need for travel, there are many complexities around having shared care agreements. We can understand if General Practitioners are reluctant to sign prescriptions for CBMPs while these are unlicensed and there is still a lack of evidence and educational support available, or for potential new treatments. Arrangements for shared care would have to be very tightly controlled and this could be difficult. A more pragmatic approach would be to have prescribing from the appropriate consultants and supply to be made through community pharmacies where an agreed supply arrangement/procedure has been established - good communication and a formal process agreed between these two healthcare professionals will be essential. This would give convenience to patients and negate the need for extra hospital visits.
9	Guideline	7	7	NICE has considered a comprehensive list of factors to support prescribers in their decision making.
10	Guideline	8	4	The information on shared decision making is essential to ensure patients and their families fully understand the unlicensed nature of the products and the potential consequences of this.
11	Guideline	9	15	We agree with recommendations for more research into fibromyalgia. CBMPs might “improve safety” in patients with treatment resistant neuropathic pain (fibromyalgia) by either replacing or reducing doses of medicines used in standard care.
12	Guideline	9	22	We would like to see more research into the clinical effectiveness for CBMPs in both adults and children. A validated model must be used to estimate this. Criteria for this model might have to be revised from standard QALYs to give realistic results until a more robust evidence base is available. It is not clear from the rationale presented why higher levels of response have been used in the cost analysis than in the clinical effectiveness review and why there should be any difference?

13	Guideline	10	3	We support more research into CBD for severe treatment resistant epilepsy, including post marketing clinical trials for Epidiolex which now has approval in other countries.
14	Guideline	10	8	Research into the possible combinations of CBD and THC and the synergistic effect of this combination is required. Clinical trials for products already licensed in other countries would increase patient access to treatment and facilitate prescribing in a structured way. Until the long term effects are established this approach should always be after standard treatments have been tried without success. This may help stop families attempting to import products individually and reduce people resorting to internet sales where quality cannot be assured.
15	Guideline	10	15	We support further research on spasticity. It is our understanding that most evidence is qualitative from patient reporting and without more robust evidence some patients may not be receiving a treatment which would improve their quality of life. We have concerns that the rigid criteria being used to model cost effectiveness is not a person-centred approach which will facilitate prescribing and accommodate the small numbers of people who have said they are already benefiting from CBMPs.
16	Guideline	10	23	We support further research into the clinical effectiveness of chemotherapy induced intractable nausea and vomiting. Prescribing in this area could be for a larger patient group and cost effectiveness is important but the short-term nature of chemotherapy treatment and the longer-term benefits if people are still able to work and carry on normal life must be considered when evaluating overall cost.
17	Guideline	14	19	We would welcome more clinical trials to evaluate the benefits in chronic pain. CBMPs have been used in other countries as an alternative to opioids or to reduce opioid use and more research is required to fully assess this.
18	Guideline	18	22	We agree that there are challenges for ongoing monitoring and prescribing for patients, but person centred solutions must be sought to facilitate this which include robust clinical governance. Signing of any prescription assumes responsibility. Is this an option for GPs at the moment with unlicensed products and a clear recommendation for consultant prescribing of all CBMPs? The guideline has made detailed recommendations for shared care, but this aspect still needs further consideration. New models for clinical trials might be required using outreach into community and other health care professionals including pharmacists working in GP practice and in community. An integrated approach is required. With protocols in place and innovative IT solutions, including remote consultations hospital visits could be minimised.
19	Guideline	General	General	The review is a comprehensive assessment of the available randomised controlled trials (RCTs) (and observational studies where included) and we broadly support the findings of clinical effectiveness based on the evidence assessed by NICE. We agree with NICE that we need high quality evidence for CBMPs as the evidence currently available is generally of poor quality. We need to encourage more clinical trials of CBMPs to enable more products to become licensed in the UK thus ensuring consistent quality, safety and efficacy. including products that are licensed for medicinal use in other countries. We should currently consider CBMPs as a treatment of last resort for patients when all other treatment options have failed. Ideally, they should only be used in those conditions where there is some evidence that they are

				clinically effective. We are disappointed that only one product (Nabilone) is recommended by NICE for use in specific situations in intractable nausea and vomiting. We are pleased to see the prescribing issues well outlined in the guideline but think some aspects of shared care still need to be considered.
20	Guideline	General	General	There is nothing in the guideline to guide prescribers if they have patient demand for conditions not mentioned. Intractable vomiting can be due to conditions other than a reaction to chemotherapy. A general principle should now be that all new prescribing is part of clinical trials. It is not clear why Sativex and other cannabinoids are excluded from the guidelines despite the fact they may have a role in the conditions discussed in the scope.
21	Guideline	General	General	RCTs are relied heavily on by NICE in the analysis. While this has been recognised as the gold standard in terms of evidence, other data are available that could help inform decisions. CBMPs are an emerging treatment option and we should look at all the evidence. At this stage we should use real-world data/observational data/patient case studies and experiences to inform our position on clinical efficacy until data from RCTs become available. It is interesting to note that Drugs Science have recently announced they will carry out 'real-world data' research into the prescription of cannabis-based medicinal products, using data on the health, lives and experiences of 20,000 patients. This study is due to begin in September 2019 and it will be interesting to see the impact of the outcomes of this research. There needs to be the ability to prescribe for patients in a compassionate way until more detailed data become available. The guideline as written does not allow flexibility for this.
22	Guideline	General	General	It is disappointing that NICE have placed such a huge reliance on the economic analysis (often modelled rather than based on published data) to base decisions on efficacy/suitability. This could underestimate the potential benefits of treatments and their place in therapy.
23	Guideline	General	General	In spasticity, the committee considered the evidence from two published economic evaluations but noted that they were contradictory and subject to potentially serious limitations. A new economic model was developed specifically for the Cannabis guideline. It is unclear, how the published economic evaluations were contradictory. It is also not clear whether the new evaluation was consistent with one of the published ones.

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.

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- 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
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- **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.

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