Cannabis-derived medicinal products

Application form for the Expert Panel

The purpose of this Expert Panel is to assess clinical aspects of applications for special licences for cannabis-derived medicinal products, currently in Schedule 1 of the Misuse or Drugs Regulations 2001. The application process is designed to test whether it is possible to demonstrate that an individual patient has an exceptional clinical need which can only be met through the use of cannabis-derived medicinal products.

This application form is based on the Individual Funding Request form[1].

It is the responsibility of the referring clinician to ensure all the appropriate and required clinical information is provided through this application form.

Further guidance can be found at Section 6 detailing the requirement for a clear articulation of why the clinical need is exceptional. It will be important to demonstrate exceptional clinical need in order for an application to be successful.

Information is requested in relation to the following areas:

- The lead clinical applicant
- The patient/GP
- Nature of the condition and the treatment for which access to the substance or product is requested
- Clinical support for the application
- Consent from the lead clinical applicant and on behalf of the patient or patient representative
- Clinical outcomes
- Clinical background
- Clinical exceptionality

The Panel members themselves cannot make clinical decisions for a patient not directly under their care. However, the Panel will assess whether the lead clinical applicant (attending doctor), is making a logical and reasonable request for a specific treatment to be available for the individual patient for whom s/he holds clinical responsibility.

Requests will only be considered on the information provided in the application and supporting papers. The information requested at question 2g and 2h is collected for monitoring purposes in an anonymised format to assist in ensuring that we are complying with the equality legislation requirements This information will be redacted by the Secretariat prior to sharing with the panel.

Please do not include patient or trust/requesting clinician identifiable data in any free text sections. Where there are large amounts of identifiable data included the application will be returned to you for redaction and resubmission.

In cases of clinical supply and use of cannabis-derived medicinal products, consideration by the Expert Advisory Panel is a pre-condition of any subsequent formal application for a Schedule 1 licence to the Home Secretary or Department of Health of Northern Ireland.

Section 1 - Lead Clinical applicant

1a)	Name of clinician who will undertake the intervention:	Click here to enter text.
1b)	Job title/role:	Click here to enter text.
1c)	Email address:	Click here to enter text.

[1] https://www.england.nhs.uk/publication/standard-operating-procedures-individual-funding-requests/

1d) Telephone number:	Click here to enter text.
1e) Do you hold a current licence to practise?	Click here to enter text.
1f) Please provide your GMC register number	Click here to enter text.
1g) Please provide details of your specialism	Click here to enter text.
1h) Please provide details of your sub-specialism	Click here to enter text.
Section 2 - Patient/GP details	
2a) Patient's first name:	Click here to enter text.
2b) Patient's last name:	Click here to enter text.
2c) NHS/ H&C/ CHI number:	Click here to enter text.
2d) Patient's hospital no:	Click here to enter text.
2e) Date of birth:	Click here to enter text.
2f) Patient's age at time of submission:	Click here to enter text.
2g) Gender:	Click here to enter text.
2h) Ethnicity:	Click here to enter text.
2i) Patient's address:	Click here to enter text.
2j) Patient's postcode:	Click here to enter text.
2k) GP practice name:	Click here to enter text.
2l) GP postcode:	Click here to enter text.

Section 3 – Request details	
3a) Type of treatment requested:	Click here to enter text.
3b) Primary diagnosis most relevant to this application and any relevant co-morbidities:	Click here to enter text.
3c) Clinical reasons (which will affect the prioritisation of the application) i.e. the risk of adverse clinical outcomes to the individual patient if not granted:	Click here to enter text.
3d) Evidence that the patient has exceptional clinical circumstances, in line with the principles applied to Individual Funding Requests within the NHS/ HSC[2]	Click here to enter text.
3e) Evidence that there is no equivalent non-Schedule 1 medicinal product (whether licensed, or unlicensed) or other interventional procedure available in the UK that would meet the specific need:	Click here to enter text.
3f) Confirmation of acceptance of risks and liability by the clinician concerned and that the patient (or parents/guardian) has fully consented:	Click here to enter text.
3g) Proposed start date of treatment:	Click here to enter a date.
3h) Proposed treatment stop date (if applicable):	Click here to enter a date.

[2] https://www.england.nhs.uk/publication/standard-operating-procedures-individual-funding-requests/

3i) Details of the product being prescribed by name or chemical make-up; where it is intended that it will be sourced from and what arrangements there are for supply when the patient is in the community:	Click here to enter a date.
Clinical Support for the application	
3j) Name and email of Medical Director or, in exceptional circumstances to avoid delays in submission, the Deputy Medical Director or equivalent* *If the application is from outside the NHS/ HSC, please provide name and email address of relevant specialist. This specialist needs to have no personal or commercial connection to the lead clinical applicant, and be in good standing with the GMC	Click here to enter text - name. Click here to enter text – email.
3k) Confirm, where possible, that the Medical Director/Deputy Medical Director or equivalent* supports this application *If the application is from outside the NHS/ HSC, please provide name and email address of relevant specialist. This specialist needs to have no personal or commercial connection to the lead clinical applicant, and be in good standing with the GMC	☐ Yes ☐ No

Consent from the lead clinical applicant	
3l) This application form has been discussed, in full, with the patient or patient representative. They are aware and have given their explicit consent for the advisory panel to receive and review confidential clinical information about their health to enable full consideration of this application.	☐ Yes ☐ No
3m) In submitting this application you, the lead clinical applicant, are confirming that the patient or patient representative understands the risks of taking the cannabis-derived medicinal products for which you are seeking a licence.	☐ Yes ☐ No
3n) In submitting this application you are under an obligation to advise the patient or patient representative of the details of the reasons for the Panel's advice. **I confirm that I will advise the patient or patient representative of the reasons for the decision.**	☐ Yes ☐ No

4- Clinical Outcomes	
4a) What are the intended clinical outcomes and how will the benefits of the treatment be measured (including where appropriate the validated clinical tools to be used)?	Click here to enter text.
4b) Within what timeframe will these outcomes be determined?	Click here to enter text.
4c) What 'stopping' criteria will be in place to assess when the treatment is ineffective and treatment will be withdrawn?	Click here to enter text.
4d) There is an expectation that the treating clinician should monitor outcomes and retain evidence so that future reports can be produced if required for review. What mechanisms will be in place to provide the panel with clinical outcome reports if the treatment is approved? Please provide detail of how you will report to the panel upon request.	Click here to enter text.

Section 5 – Clinical Background	
5a) Outline the background to the patient's clinical situation relevant to this request, timeline, current status and symptoms. Please give validated clinical measures, named in full.	Click here to enter text.
5b) Epilepsy Background (if applicable)	
i. Age of onset of Epilepsy	Click here to enter text.
ii. Epilepsy syndrome and other co-morbid disorders	Click here to enter text.
iii. Brief description of seizure type/s	Click here to enter text.
Impact of seizures over the last 6 months:	
iv. Frequency, including clustering/variability	Click here to enter text.
v. Number of unscheduled attendances	Click here to enter text.
vi. Number of school days missed	Click here to enter text.

5c) Treatment History						
	Treatment	Regimen	Start	Stop	Response	Funding
Current	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Previous:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Previous:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Previous:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Previous:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Previous:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

5d) Additional comments on current or previous treatments:	Click here to enter text.
5e) What are the alternative standard treatments available to patients with this condition/stage of the disease and why are they not appropriate for this patient?	Click here to enter text.
5f) Prognosis – what are the anticipated clinical benefits in this individual case of the particular treatment requested over other available options?	Click here to enter text.

5g) Risk/benefit profile of this treatment compared to standard treatments in this individual case:	Click here to enter text.
5h) Anticipated prognosis if treatment requested is not funded:	Click here to enter text.
5i) How long have you cared for this patient	Click here to enter text.
5j) Will you be continuing to care for this patient?	Click here to enter text.

Additional Treatment Information

Section 6 – Clinical Exceptionality

In this section; the panel is looking for evidence that this patient has exceptional clinical circumstances

There can be no exhaustive description of the situations which are likely to come within the definition of exceptional clinical circumstances. The onus is on the clinician making the request to set out the grounds for clinical exceptionality clearly for the Panel.

'Exceptional' for the Panel means a person to whom the general rule (the prohibition on production and supply under criminal law) should not apply. This implies that there is likely to be something about their clinical situation which was not considered when formulating the general rule, or was considered but the view was taken that it was sufficiently exceptional that it could be met on a case by case basis via the licensing system. Very few patients have clinical circumstances which are genuinely exceptional. To justify treating a patient with cannabis derived medicinal products, the Panel needs to be satisfied that the clinician has demonstrated that this patient's individual clinical circumstances are clearly different to those of other patients, and that because of this difference, a licence should be granted. Simply put, the consideration is whether it is reasonable to grant a licence for a treatment when the treatment is not widely available to others.

In considering whether a request should be made to the panel, the clinician should consider whether this individual patient is likely to respond to the treatment in a way that exceeds the response of other patients in the group to which the general policy applies, and whether there is evidence to support this view.

In the case of applications to the Expert Panel the essential question to be addressed is whether the use of cannabis derived medicinal products, with the attendant clinical risks, can be justified, given the particular clinical presentation of the patient concerned. For that reason, applicants will need to demonstrate that they have reasonably excluded standard care approaches, for example that the severity of the patient's symptoms lie outside what may normally be expected; and that they have drawn on the widest possible sources of evidence concerning safety and efficacy. Non-clinical factors will not be considered by the Panel.

6a) There is no equivalent non-Schedule 1 medicinal product (whether licensed, or unlicensed) or other intervention or procedure available in the UK that would meet the specific need:	☐ Yes Click here to enter text – provide comprehensive comments.
6b) A reasonable case can be made that, in accordance with the guidance above, the patient has exceptional clinical circumstances:	☐ Yes Click here to enter text – provide comprehensive comments.

7- Evidence	
7a) Please provide a summary of the evidence base relevant to this application to demonstrate the clinical effectiveness, and safety of this procedure/treatment.	Click here to enter text
7b) Is the procedure/treatment part of a current or planned national or international clinical trial or other follow-up studies?	☐ Yes ☐ No
If Yes, please give details: Click here to enter text.	

Section 8 – SUBMIT	
When you are satisfied that you have completed all sections you will need to submit the request for consideration by the Panel. If the Panel Secretariat needs more information they will email you to ask that you provide more details and if this happens, the timeline for the request is suspended until this is received.	
Are there any other comments / considerations that are appropriate to bring to the attention of the Panel?	Click here to enter text.
Please complete and return this form in MSWord to: secretariat@Expertpanel.gov.uk	