## Cannabis based medicinal products panel

### Terms of Reference

I. A time limited expert panel of clinicians is being set up by Professor Dame Sally Davies. The intention is that the panel will remain in existence until such time as Ministers decide whether to reschedule cannabis and cannabis-like products following the advice from Professor Dame Sally Davies and the Advisory Council on the Misuse of Drugs;

II. The panel will establish a process to assess applications for special licences to prescribe cannabis based medicinal products and recommend the application to the Home Secretary and the Department of Health in Northern Ireland;

III. A special advisory group met on Friday 22nd June and made recommendations on the process of advising the Home Secretary and the Department of Health in Northern Ireland and the panel composition;

IV. Professor Dame Sally Davies, with input from UK CMOs, will recommend an independent chair and clinical members for the panel to the Health and Social Care Secretary of State;

V. Panel appointments will last one year or end when the panel is stood down, whichever is the sooner;

VI. The expert panel will only look at applications for Schedule 1 drugs in the cannabis or cannabis derivative class and only at applications relating to clinical use. Applications for Schedule 1 drugs licences for research or industrial purposes should not be submitted to the panel.

VII. All applications for a Schedule 1 drugs licence will be made through the independent Secretariat for the panel who will be responsible for informing applicants of unsuccessful applications.

VIII. Individual applications may be considered by the expert panel as a whole or a smaller group, as determined by the chair, acting as the panel. A majority vote of the panel will be sufficient for recommendations to the Home Secretary or the Department of Health of Northern Ireland. A submission will then be sent to the Home Secretary or the Department of Health in Northern Ireland. The recommendation of the Expert Panel will be sent to either the Home Secretary or the Department of Health in Northern Ireland for a decision as to whether to approve a licence;

IX. The independent Secretariat for the panel will be sponsored by the Home Office;

X. Depending on the jurisdiction, the Home Office or the Department of Health in Northern Ireland will issue the licence, if the decision is taken to accept the expert panel's recommendation;

XI. The responsibility for considering the practicalities of obtaining the cannabis based medicinal products, as with all clinical cases, remains with the practising clinician and their supporting organisation;

XII. The panel will not provide clinical advice (recommend drug; dosage etc.); this will remain the responsibility of the practising clinician;

XIII. The expert panel of clinicians will only consider applications made by GMC registered specialists listed on the relevant specialist register and with an active licence to practice, countersigned by a medical director or equivalent*. Applications solely from General Practitioners will not be accepted by the panel;

XIV. The Expert Panel will prioritise applications based on clinical need and will consider applications against the following criteria:

- There is no non-Schedule 1 medicinal product (whether licensed, or unlicensed) available in the UK that would meet the specific need;
- Confirmation of acceptance of risks and liability by the clinician concerned and that the patient (or parents/guardian) has fully consented;
- Evidence that the patient has exceptional clinical circumstances, in line with the principles applied to Individual Funding Requests within the NHS;

XV. The expert panel's assessment can be informed by the following additional factors:

- Whether the product has already been used by the patient under direction of a registered medical practitioner (in another jurisdiction) and been shown to work in their specific case;

or

- Whether there is an existing clinical trial that demonstrates effective use of the requested medication for the patient's condition;
- Other cases which do not meet either of the two criteria above. These will be exceptional;

XVI. The panel will be assessing whether the attending clinician, who has the responsibility for the case, is making a logical and reasonable request for a specific case. The panel cannot make personal clinical treatment decisions for an individual not directly under their care;

XVII. Any treatment involving a cannabis based medicinal products will continue to require a licence as issued by the Home Office or the Department for Health in Northern Ireland;

XVIII. It is anticipated that the Home Office and the Department of Health in Northern Ireland will expect all applications for licences for the supply and possession for clinical uses of Schedule 1 cannabis based medicinal

products, to be made via this process, apart from applications relating to clinical trials;

XIX. The panel is **not** being set up to advise on the use of recreational cannabis or the nature of the classification. The panel is being set up only to advise on the use of cannabis based medicinal products for specific named patients. Cannabis and related products will remain controlled drugs; they will also remain Class B substances under the Misuse of Drugs Act 1971;

**Timings**

The first meeting of the time limited expert panel of clinicians is expected to take place in the week commencing the 25th June.

*If the application is from outside the NHS, please provide name and email address of the 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