



General Medical Council (GMC) guidelines for prescribing medicines 'off label'

Prescribing midazolam and opioids for covid was off label as these drugs did not have a UK marketing authorisation for this use when NICE wrote their guidance in April 2020.

From the General Medical Council guidance:

Unlicensed medicines are commonly used in some areas of medicine, such as in paediatrics, psychiatry and palliative care.

In this guidance, the term 'unlicensed medicine' is used to describe medicines which are used outside the terms of their UK licence or that have no licence for use in the UK.

You should usually prescribe licensed medicines in accordance with the terms of their licence. However, you may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient.

When prescribing an unlicensed medicine, you must:

- be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
- take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring and any follow up treatment, or make sure that arrangements are in place for another suitable doctor to do so
- make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine."

More information can be found here:

<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines>