Prescribing - Unlicensed Medicines

The term 'unlicensed medicine' is used to describe medicines that are used outside the terms of their UK licence or which have no licence for use in the UK. Unlicensed medicines are in common use especially in paediatrics, psychiatry and palliative care.

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.

Para 69 and 70 of the GMC Guidance state:

Prescribing unlicensed medicines may be necessary where:

There is no suitably licensed medicine that will meet the patient's need, for example, where:

i. there is no licensed medicine applicable to the particular patient. For example, if the patient is a child and a medicine licensed only for adult patients would meet the needs of the child; or

ii. a medicine licensed to treat a condition or symptom in children would nonetheless not meet the specific assessed needs of the particular child patient, but a medicine licensed for the same condition or symptom in adults would do so; or

iii. the dosage specified for a licensed medicine would not meet the patient's need; or

iv. the patient needs a medicine in a formulation that is not specified in an applicable licence.

b. Or where a suitably licensed medicine that would meet the patient's need is not available. This may arise where, for example, there is a temporary shortage in supply; or

c. The prescribing forms part of a properly approved research project.

70 When prescribing an unlicensed medicine you must:

1. be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
2. take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so
3. 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.

LMC Comment: This is the area that has received most comment. There are many common medications which are prescribed off licence. The most commonly quoted is amitriptyline for pain, which is not licenced, whereas pregabalin, gabapentin and duloxetine are. If this advice is followed it would probably mean that every doctor prescribing amitriptyline are in breach of GMC guidelines.

Before any GP perceptive action please wait for more definitive guidance. The GPC is seeking clarification from the GMC and when this becomes available we will share that with you.
Related guidance...

Prescribing - Co-proxamol
In January 2008 the normal distribution of co-proxamol ceased but its usage has not been banned outright. The Medicines and Healthcare...

Prescribing - Self Prescribing & Family Members
Over the last year LMC has been made aware of a number of GPs who have been reported to the GMC for self-prescribing. The LMC would...

Patient Specific Directions (PSDs) and Patient Group Directions (PGDs)
Patient Specific Directions (PSDs) The Medicines Act 1968 does not permit nurses who are not qualified prescribers to administer or...

Good Practice in Prescribing
This guidance was published by the GMC on 31st January and came into effect on 25th February 2013. In 'Good Medical Practice' it is...

Prescribing - Nurseries, schools and OTC Medications
Non-prescription (OTC) medication does not need a GP signature/authorisation in order for the school/nursery/childminder to give it. It...

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