

PATIENT INFORMATION

Understanding why your doctor has decided not to prescribe an unlicensed medicine

What is this leaflet about?

Your doctor has given you this leaflet because you have requested a prescription for a medicine that is not currently licensed in the United Kingdom which s/he has decided not to prescribe. This leaflet is intended to help you understand why your doctor does not feel that it is appropriate to prescribe an unlicensed medicine for you, and to help answer any questions that you may have.

Why are medicines licensed?

Pharmaceutical companies must hold a licence for each medicine that they sell in the United Kingdom. The Medicines and Healthcare products Regulatory Agency (MHRA) issue these licences only after they have assessed information on the quality, safety and efficacy of the medicine. They have to be sure that the medicine is made to an acceptable standard of quality and that it works to treat the illness concerned, the incidence of side effects is understood and any risks can be managed. Medicines are tested in clinical trials to generate the information that is necessary for licensing.

As an NHS patient, isn't it right that my doctor must prescribe for me whatever I want (including unlicensed medicines)?

Under NHS regulations your doctor will prescribe for you any medicines that s/he feels are needed for your care. Patients are therefore entitled to any treatment that the doctor feels is necessary, not what the patient feels should be prescribed. Doctors are responsible for the prescribing decisions they make and for any subsequent follow up that is required.

When a doctor signs a prescription s/he takes full legal responsibility for the treatment. Doctors should only prescribe if they feel that the medicine requested (by patient or other colleague including consultants) is appropriate and if they are sufficiently knowledgeable about the use, side effects, drug interactions and monitoring of a medicine to take personal legal responsibility for writing the prescription. Sometimes treatments are new, experimental or for unlicensed uses. All doctors have the right to refuse to prescribe a medicine that they are not prepared to take clinical responsibility for.

When should an unlicensed medicine be considered?

Unlicensed medicines should only be used where:

- There is no licensed alternative available to meet the clinical need of the patient.
- The clinical benefits are considered to outweigh the potential risks of treatment and that use is clearly justified.

Unlicensed medicines often lack the information on safety and clinical benefits which doctors rely on to base their prescribing decision making. Without strong evidence that these products are superior or safer than licensed medicines, there is no clear reason for doctors to risk prescribing them to their patients.

It is recommended that unlicensed medicines are NOT routinely prescribed by healthcare professionals in Derbyshire.

Where can I get more information?

For more information, please speak to your community pharmacist or contact your GP. Alternatively, you can contact Patient Advice & Liaison Service (PALS) on freephone 0800 032 32 35.

If you would like some help in accessing this document please email ddicb.PALS@nhs.net or call the Patient Advice and Liaison Service (PALS) on 0800 032 32 35.