

Information for patients taking unlicensed medicines

Introduction

In the UK, most medicines are 'licensed' but some are not. This leaflet explains why medicines are licensed and why some useful medicines do not have licences. You have been given this leaflet by your doctor or pharmacist because the medicine prescribed for you is not 'licensed' or is being used for a reason not covered by the licence. We want to reassure you that we have thought very carefully about the best medicine for you. This leaflet answers some of the commonly asked questions.

Why are medicines 'licensed'?

The makers of medicines must ask the Government for a Marketing Authorisation (previously called a Product Licence, and still commonly referred to as such) if they want to sell their medicines in the UK. They show the Government's Medicines and Healthcare products Regulatory Agency (MHRA) that their medicine works for the illness to be treated, the side effects that may be expected and that it has been made to a high standard.

How do the makers test medicines?

To be sure that a medicine works and is safe, the maker has to test it first on a number of people in what is called a 'clinical trial'. Information from clinical trials is given to the MHRA when the maker asks for a Product Licence.

Why don't all medicines have licences?

Medicines can only be licensed for conditions that have been studied in a clinical trial. However, many illnesses have not been studied in this way, but still need to be treated. In these situations, doctors and pharmacists can use their medical experience and knowledge to recommend the use of an unlicensed medicine.

Reference No.

GHPI0452_02_25

Department

Pharmacy

Review due

February 2028

Patient Information

They may choose to use:

- A medicine that is currently undergoing clinical trials, but does not yet have a licence.
- A medicine that used to be licensed in the UK, but is no longer marketed (for example, because it was no longer profitable).
- A medicine that is only licensed abroad and needs to be imported.
- A medicine that needs to be made specially, because it is not readily available.
- A medicine that has no licence at all. These are usually medicines used to treat rare conditions, in which case the maker may consider it too expensive to do the clinical trials needed for a licence.
- A licensed medicine that is not available in a suitable form for you. For example, if you have difficulty swallowing, but the medicine is only made in tablet form, an (unlicensed) liquid form may be specially prepared.

Why have I been given an unlicensed medicine?

Your doctor has prescribed an unlicensed medicine because no suitable licensed alternative is available to treat your condition. Your doctor will have thought very carefully about prescribing the most appropriate medicine for you.

How will I know that my medicine is not licensed?

Your doctor should tell you whether the medicines they are prescribing are unlicensed and you may notice that the information leaflet given with the medicine doesn't refer to your particular condition or illness.

**Patient
Information****Will I always be able to obtain my medicine easily?**

Some unlicensed medicines may take longer to obtain than others depending on whether they have to be imported or be made specifically for you. Your pharmacist may tell you this and make special arrangements for you to get your medicines.

Should I be worried about taking this medicine?

If you are still worried after reading this leaflet, please talk to your doctor or pharmacist. They are looking after you and have thought carefully about the best medicine for you.

What if I don't want to take an unlicensed medicine?

Talk it over with your doctor (or pharmacist) and tell them what you are worried about and they will be happy to discuss your concerns. They can also tell you about other available treatments and why they think this is the best one for you.

Can I get more information about my unlicensed medicine?

Your pharmacist may have a special information leaflet about your medicine or illness, please ask. Often there are support groups for people with a particular illness or condition. If you are a member, you could talk to someone from that group. If you are not a member or don't know if there is a group, ask your doctor, nurse or pharmacist for information. If you are unsure or have any further questions, please contact the doctor or pharmacist in charge of your care who prescribed the medication.

Patient Information

Contact information

Medicines Helpline

Cheltenham General Hospital

Tel: 0300 422 2805

Monday to Friday, 3:00pm to 4:00pm

Gloucestershire Royal Hospital

Tel: 0300 422 6837

Monday to Friday, 10:00am to 11:00am

Content reviewed: February 2025

Making a choice

Shared Decision Making

If you are asked to make a choice, you may have lots of questions that you want to ask. You may also want to talk over your options with your family or friends. It can help to write a list of the questions you want answered and take it to your appointment.



Ask 3 Questions

To begin with, try to make sure you get the answers to three key questions if you are asked to make a choice about your healthcare.

1. What are my options?
2. What are the pros and cons of each option for me?
3. How do I get support to help me make a decision that is right for me?

These resources have been adapted with kind permission from the MAGIC Programme, supported by the Health Foundation

* Ask 3 Questions is based on Shepherd HL, et al. Three questions that patients can ask to improve the quality of information physicians give about treatment options: A cross-over trial. Patient Education and Counseling, 2011;84: 379-85



<https://aqua.nhs.uk/resources/shared-decision-making-case-studies/>