

Information about unlicensed medicines

This leaflet is for patients and relatives and explains why medicines are licensed and why some useful medicines do not have licences. You have been given this leaflet because some medicines prescribed in the Trust are not 'licensed'. We want to reassure you that we have thought very carefully about the best medicine for you, and to answer any questions you may have.

This information has been produced by the Pharmacy Department.

What are medicines?

Medicines are used to detect, treat or prevent disease; provide contraception; 'put you to sleep' during an operation or bring about changes in bodily functions. In the UK most medicines are 'licensed' but some are not.

Why are medicines 'licensed'?

Before a medicine is allowed to be marketed in the UK, drug companies must ask the Medicines and Healthcare Products Regulatory Agency (MHRA), a part of the Department of Health, for a 'licence' for the medicine.

The company has to show the MHRA that the medicine works well, does not have too many side effects and has been made to a high standard.

How are medicines tested?

To be sure that a medicine works and is safe, medicines are first tried on volunteer groups of patients in what is called a 'clinical trial'. The information from the trials, together with details of how the medicine is made, how the medicine is to be used, and the leaflets to be provided to doctors and patients are all given to the MHRA for approval. If approved, the medicine is given a 'licence'. This will specify the purposes for which the medicine is to be used and, sometimes, the categories of patients it is intended to be used for.

Why aren't all medicines covered by a 'licence'?

There are many reasons why, but they can be put into two main groups.

The first group is where medicines are used for illnesses, conditions, diagnostic tests or age groups not covered by their licence. Sometimes the 'licence' is for one illness but doctors find it works very well for another condition. The clinical trial may only have been performed with a set age group of patients but doctors find it works very well for other age groups too. This is often called 'off label' use.

The second group is where medicines have no licence at all.

They may be:

- Medicines licensed in other countries.
- Medicines made when it is too expensive to obtain a licence.
- Medicines prepared to order so it is suitable for the patient, e.g. liquids made from tablets.
- Medicines readymade for use in hospitals, to reduce risks of infection or errors in preparation.
- Medicines that are still in 'clinical trial', but have been shown to be of benefit in treating disease.
- Some items are marketed as foods or cosmetics and will not have a 'licence'.

How do I know that these medicines are safe and will work?

Doctors think carefully about using such medicines and will have read information and taken recommendations from other specialists to confirm that the medicine would be right for you.

Pharmacists will confirm that the medicine is appropriate for you.

In addition, all unlicensed medicines used within the Trust and supplied by the Trust's Pharmacy Department are checked by specialist pharmacy staff to ensure that they are made to a high standard.

How will I know if my medicine is not licensed?

Your doctor or pharmacist should tell you or when you read the information leaflet with the medicine you may notice that the information is not quite 'right'. The leaflet may not talk about your particular illness or condition or it may say that it should not be used for your age group.

Unlicensed medicines may be made to order and may take longer to obtain. Pharmacy can provide information on this to you, your GP or your local pharmacy if required.

What should I do if I'm worried about taking these medicines?

Doctors and pharmacists have a lot of experience with medicines, whether licensed or not, and will have thought very carefully about the best medicine for you. If you are worried, please talk to your doctor (or pharmacist). They can tell you more about the medicine. They can also tell you about all the treatments available and why they think this is the best one.

Can I get more information about my unlicensed medicine?

Please ask your doctor or pharmacist - they may have a special information leaflet. Often there are patient support groups and if you are a member you could talk to someone from the group. If you are not a member or don't know if there is a group, ask your doctor, pharmacist or nurse for more information.

Royal Berkshire NHS Foundation Trust, London Road, Reading RG1 5AN

Telephone 0118 322 5111 www.royalberkshire.nhs.uk

This document can be made available in other languages and formats upon request.

Written July 2007

Reviewed: March 2018. Review due: March 2020