

## Introduction

You might have been given this leaflet because your doctor has prescribed a medicine for you that is to be used beyond the conditions of its licence (called using a medicine outside its licence). You should be reassured that your medical team will have thought carefully about which medicines are best for you in your situation.

This leaflet will help you to understand some important aspects of medicine licensing regulations and how these issues might affect you. If you have any questions about any aspect of your medication you should ask your healthcare team.

## What is the licensing process?

Most medicines prescribed by a doctor or bought over the counter from a pharmacist have a licence for use. When a manufacturer produces and sells any medicine in the UK they must first obtain a licence (called a product licence or marketing authorisation) from the Medicines Control Agency.

The licence describes the way in which the drug can be given, what conditions it can be used to treat, the doses that can be given and which patients can be treated. To obtain

a licence, the manufacturer must prove that the medicine works in the condition for which it is to be given, that it does not have too many side effects or risks and that it has been manufactured to a high standard.

The process of obtaining a licence is very expensive for the manufacturer. The licence is there to restrict the way in which the manufacturer promotes and sells the drug. The licensing process does not restrict the prescribing of any medicine by a doctor provided the doctor has assured themselves that the medicine is safe and effective for that patient.

## Why are medicines sometimes used outside their licence?

Sometimes a medicine has been licensed for a certain use and later experience or research shows that it works for other conditions. There is no legal requirement for the medicine manufacturer to apply to the Medicines Control Agency to try to have the more recent information added to the licence. In some situations it is not economical for the manufacturer to obtain or extend a licence.

There is a legal obligation for the manufacturer to include a Patient Information Leaflet with all medicines. This leaflet must be given to you and it must only contain the information from the licence. Therefore some

of the uses for the medicine will not appear on the Patient Information Leaflet. This can be confusing for patients and their carers.

An example of this is the common use of antidepressant medicines to treat pain. These medicines have a licence for use in depression, but not in pain – so the information leaflet will talk about depression and not refer to pain. This happens purely because the Patient Information Leaflet reflects the licence. If you are given an antidepressant drug it does not necessarily mean that your doctor has decided you are depressed. If he thought you were depressed, he would have discussed this with you.

Examples of other circumstances where medicines may be used outside their licence include:

- Medicines licensed for use in certain age groups that are used in a different age group
- Medicines licensed for use at one dose that are used at a different dose
- Medicines licensed for use by injection that are given as tablets
- Medicines that do not have a licence for a disease because it is so rare

## Can doctors prescribe medicines outside their licence?

It is legal for a doctor to prescribe a medicine outside its licence. A pharmacist can legally dispense and a nurse can legally administer these medicines. It is common for medicines to be used in this way outside their licence.

For example, in specialist palliative care, up to two thirds of patients receive medicines that are not licensed for that indication. Doctors usually only do this when there is clinical experience or research to support such use and when there is no suitable licensed alternative medicine.

## How will I know if the medicines I have been prescribed are outside their licence?

Your doctor, pharmacist or nurse may tell you this. However in pain management and palliative care practice the use of medicines outside their licence is very common and so your health care team may not refer to this specifically. The health care team has a lot of experience using medicines in this way. They will have considered very carefully what is best for you.

It is very important that you receive a clear explanation of the reasons that you are

taking any medicines, how you should take your medicines, and what benefits and side effects might be expected. This is just as important when medicines are used according to the licence as when they are used outside their licence. As with all medicines, if you believe you experience a side effect from this medicine, you should inform your health care team.

Your verbal agreement should be obtained, whenever possible, before prescribing any medicine. It is often unnecessary to take additional steps when prescribing medicines outside their licence.

## What should I do if I'm unsure about my medicines?

If you are still unsure or worried about your medicines after reading this leaflet, please talk to your health care team about your concerns. The doctors, pharmacists, and nurses will be able to answer your questions and provide further information if necessary.

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*Copies of this leaflet can be downloaded from:*  
**[www.painsociety.org](http://www.painsociety.org)**  
**[www.palliative-medicine.org](http://www.palliative-medicine.org)**

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# THE USE OF MEDICINES BEYOND LICENCE

# Information for Patients

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