

Using medicines outside their licence

Before medicines can be used they have to be licensed for use by the Medicines and Healthcare product Regulatory Agency (MHRA) or the European Medicines Agency (EMA).

Medicines prescribed by a doctor, and those you can buy over the counter at a pharmacy, are licensed in this way. The licence shows the conditions that a medicine can be used to treat, what type of patients it can be given to, and the doses that should be used. This information is in the Patient Information Leaflet (PIL) which is included with every medicine.

What is meant by 'using medicines outside their licence'?

This is also known as off-label use. It means that a medicine is being used:

- In doses outside the range stated in the licence
- For a different patient group e.g. children rather than adults
- As a generic medicine (medicines not having a trademark or brand name) for conditions not included in the licence
- For conditions for which there are no other treatments
- Administered in a different way, such as giving an injection orally or crushing a tablet before the patient takes it

Is it common for medicines to be used outside their licence?

It is very common in some areas such as palliative care, pain management and paediatrics for medicines to be used outside of their licence.

What is an unlicensed medicine?

An unlicensed medicine is one which does not have a licence within the UK. This applies to:

- A mixture of two or more medicines in a syringe pump or mixing medicines before they are given in an injection
- A medicine manufactured specifically for your use by a pharmacist
- Medicines that have a licence in another country but not in the UK
- A medicine bought from a 'specials medicines' manufacturer (specials are products which have been specially manufactured or imported for the treatment of an individual patient)
- New drugs undergoing clinical trials
- Medicines where the licence has been suspended or not renewed

Prescribing off-label or unlicensed medicines

In this country, doctors may legally prescribe medicines outside their licence.

Other health professionals such as pharmacists or nurses may also prescribe off-label or unlicensed medicines as long as it is within their area of expertise. They are responsible for the consequences.

Specialist services recommending the use of such medicines to other doctors involved in your treatment should explain why this is necessary but they can decline to prescribe them.

