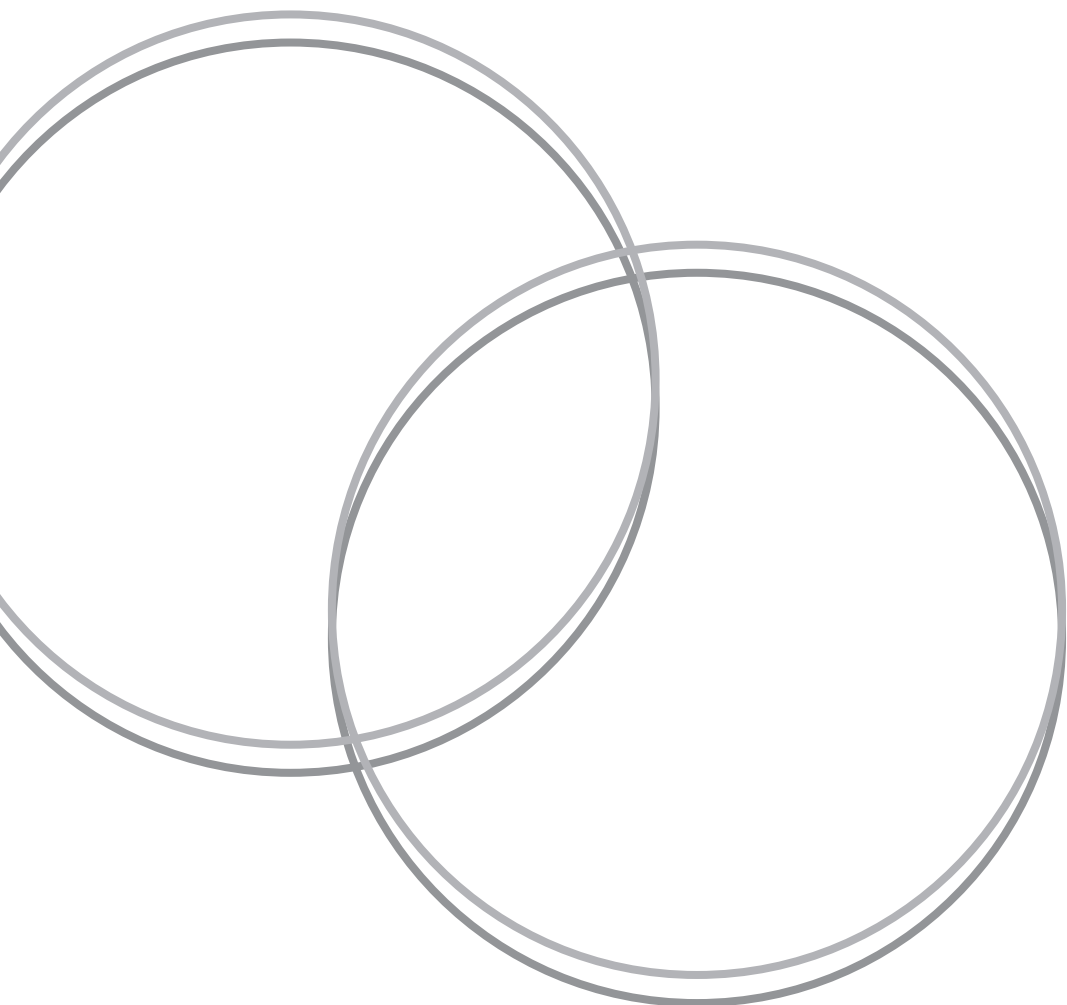


# Unlicensed and “Off-label” Medicines

Information for patients, parents and carers



## **What is this leaflet about?**

This leaflet explains what 'unlicensed' and 'offlabel' mean and why some medicines are used in this way. You may wish to discuss this further with your doctor, pharmacist, or healthcare professional that is responsible for your care.

## **What is a medicine?**

Medicines are products used to prevent or treat a medical condition. They can in many forms for example tablets, liquids, injections, creams and eye drops etc.

## **What is a licence?**

A drug company must have a product licence, sometimes known as a Marketing Authorisation, to advertise and sell a medicine.

The licence states which illness the medicine can be used for how much can be used how to give the medicine which group of patients it can be given to.

The licence is provided by a government organisation called the Medicines and Healthcare products Regulatory Agency, also known as MHRA.

## **How does a drug company get a licence?**

To get a licence, the drug company must prove that the drug works for the illness or condition to be treated and is safe. They do this by testing in clinical trials, usually in adults aged 18-65 years. The MHRA issue the license only after the information from the clinical trials has been checked for quality, safety and the benefits of a medicine are believed to outweigh the risks.

The drug company cannot advertise or make any recommendations about using a medicine outside the terms of its licence.

The licensing process and clinical trials are very expensive. This means that once a medicine is on the market, the company may decide not to complete extra clinical trials if the medicine is found to treat other illnesses.

# What is meant by off-label and unlicensed use?

## **“Off-label”**

“Off-label” use means that the medicine is being used in a way that is different to that described in the licence. Some examples of “off-label” uses are:

- Using a medicine for a different illness to that stated in the licence. Doctors may have found that the medicine works very well for this illness or condition. This use may be supported by expert groups, but the drug company has not applied for a license to treat this illness or condition
- Using a medicine in an age group outside the licensed range (usually children or the elderly)
- Using a medicine at a higher dose than stated in the licence.

## **Unlicensed**

- A medicine has a licence in other countries, but not the UK. It has to be imported because it is not available in the UK
- The medicine needs to be made up as a special product because it is not readily available. This is often the case for liquid formulations of medicines which only have a license for the tablet form
- A medicine that has no licence at all. These are often medicines used for treating rare illnesses. The manufacturer may have decided that it was too expensive to carry out the clinical trials or it would be difficult to find enough patients for the clinical trials needed to get a licence.

## **How do I know that an “off-label” or unlicensed medicine is safe and will work?**

Unlicensed and “off-label” medicines are only prescribed after careful consideration of other options available. Your doctors will have reviewed medical publications supporting its use, and may have taken advice from other experts. An unlicensed or “off-label” medicine will only be used if it is the most appropriate medicine for you and your illness or condition.

## **How do I know whether a medicine is unlicensed or being used “off-label”?**

Your doctor, pharmacist or healthcare professional that is responsible for your care will tell you that the medicine is not licensed or is being used outside of its license. The patient information leaflet that comes with the medicine may not say anything about how you should use it, or may say that the medicine is not suitable for being used in the way it has been prescribed for you. This does not mean that it cannot be used safely to treat your condition – it means that the drug company does not have a licence for using it in this way and so is not allowed to recommend this use.

## **Where can I get information about unlicensed and “off-label” medicines?**

Your doctor, pharmacist or healthcare professional that is responsible for your care will be able to tell you more about the medicine.

Medicines for Children ([www.medicinesforchildren.org.uk](http://www.medicinesforchildren.org.uk)) produce leaflets that are written especially for parents and carers of children who are being prescribed unlicensed medicines.

## **What else do I need to know?**

Sometimes it will take longer for the pharmacy to get you a supply of an unlicensed medicine. This means that you will need to also allow one or two weeks for them to get you further supplies of your medicine.

If you need any further information about your medicine, please contact:

### **Patients Medicine Helpline**

Tel: **01865 228 906**

This service is available: Monday to Friday 9am-5pm

The helpline will not be able to answer questions about your illness in general or other people's medications without their permission.



## Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

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