Unlicensed medicines and ‘off-label’ uses

What is this leaflet about?
Sometimes a medicine is prescribed in a way that is not covered by its UK marketing licence. This does not mean that it is unsafe for this use. This leaflet explains in more detail what ‘unlicensed’ means and why some medicines are used in this way. You may wish to discuss this further with your doctor or pharmacist.

What is a medicine?
‘Medicines’ are products used to prevent or treat a medical condition e.g. tablets, capsules, liquid medicines, injections, inhalers, creams, eye drops/ointments, suppositories, and patches.

What is a licence?
A drug company must have a product licence to advertise and sell a medicine. This will state which illness the medicine can be used for, the ages of the patients it can be used for, how much to give and how to give it. It is obtained from a government organisation called the MHRA (Medicines and Healthcare products Regulatory Agency).

How does a drug company get a licence?
To get a licence, the drug company must prove that the drug works for the illness to be treated and is safe to use. This is done by trying it first in clinical trials, usually in adults aged 18-65 years. Information from the clinical trials is then given to the MHRA when the drug company applies for a licence.

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. Once a drug is on the market, the company may decide, on cost grounds, not to try getting the original licence extended.

What is meant by unlicensed or ‘off-label use’?
‘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 an illness different to that stated in the licence. Doctors may have found that the medicine works very well for this condition, and the use may be supported by expert groups, but the drug manufacturer has not extended the licence.
- Using a medicine in an age group outside the licensed range (i.e. children, or the elderly).
- Using a medicine at a higher dose than stated in the licence. Some people need these higher doses because their body metabolises the drug quickly.

Some examples of unlicensed medicines are:
For more information, ask one of the health professionals involved in your care (e.g. doctor, pharmacist or nurse).
You can also telephone Fulbourn Hospital pharmacy department on 01223 218518. www.cpft.nhs.uk
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- A medicine that has to be imported because it is not available in the UK.
- A specially-prepared liquid form of a medicine for someone who has difficulty swallowing the licensed tablets.
- Some medicines have no licence at all, e.g. those 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 will I know that a medicine is not licensed?**
Your doctor or pharmacist should tell you. Also, you read the manufacturer’s information leaflet you may notice that some of the information does not seem to apply to you (e.g. it may not mention your illness).

If an unlicensed medicine has to be specially prepared or imported, it may be more difficult to obtain. Your pharmacist should tell you this and make sure you know how to get your medicine.

**How do I know that an unlicensed medicine is safe and will work?**
Unlicensed medicines are only prescribed after careful consideration of other options. Your doctor will have read information from medical publications supporting its use, and may have taken advice from other experts.

**Where can I get more information about my unlicensed medicine?**
The Choice and Medication website has leaflets about a wide range of individual medicines used in mental health, and this includes some unlicensed medicines and off-label uses:
http://www.choiceandmedication.org/cambridgeshire-and-peterborough/

You can also ask your doctor or pharmacist.