



THE BRITISH PAIN SOCIETY



Using medicines beyond licence

Information for patients

Prepared on behalf of
the Association for Palliative Medicine and the British Pain Society.

November 2005

To be reviewed in November 2008.

Copyright: The Association for Palliative Medicine and the British Pain Society, 2005

Published by:
The British Pain Society
21 Portland Place
London
W1B 1PY.

Website: www.britishpainsociety.org

First published by the Pain Society, January 2003
First revised edition, November 2005

ISBN 0-9546703-9-6

Contents

Introduction	1
What is the licensing process?	1
Why are medicines sometimes used outside their licence?	1
Can doctors prescribe medicines outside their licence?	3
How will I know if the medicines I have been prescribed are outside their licence?	3
What should I do if I'm not sure about my medicines?	4
The working party	5

Introduction

You might have been given this leaflet because your doctor has prescribed a medicine for you that you need to use beyond the conditions of its licence (called using a medicine outside its licence). 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 health-care 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 get a licence (called a product licence or marketing authorisation) from the Medicines and Health products Regulatory 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 get a licence, the manufacturer must prove that the medicine:

- works to treat the condition for which it is to be given;
- does not have too many side effects or risks; and
- has been made to a high standard.

It is very expensive for a manufacturer to get a licence. The licence is there to restrict the way in which the manufacturer promotes and sells the drug. The licensing process does not restrict any doctor from prescribing the medicine, as long as the doctor is sure 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. The medicine manufacturer does not have to apply to the Medicines and Health products Regulatory Agency to try to have the more recent information added to the licence. In some situations, it is not economical for the manufacturer to get or extend a licence.

By law, the manufacturer must 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. So, 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 to be used for depression but not for 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 your doctor thought you were depressed, they 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; and

- 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 (give) these medicines. It is common for medicines to be used in this way outside their licence.

For example, in specialist palliative care (specialist services that look after patients at the end of their life), up to two thirds of patients receive medicines that are not licensed for their condition. Doctors usually only do this when there is clinical experience or research to support the 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, it is very common for medicines to be used outside their licence so your health-care team may not refer to this specifically. The health-care team has a lot of experience in 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 why you are taking any medicines, how you should take your medicines, and what benefits and side effects you might expect. 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 experience a side effect from this medicine, you should tell your health-care team.

Your health-care team should get your verbal agreement, whenever possible, before prescribing any medicine. It is often unnecessary to do anything else when prescribing medicines outside their licence.

What should I do if I'm not sure about my medicines?

If you are still not sure about your medicines, or are worried about anything after reading this leaflet, please talk to your health-care team. The doctors, pharmacists and nurses will be able to answer your questions and give you any more information you need.

You can download copies of this leaflet from:

- www.britishpainsociety.org; and
- www.palliative-medicine.org.

The working party

Below is a list of the members of the joint working party of the Association for Palliative Medicine and the Pain Society (now known as the British Pain Society), who worked on this information about using drugs beyond licence in palliative care and pain management.

Chairmen

Dr M Bennett, Consultant in Palliative Medicine
Association for Palliative Medicine (APM)

Dr K H Simpson, Consultant in Pain Medicine
The Pain Society

Members

Professor S Ahmedzai, Professor of Palliative Medicine
Association for Palliative Medicine

Mrs E Brain, Lay Member
Patient Liaison Committee of The Pain Society

Dr M Branthwaite, Retired Barrister
Former consultant in Anaesthesia, Intensive Care
and Respiratory Medicine

Dr P D Collins, Consultant in Pain Medicine
The Pain Society

Mrs S Conroy, Lecturer in Paediatric Clinical Pharmacy

Dr A Franks, Consultant in Public Health Medicine
Deputy Medical Director, Acute Hospital Trust

Dr D M Justins, Consultant in Pain Medicine
The Pain Society

Dr C Stannard, Consultant in Pain Medicine
The Pain Society

Mrs T Towell, Nurse Consultant

Dr J Wedley, Consultant in Pain Medicine
Association of Anaesthetists of Great Britain and Ireland



THE BRITISH PAIN SOCIETY

21 Portland Place London W1B 1PY

T: 020 7631 8870 F: 020 7323 2015

www.britishpainsociety.org E: info@britishpainsociety.org