



# The Use of Drugs Beyond Licence in Palliative Care and Pain Management

A Position Statement Prepared on Behalf of  
The Association for Palliative Medicine and The Pain Society



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# **THE USE OF DRUGS BEYOND LICENCE IN PALLIATIVE CARE AND PAIN MANAGEMENT**

**A position statement prepared on behalf of the  
Association for Palliative Medicine and The Pain Society**

This statement summarises the views of the Association for Palliative Medicine (APM) and The Pain Society in relation to the use of drugs beyond their product licence (or marketing authorisation) in clinical practice. It is the result of conferences held by the Science Committee of the APM on May 23<sup>rd</sup> 2001, and a joint meeting between the APM and The Pain Society held on October 10<sup>th</sup> 2001. The purpose of the meetings was to discuss the clinical and legal implications of using drugs beyond licence in relation to patients, carers, professionals, and provider organisations.

**The recommendations of the Association for Palliative Medicine and The Pain Society are that:**

1. *This statement should be seen as reflecting the views of a responsible body of opinion within the clinical specialities of palliative medicine and pain management.*
2. *The use of drugs beyond licence should be seen as a legitimate aspect of clinical practice.*
3. *The use of drugs beyond licence in palliative care and pain management practice is currently both necessary and common.*
4. *Choice of treatment requires partnership between patients and healthcare professionals, and informed consent should be obtained, whenever possible, before prescribing any drug. Patients should be informed of any identifiable risks and details of any information given should be recorded. It is often unnecessary to take additional steps when recommending drugs beyond licence.*
5. *Patients, carers, and health care professionals need accurate, clear and specific information that meets their needs. The Association for Palliative Medicine and The Pain Society should work in conjunction with pharmaceutical companies to design accurate information for patients and their carers about the use of drugs beyond licence.*
6. *Health professionals involved in prescribing, dispensing and administering drugs beyond licence should select those drugs that offer the best balance of benefit against harm for any given patient.*
7. *Health professionals should inform, change and monitor their practice with regard to drugs used beyond licence in the light of evidence from audit and published research.*
8. *The Department of Health should work with health professionals and the pharmaceutical industry to enable and*

*encourage the extension of product licenses where there is evidence of benefit in circumstances of defined clinical need.*

9. *Organisations providing palliative care and pain management services should support therapeutic practices that are underpinned by evidence and advocated by a responsible body of professional opinion.*
10. *There is urgent need for the Department of Health to assist health care professionals to formulate national frameworks, guidelines, and standards for the use of drugs beyond licence. The Pain Society and the APM should work with the Department of Health, NHS Trusts, voluntary organisations, and the pharmaceutical industry to design accurate information for staff, patients, and their carers in clinical areas where drugs are used off label. Practical support is necessary to facilitate and expedite surveillance and audit which are essential to develop this initiative.*

## **CURRENT PRACTICE**

### **Definitions**

The Medicines Control Agency in the UK grants a product licence for a medical drug. The purpose of the drug licence is to regulate the activity of the pharmaceutical company when marketing the drug. The licence does not restrict the prescription of the drug by properly qualified medical practitioners. Licensed drugs can be used legally in clinical situations that fall outside the remit of the licence (referred to as 'off-label'), for example a different age group, a different indication, a different dose or route or method of administration. Use of unlicensed drugs refers to those products that have no licence for any clinical situation or may be in the process of evaluation leading to such a licence. Sometimes off-label drugs are used because manufacturers have not sought to extend the terms of the licence for economic reasons, where costs are likely to exceed financial return.

### **Clinical perspective**

A recent audit in palliative care found that off-label use is common (around 25% of prescriptions affecting 66% of patients in one specialist palliative care unit), but use of unlicensed drugs is rare. This is similar to paediatric clinical practice where audits in the UK and Europe have shown that 39-55% of prescriptions were off-label, and 7-10% of prescriptions were for unlicensed drugs. At least two thirds of children receive an off-label or unlicensed drug during an inpatient admission.

Recommendations from bodies such as the General Medical Council and the Medical Defence Organisations place a duty on doctors to act responsibly, and to provide information to patients on the nature and associated risks of any treatment, including off-label and unlicensed drugs. Furthermore, the guidance recommends that such drugs should be prescribed by a consultant or GP, following informed consent by the patient, and that this decision be recorded in the patient's notes. A survey of senior doctors working in Palliative Medicine revealed that 97% of respondents did not operate a policy in these circumstances, 93% did not limit prescribing to consultants in this way and only 4% always obtained verbal consent when using off-label drugs.

It is now a requirement for medication to be dispensed with written information provided by the manufacturer. The information refers only to indications, doses, and routes of administration for which the drug has a licence. This can lead to poor concordance with medication regimens. Patients may become anxious, and less experienced health care professionals may be confused, by conflicting information given verbally by prescribers and in written form by pharmacists. A good example is the well-established use of antidepressants or anticonvulsants for pain management, when pharmacists are compelled to give patients the information leaflet about the licensed indications, namely depression and epilepsy. The Pain Society and the APM believe that there is a need to design accurate information for patients and their carers about the use of drugs beyond licence and are seeking support in this endeavour.

### **Non-clinical perspective**

The primary medico-legal issues raised by the use of drugs beyond licence relate to consent from patients and the legal defence of the doctor's practice.

Consent is valid legally only if given by a person who is adequately informed, acting voluntarily and is competent to decide (i.e. can understand the information, retain and believe it, and use it to reach a reasoned conclusion). When these criteria cannot be fulfilled, treatment is only legally valid if given for conditions needing immediate treatment, (the doctrine of necessity). In practice, non-urgent treatment is often provided to patients who cannot give valid consent. The practitioner is expected always to act in the patient's best interests and it is both customary and courteous to discuss unusual or invasive treatments with relatives who may help refine understanding of what the incompetent patient would have chosen. However, relatives cannot, at present, provide legally valid consent on behalf of an incompetent adult. Treatment given in these circumstances is not necessarily unlawful, it is merely not protected by legal authority. In exceptional cases involving particularly sensitive treatment the guidance of the court should be sought. Specific, written consent should always be sought for the use of new drugs or drugs used innovatively, but seeking written consent is not practical in clinical circumstances where the use of off-label medications is routine, as may be the case in certain specialities.

The main concern of practitioners is that the use of unlicensed or off-label drugs could prompt legal action. A claim founded in negligence can only succeed if foreseeable injury has occurred as a consequence of breach of a duty of care. The standard expected of practitioners in the UK is primarily determined by the 'Bolam' principle (acting in accordance with a responsible body of medical opinion in that speciality), but current law requires that such opinion be logical and capable of withstanding critical questioning. A successful claim leads to an award of damages - financial compensation seeking to restore the claimant to the position he would have been in but for the negligent act. Life expectancy and loss of earnings are incorporated in the calculation of damages, so high value claims can easily arise from the management of chronic pain, but are most unlikely in palliative care. Low value claims are rarely pursued and often do not qualify for Legal Aid.

From an organisational perspective, the risks presented by staff (doctors, nurses and pharmacists) in using drugs beyond licence are best managed through a culture of clinical governance. Organisations should encourage staff to educate themselves and take responsibility for their own decisions within the framework of a corporate policy. There should be mechanisms in place to inform, change, and monitor clinical practice. Organisations should also learn from the airline industry where errors are viewed primarily as system errors rather than personal errors. Organisations should examine clinical errors with the object of establishing procedures that reduce the chance of that error being repeated. The National Patients Safety Agency encompasses this philosophy. Clinical governance should be viewed as a process for creating improved clinical outcomes and not used as a barrier to informed and risk managed practice. This process requires practical support from the Department of Health.

## **Members of the Joint Working Party of the APM and The Pain Society on the Use of Drugs Beyond Licence in Palliative Care and Pain Management**

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