This is an up-date of the statement that appears in Medicines for Children, and will appear in the next revised edition.

This statement has been drawn up by the Standing Committee on Medicines, a joint committee of the Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacists Group. It aims to inform and guide health professionals and parents who prescribe, dispense or administer medicines for children, and health service managers who have a responsibility to support them. The statement forms part of the introduction to Medicines for Children, the first national paediatric formulary offering guidance on the use of therapeutic drugs given to children.

The recommendations of the Committee are that:

● Those who prescribe for a child should choose the medicine which offers the best prospect of benefit for that child, with due regard to cost.

● The informed use of some unlicensed medicines or licensed medicines for unlicensed applications is necessary in paediatric practice.

● Health professionals should have ready access to sound information on any medicine they prescribe, dispense or administer, and its availability.

● In general, it is not necessary to take additional steps, beyond those taken when prescribing licensed medicines, to obtain the consent of parents, carers and child patients to prescribe or administer unlicensed medicines or licensed medicines for unlicensed applications.

● NHS Trusts and Health Authorities should support therapeutic practices that are advocated by a respectable, responsible body of professional opinion.

Licensing

1 For a medicine to be marketed in the United Kingdom it must have received a Product Licence, now called a marketing authorisation. It is then said to be licensed. Many medicines that are given to children are not licensed for the particular indication, age of the child, suitable formulation, or route of administration. This position arises when a pharmaceutical company has made an application to the Licensing Authority for a marketing authorisation for use of the medicine in adults, but chooses not to make an application for the use of that medicine in particular ways in children. Certain medicines that are given to children have not received a licence for any indication, and are said to be unlicensed.

2 The use of unlicensed medicines or licensed medicines for unlicensed applications is necessary in paediatric practice when there is no suitable alternative. Such uses are informed and guided by a respectable and responsible body of professional opinion.

3 The Medicines Act and Regulations (which incorporate the relevant EC directives) provide exemptions which enable doctors to:

● prescribe unlicensed medicines;
● use in particular (named) patients, unlicensed products specially prepared, imported or supplied;

● use medicines which are not authorised to be marketed, in clinical trials, after approval of the trial by the Medicines Control Agency (MCA) either through the Doctors and Dentists Exemption Scheme or, in the case of pharmaceutical industry sponsorship, through the Trials Certificate (Exemption) Scheme;

● use or advise the use of licensed medicines for indications, or in doses, or by routes of administration, outside the recommendations of the licence;

● override the warnings and the precautions given in the licence.

4 In each case, the doctor has to be able to justify the action taken as being in accordance with a respectable, responsible body of professional opinion.

The informed use of unlicensed medicines or of licensed medicines for unlicensed applications is necessary in paediatric practice.

Sources of information

5 Although the choice of a medicine is not necessarily determined by its licence status, it will take account of information made available as a consequence of licensing and contained in the marketing authorisation. When the Product Licence does not include indications for use in children, the marketing authorisation is of limited help. When the medicine is unlicensed, the necessary information must be sought elsewhere. It often is available, though might not be readily accessible.

6 To meet the need for accessible sound information and guidance the Committee has undertaken the preparation of a new formulary, *Medicines for Children*. The standing of its contributors and of those who undertake independent review will ensure that it is an authoritative statement of paediatric therapeutic practice in this country.

Information for other health professionals and the public

7 Parents, patients and teachers, and others in loco parentis, require information about medicines from health professionals, including general practitioners, paediatricians, nurses, health visitors, and pharmacists. The information must be given in a way they can understand, and be accurate and consistent. This is particularly important when the specialist who has advised the use of unlicensed medicines or licensed medicines for unlicensed applications, hands over the care of the patient and responsibility for the administration of the medicine to someone else. Given the complexity of therapeutic and pharmacological information, and the burdens upon those giving and receiving it, the need is for sound, practical and sensible arrangements for communication, supplemented by readily available sources of reference.

It is essential that health professionals should have ready access to sound information on any medicine they prescribe, dispense or administer, and on its availability.

Consent of parents, carers and patients

8 Health professionals must respect the right of child patients and their parents to participate in decisions on the health care of the child, and seek to ensure that those decisions are properly informed. In normal paediatric practice no additional steps, beyond those taken when prescribing licensed medicines, are required to obtain the consent of patients and parents / carers for the use of unlicensed medicines.

9 Clinicians are anxious that the licence status of a drug should not be perceived as reflecting what is or is not best for the child. They are mindful of a possible impact upon the confidence of parents and patients who might then be reluctant to accept advice, with consequences for a child who might not receive a medicine that offers benefit.
Most licensed medicines are dispensed in standard packages together with a Patient Information Leaflet (PIL) approved by the Licensing Authority. When the licence does not include indications for children, the PIL may caution against such use. Naturally, this may undermine confidence in the advice given by health professionals, besides provoking a call for explanation. The Committee has produced two generic PILs, for patients and parents/carers respectively, which explains why it may be necessary to prescribe unlicensed medicines or to use licensed medicines for unlicensed applications. This leaflet will be made widely available to hospitals and pharmacies and may be of practical value in such situations.

There are circumstances when a clinician will decide to give fuller information than is usually judged necessary. These may arise when a medicine is new or experimental; or carries known or possible risks of harm, even if those risks are small in relation to the disorder to be treated; or when the concerns of some parents, carers or patients generate a need for more detailed discussion and explanation on the medicines that are prescribed. In each instance, practice is guided by clinical judgement.

We consider that in general it is not necessary to take additional steps, beyond those taken when prescribing licensed medicines, to obtain the consent of parents, carers and child patients to prescribe or administer unlicensed medicines or licensed medicines for unlicensed applications.

Policies of NHS Trusts

Some NHS Trusts have suggested that a clinician should not use an unlicensed medicine, or a licensed medicine for unlicensed application. In 1993 the Department of Health stated that it would not expect that a health authority would seek to fetter a clinician’s freedom to prescribe by expressly directing its medical staff against prescribing unlicensed products or licensed products for unlicensed purposes. The Department of Health’s lawyers also stated that, should a health authority so direct its medical staff, a court would be reluctant to support the authority in those circumstances.

However the emphasis on risk management and evidence based medicine in Clinical Governance’s framework implies that Trusts may be encouraged to introduce systems and protocols to monitor, and even direct, the use of both licensed and unlicensed medicines. We understand that, because the Medicines Act’s (1968) exemptions remain current, the courts would not hold the prescription of an unlicensed medicine to be a breach of the duty of care, if that treatment was supported by a respected body of medical opinion. The best evidence available should always inform the prescription of medicines for children.

We consider that NHS Trusts should support therapeutic practices that are advocated by a respectable, responsible body of professional opinion.

References


