

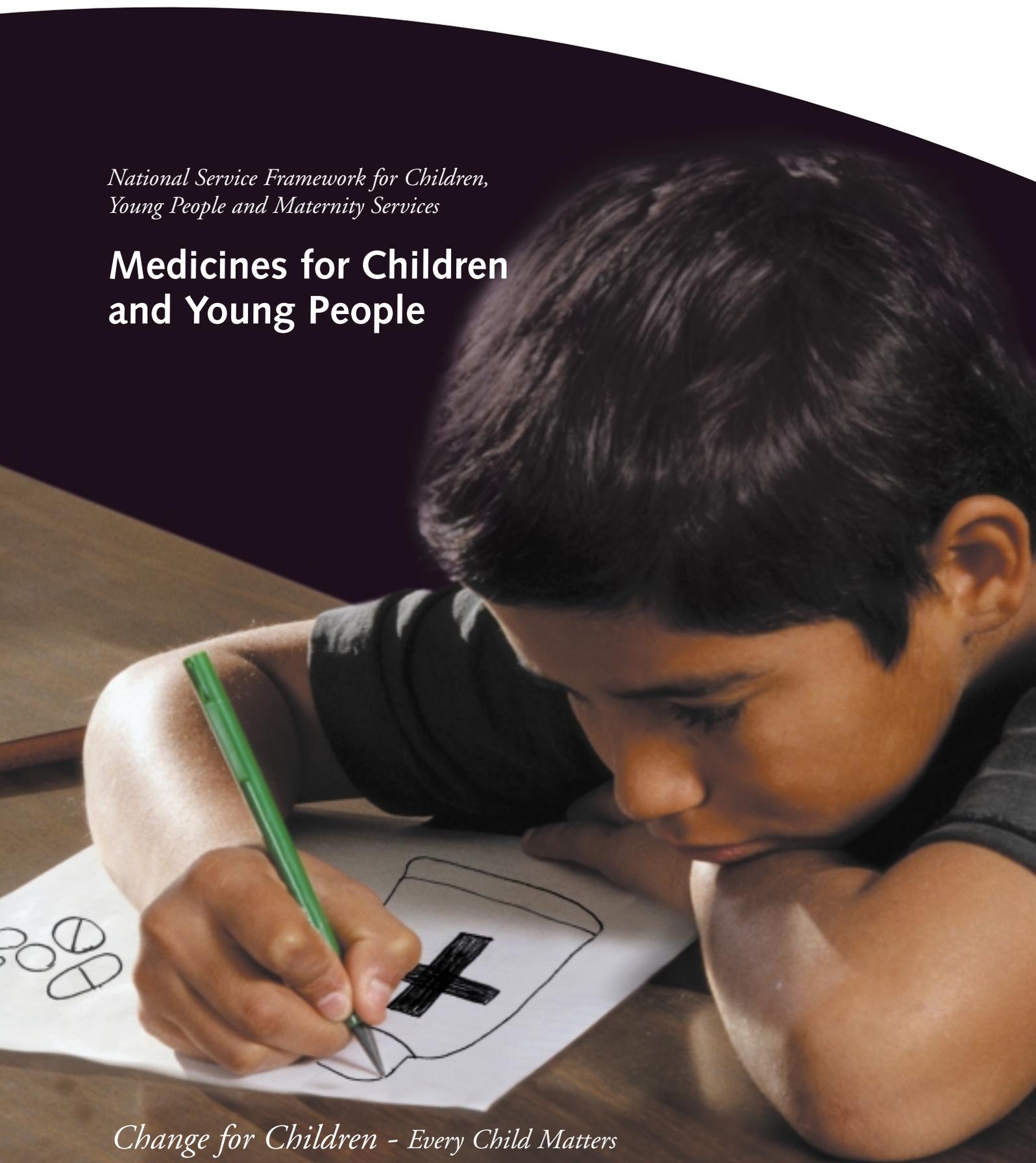
department for

**education and skills**



*National Service Framework for Children,  
Young People and Maternity Services*

## **Medicines for Children and Young People**



*Change for Children - Every Child Matters*

<b>Policy</b>	<b>Estates</b>
<b>HR/Workforce</b>	<b>Performance</b>
<b>Management</b>	<b>IM &amp; T</b>
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# Standard 10: Medicines for Children and Young People

## 1. Introduction

1.1 The National Service Framework for Children, Young People and Maternity Services establishes clear standards for promoting the health and well-being of children and young people and for providing high quality services which meet their needs.

1.2 There are eleven standards, of which this is the tenth. They cover the following areas:

**Standard 1** Promoting Health and Well-being, Identifying Needs and Intervening Early

**Standard 2** Supporting Parenting

**Standard 3** Child, Young Person and Family-centred Services

**Standard 4** Growing Up into Adulthood

**Standard 5** Safeguarding and Promoting the Welfare of Children and Young People

**Standard 6** Children and Young People who are Ill

**Standard 7** Children and Young People in Hospital

**Standard 8** Disabled Children Young People and those with Complex Health Needs

**Standard 9** The Mental Health and Psychological Well-being of Children and Young People

**Standard 10 Medicines for Children and Young People**

**Standard 11** Maternity Services

1.3 This chapter addresses the use of medicines for children and young people and should be read in conjunction with all the other Standards. The use of medicines in pregnancy is addressed in Standard 11.

1.4 Use of medicines is an integral component of each of the National Service Framework standards. There are medicines elements which apply to every standard, for example, ensuring children and young people in all settings have access to safe and clinically effective medicines in appropriate formulations; that staff are able to advise parents or carers and children and young people about their medicines, and that children, young people and their parents or carers have ready access to up-to-date information which is consistent and based on the best available evidence.

### **Vision**

#### **We want to see:**

- > All children and young people receiving medicines that are safe and effective, in formulations that can easily be administered and are appropriate to their age, having minimum impact on their education and lifestyle.
- > Medicines being prescribed, dispensed and administered by professionals who are well-trained, informed and competent to work with children to improve health outcomes and minimise harm and any side effects of medicines.
- > Children and young people and their parents or carers who are well-informed and supported to make choices about their medicines and are competent in the administration of medicines.

### **Standard:**

**Children, young people, their parents or carers, and health care professionals in all settings make decisions about medicines based on sound information about risk and benefit. They have access to safe and effective medicines that are prescribed on the basis of the best available evidence.**



### Markers of Good Practice

1. The use of medicines in children is based on the best available evidence of clinical and cost-effectiveness and safety, ideally derived from clinical trials, but also including, where appropriate, medicines that are not licensed for their age group or for their particular health problem ('off-label'), or those that do not have a licence at all ('unlicensed') in order to achieve the best possible health outcomes and minimise harm and side effects.
2. In all settings and whatever the circumstances, children and young people have equitable access to safe, clinically and cost-effective medicines in age-appropriate formulations.
3. Appropriate information and decision support is available for professionals who prescribe, dispense and administer medicines for children and young people.
4. Children, young people and their parents/carers receive consistent, up-to-date, comprehensive, timely information on the safe and effective use of medicines.
5. In all settings, professionals enable parents, young people and, where appropriate, children to be active partners in the decisions about the medicines prescribed for them.
6. Primary Care Trusts, NHS Trusts and other organisations ensure that the use of medicines in children is incorporated in their clinical governance and audit arrangements.
7. The contribution of pharmacists in the effective and safe use of medicines in children is maximised.

## 2. Rationale

- 2.1 Children are different from adults, their bodies respond to medicines differently from those of adults, and young children differently to older children. Thus detailed care and attention needs to be paid when making prescribing decisions for children and young people, taking into account their age, weight and developmental stage. Lack of evidence on the use of medicines in children and young people leads to uncertainty in dosing and, even at the most appropriate dose, may lead to differences in effectiveness and adverse effects to those seen in adults.
- 2.2 The evidence suggests that medication safety needs to be improved, particularly in babies and young children. In a hospital setting, medication errors in children occur at similar rates to adults but have three times the potential to cause harm.
- 2.3 When most new medicines are licensed or receive their Marketing Authorisation, they are only licensed for use in adults. This is because, on the whole, the manufacturer only investigates their safety and efficacy in the adult population. This may be either because there may be little commercial incentive to carry out studies in children, or because of an inability to recruit enough children into clinical trials. In 2004, the Government recognised the need for high quality research in children and young people and resolved to establish a national research network to study medicines for children.
- 2.4 Medicines prescribed for a child that are not licensed for that age group or for their health problem are referred to as 'off-label' and medicines that do not have a licence at all as 'unlicensed'. The *informed* use of unlicensed medicines or of medicines for unlicensed applications ('off label' use) is thus often unavoidable for children if they are to have access to the most effective medicines.
- 2.5 Misunderstanding the role of medicines in controlling long-term conditions leads to reduced compliance. It follows that better information, education and the involvement of parents and children in the decisions about their medicines should improve compliance, reduce the wastage of medicines and hence of NHS resources, improve quality of life and health outcomes.

Rates of compliance in children have been reported to range from 25-82%. There is evidence of adverse consequences because of low compliance in prophylactic antibiotic treatment, asthma, epilepsy and lymphoblastic leukaemia. Adolescence poses a special challenge when it comes to compliance with treatment; evidence shows low rates of compliance in, for example, cystic fibrosis, epilepsy, diabetes and asthma.

- 2.6 The age at which children are ready to take care of, and be responsible for, their own medicines, varies. Health professionals need to assess, with parents and children, the appropriate time to make this transition.
- 2.7 Some children and young people, particularly those who are disabled or have long term conditions, have to take medicines during the school day, and with some assistance from health, early years or school staff they are able to take part in most activities. There is, however, anecdotal evidence that the storage of medicines and access to medicines in these settings can vary. It is therefore important that local health and education services work together to ensure that children and young people are able to receive their medicines during the school day.
- 2.8 The use of medicines is the most common therapeutic intervention carried out in the NHS. This standard addresses the need to ensure the child or young person's safety, through the appropriate prescribing and delivery of both licensed and unlicensed medicines. It highlights the need to ensure equal access to medicines for all children and young people who require them through improved planning and collaborative arrangements. Partnership between professionals and parents or carers and their children and the provision of high quality information is crucial to ensure concordance and improve outcomes for children and young people.
- 2.9 *Management of Medicines: A resource to support implemetation of the wider aspects of medicines management for the national service frameworks for diabetes, renal services and long-term conditions*<sup>1</sup> will also be useful.

## Interventions

### 3. Safe Medication Practice

- 3.1 Errors in prescribing and administration of medicines to children are at least as common as in adults. However, the consequences of these errors can be more serious. A study of admissions to neonatal and paediatric intensive care units found an error rate of 1 every 6.8 admissions (14.7%). The risk of error in children is often compounded by the need for additional calculations to determine the dose.
- 3.2 Lack of formulations of licensed medicines for children frequently necessitates the use of products made for adults and hence the need for the calculation of doses and accurate measurement of small liquid dose volumes. A common source of error is misplacement of decimal points in dose calculations. Sometimes complex manipulations are necessary to prepare doses for very small babies.
- 3.3 Access to appropriate formulations of medicines that can be easily administered and are palatable is another important consideration. Some children may be able to and may prefer to take solid dosage forms.
- 3.4 A large number of medicines that are prescribed or dispensed to children contain sugar and are a potential cause of tooth decay. These medicines are often taken on a regular basis and are given last thing at night when there is less saliva to protect teeth from the impact of acid produced by the sugar in the medicine. Avoidance of sugared medicines is especially important in preventing tooth decay in chronically sick children needing medication on a regular basis.
- 3.5 Children may be more susceptible than adults to the toxic effects of some medicines, for example, propofol and sodium valproate. The converse is true for some other medicines, where children require higher doses than adults on a weight for weight basis because of increased rates of metabolism (for example, theophylline).

- 3.6 The Chief Pharmaceutical Officer's Report, *Building a Safer NHS for Patients – Improving Medication Safety*<sup>2</sup> explores the causes and frequency of medication errors, highlights medicines and clinical settings that carry particular risks, and identifies models of good practice to reduce risks. The report should be used to inform practice for the use of medicines for children and young people.

Primary Care Trusts and NHS Trusts ensure that:

- > Individuals who prescribe, dispense or administer medicines to children are able to demonstrate competence in the use of medicines in children, including dose and infusion calculations; this is achieved through continuing professional development;
- > Standardised charts or aide-memoirs or, preferably, validated computer software for calculating doses and infusion rates are available for potent medicines such as digoxin and opiates;
- > Drugs with high risk potential in paediatric practice are identified and the National Patient Safety Agency works with paediatric practitioners to analyse errors and improve ways of managing medicines, in order to reduce medication errors;
- > Dose, volume and rate calculations are carefully checked and documented prior to the administration of medicines;
- > The child's age, weight and intended dose in mg/kg is included on all prescriptions for medicines of high risk, where available;
- > There is prominent documentation of the allergy status in patient records which is available when prescribing medicines;
- > Oral syringes of appropriate size are used to administer all liquid medicines when the volume required does not correspond to a 5ml spoonful. For babies and younger children, it may be appropriate to use oral syringes rather than spoons to facilitate administration of all liquid medicines;
- > Injection syringes are not normally used to administer oral medicines or feeds;
- > If crushing tablets or opening capsules is unavoidable (for example, for administration through feeding tubes), the advice of a pharmacist is sought;

- > Professionals are aware that excipients in medicines also have the potential to cause adverse effects in children. Examples include aspartame in children with phenylketonuria, lactose in individuals with lactose intolerance, and colourings and preservatives in those with intolerance to these ingredients;
- > Medication errors are reported through local systems as well as national reporting and learning systems, and
- > Individuals who prescribe, dispense or administer medicines to children should be aware of the availability of sugar-free alternatives and ensure that where possible these are prescribed or dispensed in preference.

#### 4. Unlicensed and Off-label Medicines

- 4.1 Almost three quarters of medicines prescribed in neonatal intensive care units are prescribed outside of licensed indications. On children's wards, around one quarter of medicines are prescribed outside licensed indications ("off-label") in the UK and over one third of children received at least one such medicine. In paediatric pain management, 33% of medicines are prescribed off-label and in paediatric gastroenterology, the figure is 49%. In general practice, at least one in ten medicines prescribed for children are off-label or unlicensed.
- 4.2 In ideal circumstances, children and young people should have access to licensed formulations which are appropriately evaluated for use in children. However, due to a lack of licensed formulations for children, in many circumstances, the only alternative to use of licensed adult formulations is customised preparation of suitable formulations in the pharmacy. A range of guidance is available to inform practice in the use of unlicensed and off-label medicines as listed in Box 1.

## **Box 1: Guidance for the Use of Unlicensed and Off-label Medicines**

*The Hospital Medicines Management (MM) Framework*<sup>3</sup>

([www.dh.gov.uk/assetRoot/04/06/82/07/04068207.pdf](http://www.dh.gov.uk/assetRoot/04/06/82/07/04068207.pdf)) includes standards for the use of unlicensed medicines. Standard 33 and 34 make it clear that unlicensed medicines should be subject to the same clinical governance procedures as licensed medicines.

*A Guide to Preparation of Non-Sterile Extemporaneous Products in NHS Hospitals*<sup>4</sup> has recently been published by the NHS Pharmaceutical Quality Assurance Committee. (Available from [vfm@stmarys.demon.co.uk](mailto:vfm@stmarys.demon.co.uk)).

- 4.3 European legislation is in progress to provide obligations and incentives to develop medicines for use in children where there is a therapeutic need. This should result both in more medicines being licensed for use in children and in new information for prescribers regarding contraindications, special precautions for use and monitoring, as well as providing more information for children, young people and their parents or carers. The legislation to enable more products to be available for children should be in place by 2006. In the meantime, work is progressing to encourage the pharmaceutical industry to make more formulations available for children.
- 4.4 A programme for the modernisation of NHS medicines manufacturing services is underway to ensure that NHS pharmacy services have the capacity to provide the medicines patients need, where appropriate licensed products are not available from the pharmaceutical industry.

Primary Care Trusts and NHS Trusts ensure that:

- > Customised formulations for individual children are only used when the patient has a clinical need that cannot be adequately met by a licensed medicine;
- > Prescribers, dispensers and those administering medicines are able to show that they adhere to the Hospital Medicines Management (MM) Framework standards for the use of unlicensed medicines and that this is overseen by the Drugs and Therapeutics Committee;
- > In primary care, the use of unlicensed medicines is overseen by the Area Prescribing Committee (or equivalent);
- > Facilities and equipment used for extemporaneous dispensing are appropriate and this work is carried out by trained staff under the supervision of a pharmacist and following national guidelines, and
- > Community and hospital pharmacies that do not have a manufacturing licence (where products are prepared in accordance with a prescription under the exemptions conferred on pharmacies under Section 10 of the Medicines Act), follow national guidance (*Guide to the Preparation of Non Sterile Extemporaneous Products in NHS Hospitals*<sup>4</sup>).

## 5. Enhanced Decision Support for Prescribers

- 5.1 The evidence base for the use of medicines in children is weak in comparison to that for adults. Many medicines used in children do not have a Marketing Authorisation or licence relating to use in children and it is accepted that good practice includes using medicines for which there is a 'sound theoretical basis', supported by information and/or experience, for believing that they are effective in children.
- 5.2 Prescribing medicines for children can be challenging, especially for those professionals who do not routinely work within children's services. The doses of medicines prescribed need to take account of the age and weight of the child, their developmental stage and co-morbidities.

- 5.3 The British National Formulary for Children will provide authoritative and up-to-date advice on the use of medicines in children. It will be produced by an expert Formulary Committee, will take account of recent NICE and CSM guidance, will be revised annually, and will be distributed to doctors and pharmacists. Its format will resemble the adult BNF, and an electronic version is also planned.
- 5.4 The evidence base on safety and efficacy of complementary therapies is sparse and data are still emerging on possible risks, for example, interactions between herbal and conventional medicines and toxicity from herbal medicines. Parents, young people and health professionals need better information on the safety and efficacy of complementary therapies.  
*See section 9.6*
- 5.5 More information is needed for those prescribing medicines for children receiving palliative care and there is a lack of research data to support prescribing of many medicines for palliative care. Cancer Networks are developing palliative care formularies for children.
- 5.6 Effective communication is required between hospital consultants and general practitioners. Children and young people and their parents or carers sometimes experience difficulty in accessing medicines in the community following discharge from hospital resulting in confusion and anxiety for parents, carers and young people. *EL (91) 127<sup>5</sup>* provides guidance on responsibility for prescribing between hospitals and general practitioners, and focuses on the concept of shared care. It emphasises the need for good communication between prescribers in secondary and primary care. Information exchange can also be facilitated by the use of Personal Child Health Records and/or compatible, electronic information systems.  
*See Standard 3*

Primary Care Trusts and NHS Trusts ensure that:

- > Health professionals who prescribe, dispense and administer medicines for children are able to access support and information from paediatric specialists who have the knowledge and expertise in the handling of medicines by children. In NHS Trusts, this can be achieved through the Medicines Information Network;
- > To reduce avoidable problems when a child is transferring between secondary and primary care, clear and prompt written communication takes place between hospital specialists, general practitioners and, where appropriate, the community pharmacist, about the medicines and doses they have prescribed for a child, and
- > Personal Child Health Records are used as well as NHS-based records when medicines are unusual, or when the dose is changed frequently. Hospital pharmacists communicate directly with colleagues in other hospitals and in the community when a child or young person is transferred or discharged, when medicines are unusual, require special preparation or consideration, or are difficult to obtain.

## 6. Improving Access to Medicines

6.1 Access to safe and effective medicines for children and young people needs to be enhanced. Some medicines that are used in children may be unfamiliar to doctors and pharmacists who do not work regularly with children. Some may be difficult to obtain in the community. Access to medicines which are obtainable only from hospital pharmacies can cause inconvenience, distress and frustration for children, young people, parents or carers.

6.2 Over the next few years, prescribing responsibilities will be extended to health professionals other than doctors. Currently, there are extended formulary nurse prescribers and supplementary prescribing pharmacists and nurses helping to improve access to medicines and choice for patients. It is proposed that the formulary for extended formulary nurse prescribers will be expanded over time. Supplementary prescribing will enable pharmacists and nurses to prescribe medicines outside licensed indications provided these are included within individualised clinical management plans. These new prescribers should be supported and used where it is appropriate and safe to do so. Work has also commenced to enable allied health professionals to become supplementary prescribers.

- 6.3 Appropriate use of Patient Group Directions, independent and supplementary prescribing and review of traditional medicines supply systems can help to improve access by ensuring that prescribing, administration and supply of medicines are convenient and suit the needs of young people and their parents or carers. It also improves choice for patients in accessing medicines and utilises professional skills better.
- 6.4 'One stop' dispensing to speed up discharge, re-use of patients' own medicines and patient/parent self-administration of medicines has now been implemented, where appropriate, in the majority of hospitals. Best practice in these areas should be further spread. The forthcoming Hospital Medicines Management Collaborative will help to address this.
- 6.5 Access to Controlled Drugs for use in palliative care in the home can cause problems over transportation, disposal and documentation. Guidance from the National Prescribing Centre, *A guide to good practice in the management of controlled drugs in primary care (England)*<sup>6</sup> ([www.npc.co.uk](http://www.npc.co.uk)) will help to address some of these issues.
- 6.6 Enhanced availability of medicines, including those for palliative care and associated out-of-hours advice, is needed. An out-of-hours medicines supply guide will be published during 2004 which will include a formulary for use out-of-hours<sup>7</sup>.
- 6.7 Compliance aids may assist some children and their families in managing their medicines. Before children are given compliance aids, an assessment should be undertaken to ascertain if they are appropriate.

Primary Care Trusts and NHS Trusts work collaboratively to ensure that there is equitable access to clinically and cost-effective treatments in all settings.

Primary Care Trusts and NHS Trusts review their policies and practices to ensure that non-medical prescribing and the use of Patient Group Directions are used where clinically appropriate and safe for patients, to enhance access and meet the needs of children and their families.

When children or young people with long term conditions or their parents or carers are competent in managing their medicines, they are allowed to do so during hospital stays. Care given in hospital is, as far as possible, similar to that given at home.

Primary Care Trusts and NHS Trusts ensure that NICE appraisals and guidelines are available and incorporated into local practice.

Pharmacists provide compliance aids where appropriate and agreed locally, carry out regular medication reviews for those children and young people on complex long-term treatments, and advise on appropriate formulations of prescribed medicines and on the treatment of minor ailments.

## **7. Information for Children and Young People and their Parents or Carers**

*See Standards 2 and 3*

- 7.1** Clear, understandable and up-to-date information is required, in a variety of media, formats and languages including an honest assessment of the risks and benefits of medicines, side effects and long-term effects. Improved availability of information can contribute to concordance.

- 7.2 Young people and their parents or carers do not always have access to information about “off-label” use of medicines. The standard manufacturers’ Patient Information Leaflet (PIL) only provides information for licensed indications and if medicines are not licensed for use in children, will state that it should not be used for children. This can be a source of confusion and potential concern for children and their families. PILs produced by manufacturers of medicines may not always be easily understood by children (and some adults) and usually they are not available in foreign languages. Consideration needs to be given to make available information when unlicensed medicines and off-label medicines are dispensed so that parents, children and young people can be supported in the use of these medicines.
- 7.3 A study of the readability of 10 manufacturers’ Patient Information Leaflets for commonly-used medicines for children showed that nine could not be read at a reading age of 13 (9% of adults read at that level). The needs of patients whose first language is not English need to be better met. Use of the websites [www.mypil.com](http://www.mypil.com) and [www.harpweb.org.uk](http://www.harpweb.org.uk) could help to meet the needs of these people.
- 7.4 Provision of general information of the reasons why some medicines for children and young people are unlicensed or used outside the terms of their licence can supplement information provided by doctors and pharmacists. Two Patient Information Leaflets (one for parents/carers and one for older children) have been produced by the Joint Standing Medicines Committee of the Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacists’ Group and are available on their website – [www.rcpch.ac.uk/publications/formulary\\_medicines.html](http://www.rcpch.ac.uk/publications/formulary_medicines.html).
- 7.5 Pharmacists and other staff can support parents or carers and children and young people in providing information about medicines and promoting the use of information resources such as [www.nhs.direct.uk](http://www.nhs.direct.uk), [www.dipex.org](http://www.dipex.org), and [www.teenagehealthfreak.org](http://www.teenagehealthfreak.org). Medicine-specific information is being developed for all medicines used within paediatrics, focusing on the needs of children, young people, parents and carers.

Primary Care Trusts and NHS Trusts ensure that:

- > Tailored information is provided to young people and their carers, where available, for off-label or unlicensed medicines, to explain the use of the medicine for their particular condition;
- > Labels in larger type and Braille are, where possible, provided for parents and children and young people who are visually impaired;
- > Innovative ways to get messages across to parents or carers and children and young people are considered (for example, using computer games or text messaging), and
- > Young people and parents or carers receive copies of relevant letters about their health. Health professionals may need to develop appropriate writing styles for this.

## 8. Concordance and Partnership in Taking Medicines

- 8.1 The concept of compliance (the extent to which the prescriber's instructions are followed) is now widely regarded as outdated. Instead the aim is to achieve concordance, where there is shared decision-making between parents or carers, children and young people, and professionals. Time and effort invested in a concordant discussion between the health care professional and the child or young person and their family in their treatment should result in more effective use of medicines. Children and young people and parents or carers need to be helped to be active partners in discussions about their medicines, in which the risks and benefits of treatment are discussed, taking into account their values and beliefs, as well as the effects of the proposed treatment on daily living.
- 8.2 Moving from the traditional model of compliance towards concordance will involve learning and a culture change for health professionals, children and parents. The Medicines Partnership Taskforce is developing training for clinicians on concordant medication reviews in epilepsy for doctors, nurses and pharmacists. Learning from this initiative could be used to spread good practice for other medical conditions. (See [www.medicines-partnership.org](http://www.medicines-partnership.org)).

8.3 As children grow and develop, they should be encouraged to participate in decisions about their medicines and to take responsibility for taking their medicines. Older children with a long-term illness should, where possible, assume complete responsibility under the supervision of their parent/carer. Children develop at different rates and hence their ability to take responsibility for their own medicines varies. This should be borne in mind when making a decision about transferring responsibility to the child or young person for their own medicines. There is no set age when this transition should be made. Health professionals should assess, with each individual child, parents and/or carers when they can and want to be responsible for their own medicines. *See Standards 3 and 4*

Clinicians are able to demonstrate that they have sought and acted on patients' and their parents or carers views and that patients' agreement was sought for the medicine regime they have jointly agreed, especially for children or young people with long term or complex medication needs.

Young people, children and their parents or carers are involved in the design and delivery of professional development programmes on concordance.

Primary Care Trusts and NHS Trusts ensure that appropriate guidance is followed for consent and the use of medicines in children and young people.

*See Standards 3 and 7*

## 9. Medication Review

- 9.1 Medication review has been defined as: “A structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste”<sup>8</sup>.
- 9.2 The report of the national clinical audit of Sudden Unexpected Death in Epilepsy (SuDEp) found inadequate medicines management in 47% of deaths in children<sup>9</sup>. Aspects identified include prescribing of inappropriate drugs and doses, and lack of regular medication reviews. The audit also found that children and parents received insufficient information, especially about the side effects of medicines and the possibility of sudden death from epilepsy.
- 9.3 There is good evidence to show that medication reviews can improve safety, enhance appropriateness of prescribing and reduce unnecessary use of medicines resulting in improved health outcomes. Medication reviews can identify inappropriate doses being prescribed (too high or too low), side effects that a patient may be experiencing, the information needs of patients, and when to change or stop treatment.



- 9.4 A concordant discussion during a medication review can provide an opportunity to discuss reasons for non-compliance with prescribed medicines. Medication reviews also provide an opportunity to carry out a wider review of the patient's clinical condition, which may involve different health professionals. The Medicines Partnership has developed a medication review guide for both professionals *Room for Review*<sup>8</sup> and patients/parents *Focus on your Medicines - a patient guide to medication review*<sup>10</sup>. See [www.medicine-partnership.org/welcome](http://www.medicine-partnership.org/welcome)
- 9.5 Reviewing and improving repeat prescribing systems, which identify when a medication review needs to be carried out, can be beneficial for patients. The National Prescribing Centre published *Saving time, helping patients: A good practice guide to quality repeat prescribing*<sup>11</sup> in January 2004, a resource to help general practices to review their repeat prescribing processes and to develop services that are efficient, effective, safe and convenient for patients, carers, and healthcare staff. This guide has been commended by the Royal College of General Practitioners and the General Practice Committee Prescribing sub-committee of the British Medical Association.
- 9.6 It is important that medication histories take account of the use of complementary therapies. Parents may feel discouraged from discussing complementary therapies in consultations with health professionals, resulting in incomplete medication histories.

Primary Care Trusts and NHS Trusts ensure that:

- > All children with epilepsy have regular medication reviews (in line with the SuDEp recommendation);
- > Mechanisms are in place for regular review of medicines used to treat children and young people with complex, long term conditions;
- > There is equitable access to medication reviews, where appropriate, for children in all settings including children's homes and young offenders institutions, and
- > Professionals taking medication histories ensure that the use of complementary therapies is taken into account.

## 10. Medication at Home, in Care and Education Settings

### Home and Care Settings

- 10.1** Homecare and outreach services are increasingly being used, through the development of Children's Community Teams (*see Standard 6*), with the aim of managing patients in or as close to their own homes as possible. Some medicines prescribed for children in these settings require complex administration arrangements. This creates a requirement for greater support for parents or carers who administer increasingly complex medicines in the home. The use of insulin pumps at home, for example, is increasing.
- 10.2** The incidence of accidental poisoning is unequal across socio-economic groups, and is most common among children from the most disadvantaged families. Child resistant containers have reduced deaths in children through accidental ingestion but there remains a need for vigilance by parents or carers.

NHS Trusts ensure that parents or carers of children (and, where appropriate, children and young people themselves) on complex medical regimes are supported and trained in the use of these medicines prior to discharge from hospital.

Further support is given by healthcare professionals to help children, young people and their parents or carers when changes to complex treatment are made.

When prescribing, dispensing and administering medicines for either adults or children or young people who are at home, healthcare professionals alert parents or carers to the potential dangers of the medicines and advise them on appropriate storage.

### Early Years and Childcare Settings

- 10.3** Day care providers are required under the *Children Act 1989*<sup>12</sup> to adhere to the national standards for day care and childminding<sup>13</sup> of children under eight years of age. The *Administration and Control of Medicines in Care Homes and Children's Services*<sup>14</sup>, published by the Royal Pharmaceutical Society of Great Britain provides advice on the provision, supply and storage of medicines to

enable services to meet national standards for handling medicines safely. These standards set out the requirements for child care in early years settings in the private, voluntary and maintained sectors. Providers must have a clearly understood policy on the administration of medicines. This includes storage, record-keeping, written parental consent and a training requirement if the administration of prescription medicines requires technical or medical knowledge. Medicines must be stored safely and be inaccessible to children. The national standards also include a first aid training requirement.

Primary Care Trusts and Local Authorities ensure that staff working in early years and childcare settings have access to appropriate advice, training and support from local health agencies to help them fulfill their requirements on the management of prescribed medicines.

Policies are in place for the safe storage, supply and administration of medicines.

## Schools

**10.4** Government guidance for schools *Supporting pupils with medical needs: a good practice guide*<sup>15</sup>, has been written to help schools draw up policies on managing medicines in schools, and to put in place effective management systems to support individual pupils with medical needs. The accompanying Circular 14/96 *Supporting pupils with medical needs in school*<sup>16</sup>, 1996 sets out the legal framework for mainstream schools and local education authorities in supporting pupils with medical needs.

**10.5** Most children who need their medicines during the school day can attend school regularly and, with some support from their school, can take part in most normal school activities. Appropriate training and support from healthcare professionals can enable schools to support pupils with their medicines. For teachers, and most school support staff, managing a pupil's medicine is a voluntary role additional to their other duties.

- 10.6** Local healthcare professionals (such as school nurses), play a vital role in helping ensure pupils receive their medicine during the school day, by providing training and support to schools. All schools - including mainstream, special and residential – need the dedicated support of local health professionals if pupils are to have access to their medicines and to ensure that all medicines are managed safely by schools.
- 10.7** The use of Controlled Drugs in schools is sometimes essential, e.g. for children and young people who require methylphenidate for Attention Deficit Hyperactivity Disorder. The safe storage and use of these drugs can present problems for the school. There are plans for formalising through legislation, the management of Controlled Drugs in institutions including schools.
- 10.8** Schools need to consider carefully their arrangements for managing an individual pupil's medicine. Ultimately, the employer of school staff at a maintained school (either the Local Authority or the school's governing body), has responsibility for the health and safety of staff, pupils and visitors and must be satisfied that the arrangements for managing medicines safely in school protect - as far as is reasonably possible - the health and safety of staff, pupils and visitors.
- 10.9** Some medical conditions may be classed as a disability. Part 4 of the Disability Discrimination Act (DDA) places duties on the responsible body of a school and it will need to consider what arrangements can reasonably be made to help support a pupil (or prospective pupil) who has a disability. The Disability Rights Commission has produced a Code of Practice for Schools. Advice and training from local healthcare professionals will help schools when looking at what arrangements they may reasonably make to support a pupil with a disability.

Local health agencies, local authorities and schools work closely to ensure that children with complex medical regimes, whether through chronic ill health or disability, receive the specific support they need so that they can attend school – whether a special school or mainstream - on a regular basis. Where support is provided by school staff, they are fully trained by health professionals.

**Primary Care Trusts ensure that:**

- > Appropriately trained, named nurses are available to all mainstream and special schools (*see Standard 1*). Schools have access to appropriate advice, training and support from local health professionals (including pharmacists) so that they can make decisions on supporting pupils with their medicines;
- > A range of options are explored to enable children and young people to receive their medicines during the school day, including:
  - > Prescribers consider the use of medicines which need to be administered only once or twice a day (where appropriate) for children and young people so that they can be taken outside school hours, and
  - > Prescribers consider providing two prescriptions, where appropriate and practicable, for a pupil's medicine: one for home and one for use at school, avoiding the need for repackaging or relabelling of medicines by parents.

**Schools ensure that:**

- > they have sufficient members of support staff who are employed and appropriately trained to manage medicines as part of their duties;
- > any member of staff undertaking the management of medicines, either voluntarily or as part of their terms and conditions of service, is appropriately trained, acting within the scope of their employment, and is indemnified by their employer's insurance arrangements, and
- > travel-to-school escorts are advised, and trained where appropriate, on what to do in an emergency.

**Schools ensure that they have:**

- > policies on medicines which are compliant with relevant legislation and guidelines, and in accordance with their duties under Part 4 of the DDA and do not discriminate against disabled pupils (or prospective pupils) in relation to education and associated services;
- > clear procedures for staff on managing medicines, including a robust system for record-keeping and an audit trail, and
- > staff managing medicines follow the prescriber's instructions as noted on the label on the container of the dispensed medicine. It is not safe practice to follow relabelled/rewritten instructions or to receive and use repackaged medicines other than as originally dispensed.

## 11. Children in Special Circumstances

- 11.1 Some children may be cared for by several different health and social care professionals and communication between these different professionals is not always effective.
- 11.2 When children and young people are living away from home, for all or part of the time, it is important that information about the nature of any medical condition and the medicines required, are passed on to all carers and professionals. Information should also include the role the child or young person themselves plays in the administration of their medicines.
- 11.3 Providers of care services for children are regulated by the *Care Standards Act 2000 (England and Wales)*<sup>17</sup>, and *The Regulation of Care (Scotland) Act 2001*<sup>18</sup>. Registered services are monitored according to the National Minimum Standards. Further information is accessible on [www.csci.org.uk](http://www.csci.org.uk) (England); [www.wales.gov.uk/subisocialpolicycarestandards](http://www.wales.gov.uk/subisocialpolicycarestandards) (Wales); and [www.carecommission.com](http://www.carecommission.com) (Scotland).
- 11.4 There have been cases where children have been deliberately harmed by parents or carers using prescribed medicines. In addition, some children or young people may harm themselves with prescribed or over-the-counter medicines. Health care professionals should be alert to the potential for such harm.  
*See Standard 5*
- 11.5 Specific groups of children and young people have particular needs, for example, young offenders need better access to services for drug misuse, contraception, management of minor ailments and public health measures such as completion of vaccination programmes.

If there are concerns that a child is being deliberately harmed through inappropriate use of prescribed medicines, the Government Guidance *Safeguarding Children in whom Illness is Fabricated or Induced*<sup>19</sup> is followed. *See Standard 5*

Primary Care Trusts and Local Authorities ensure that children and young people in special circumstances have access to appropriate medicines.

### **Substance Misuse**

**11.6** Services and information for children need to be provided in ways that meet their needs using a range of communication methods. Initiatives include the Department of Health campaign [www.talktofrank.com](http://www.talktofrank.com). Websites such as [www.teenagehealthfreak.com](http://www.teenagehealthfreak.com) are also useful. *See Standard 4*

**11.7** Some community pharmacies provide services for substance misusers including needle and syringe exchange schemes, and dispensing and supervising administration of methadone. The proposed new contractual framework for community pharmacists is expected to include this as part of enhanced locally commissioned services.

Primary Care Trusts consider the need for the development of methadone administration and needle exchange schemes, as part of a treatment programme for young people.

## **12. Disabled Children and Young People and those with Complex Health Needs**

**12.1** Disabled children and young people have special needs in addition to the wider issues already raised. Some require many different medicines, and the potential for adverse effects and drug interactions is high. There may be alternative methods of administration for some medicines, particularly through feeding tubes, where there is an increased risk of drug-drug and drug-food interactions. Some specially prepared liquid medicine formulations may have a short shelf life.

- 12.2** With the inclusion of disabled children and young people in mainstream schools, there should be provision for administration of medicines especially where complex administration options are required; for example rectal administration, the use of infusion pumps or oxygen therapy.

*See Standards 6 and 8*

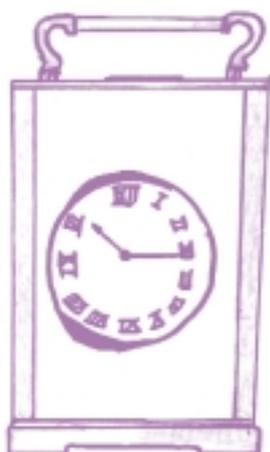
Primary Care Trusts and Local Authorities ensure that:

- > Children and young people who are disabled have access to appropriate medicines which are carefully monitored and reviewed on a regular basis, and
- > Children and young people who need complex interventions with medicines such as oxygen which requires equipment are provided with suitable equipment which allows mobility of both the parent or carer and their child and facilitates school attendance.

### **13. Children and Young People with Mental Health Disorders**

- 13.1** The choice of treatment and appropriate prescribing can pose a challenge for services caring for children and young people with mental health problems. Over one million children have a mental health problem. The evidence base for the use of medicines in this area is particularly sparse, except for the treatment of attention deficit hyperactivity disorder (ADHD).
- 13.2** The more widespread use of psychoactive medication is relatively recent in primary care, child mental health and paediatric practice. The recent Committee on Safety of Medicines<sup>20</sup> advice on the use of Selective Serotonin Reuptake Inhibitors (SSRIs) in children underlines the lack of studies in children and young people and sends a strong cautionary message about safe clinical practice. Many professionals have not yet received sufficient training in this area to feel competent, and others remain concerned about the prescribing of medicines for children and young people with mental health problems. The development of multi-disciplinary training programmes and improved access to up-to-date information for professionals will help to address this issue.

- 13.3 There is a need for improved communication and partnerships between professionals who work with children with mental health disorders to ensure that children and young people receive prompt and appropriate treatment to help them to address their problems. Some professionals and parents have encountered negative attitudes to children who require medicines in schools (particularly those requiring medicines for the treatment of ADHD) and other parents or carers have found it difficult to access appropriate treatment for their children.
- 13.4 Children and young people with mental health disorders which require treatment with medicines often have persistent and complex problems which may require the use of a variety of different medicines and doses at different times. It is important that record-keeping systems are developed locally, which enable parents or carers, children and young people and relevant professionals to be clear about the use, dosage and effects of the medicines used. Medication reviews are particularly valuable for these children and young people. *See section 9*
- 13.5 Acute states of mental illness can occur in acute psychiatric episodes and sometimes call for rapid decisions about whether medication should be used to treat a severely distressed child or young person. The development of guidelines in accident and emergency departments and paediatric wards, which are developed in collaboration with specialist advice, will ensure that children and young people in these situations receive safe and appropriate treatment. *See Standards 7 and 9*



Primary Care Trusts, Local Authorities and NHS Trusts ensure that:

- > Professionals working with children and young people with mental health problems who require medicines, receive training and information regarding effective treatment, and
- > Systems are in place to ensure that this information is regularly reviewed and updated.

Primary Care Trusts, and NHS Trusts ensure that:

- > Consistent policies for the appropriate provision of psychoactive medication, and ongoing support and monitoring of children and young people requiring these medicines, are developed between services (for example, between paediatricians, child and adolescent psychiatrists and general practitioners);
- > Local arrangements are in place which identify responsibilities for prescribing and for providing repeat prescriptions;
- > Record-keeping systems allow appropriate monitoring and promote safe practice;
- > Medication reviews are undertaken for children and young people with a mental disorder in line with section 9, and
- > Protocols are developed in appropriate acute hospital settings, in collaboration with local CAMHS expertise, for children and young people who require urgent administration of medicines for mental health disorders.

## 14. The Role of Pharmacists

- 14.1 Pharmacists working in Primary Care, in the community and in hospitals have a central role in the safe and effective use of medicines for children and young people.
- 14.2 Greater use could be made of community pharmacies as a community health resource. Many consultations with general practitioners or practice nurses for minor illness, could be dealt with by the community pharmacist. Recent evidence also shows that 20% of calls to a primary care out-of-hours centre and at least 8% accident and emergency department consultations could be handled by a community pharmacist.

- 14.3 Hospital pharmacists, working as part of multidisciplinary teams, may specialise in neonatal or paediatric pharmacy or in particular specialties, such as oncology, intensive care, cardiac and renal medicine. They have an important role in the provision of a comprehensive hospital service for children and young people. This may include arrangements for the child's treatment following discharge including liaising with community services. Future developments, such as robotic dispensing and electronic prescribing will enhance the contribution that hospital pharmacies and others can make to the multi-disciplinary care of children.
- 14.4 There are examples of local schemes in around 60 Primary Care Trusts where community pharmacists advise on minor ailments and supply medicines from a limited formulary for children on the NHS. Data from the first such scheme now span over four years, and evaluation showed a 40% transfer of consultations from general practitioners to pharmacists<sup>21</sup>. *Building on the Best: Choice Responsiveness and Equity in the NHS*<sup>22</sup>, recommends that all Primary Care Trusts consider carefully targeted schemes to meet the needs of patients who would otherwise visit their doctor for a prescription.
- 14.5 Pharmacists may provide Stop Smoking advice and, where appropriate, referral to an NHS Stop Smoking service. They may also act as Stop Smoking advisers and are well-placed to do so. (See Department of Health's national target on Improving the health of the population.)
- 14.6 Pharmacists who work in the heart of the community should be encouraged to focus on the most hard-to-reach and vulnerable families in their community, working with health visitors, midwives and others to provide support, information and advice to those who need it most. They also have an important part to play in promoting healthy lifestyle messages in relation to nutrition, physical activity and reducing alcohol intake.

- 14.7 Most teenagers (80%) using community pharmacies to access emergency hormonal contraception generally find the level of privacy acceptable. However, there is room for improvement through premises design and the use of consultation areas. Community pharmacists are subject to the *Royal Pharmaceutical Society of Great Britain's (RPSGB) Code of Ethics*<sup>23</sup> in relation to confidentiality. There is evidence that some (20%) young women accessing emergency hormonal contraception through pharmacies have concerns about confidentiality. Promoting the confidentiality requirements that apply to pharmacists through the RPSGB Code of Ethics could increase young people's confidence to approach them for advice. *See Standard 3*

Primary Care Trust pharmacists are engaged in commissioning medicine management services for children, influencing prescribing by general practitioners, developing shared care guidelines and ensuring that policies exist for the safe and effective use of medicines across the primary, secondary and tertiary care interfaces.

Community pharmacists are used as an appropriately informed and skilled resource to support self-care for parents, children and young people and sign-posting to other services.

Primary Care Trusts and NHS Trusts maximise the contribution of pharmacists, their staff and the premises in which they work to improve health and reduce health inequalities.

Pharmacists should take opportunities to provide healthy lifestyle advice including advice on physical activity, stopping smoking, reducing alcohol intake and substance misuse, especially in areas of deprivation.

Hospital pharmacists ensure that medicines are managed safely and effectively and that they are appropriate for the age, development and clinical status of the child or young person. They can also provide advice on the clinical and cost-effectiveness of medicines.

## 15. Clinical Governance Arrangements

- 15.1 The use of off-label and unlicensed medicines and the lack of evidence on safety and efficacy have particular implications for clinical governance. Particular issues to be addressed in this context may include the use of antibiotics.
- 15.2 Prescribing of antibiotics by general practitioners has been gradually decreasing in recent years. However, some antibiotic prescribing for children continues to be inappropriate. Antibiotics are still prescribed for conditions where there is evidence of little or no benefit e.g. ear infections, sore throats and upper respiratory viral infections. The Specialist Advisory Committee on Anti-microbial Resistance has a Paediatric Sub-Group, which is assessing the influence of antibiotic prescribing on the development of resistance. Hospital prescribing of antibiotics also needs to be further improved. The Department of Health has invested £12 million over three years to build on pharmacists' present involvement in anti-microbial prescribing and usage, to help reduce the hazards to public health posed by microbial resistance. Prescribing in children could be one of the considerations for action.
- 15.3 Primary Care Trusts and NHS Trusts may wish to develop a framework of what constitutes 'good prescribing' for children in primary and secondary care.

Primary Care Trusts and NHS Trusts ensure that:

- > Clear policies and procedures are developed by health care providers on the use of off-label and unlicensed medicines in children in line with Standard 12 of the *Hospital Medicines Management Framework*<sup>3</sup>;
- > Prescribing of antibiotics should be in line with best practice and monitored with a view to reducing antimicrobial resistance;
- > Local standards for extemporaneous dispensing of medicines and policies on purchasing and quality control of unlicensed medicines are developed in line with standards 33 and 34 of the *Hospital Medicine Management Framework*<sup>3</sup>, and
- > Health care providers report and monitor medication errors.

Primary Care Trusts and Local Authorities ensure that:

- > Monitoring systems are in place for the implementation of guidance on safe use of medicines in children's homes and children's services.

## 16. Training and Development

- 16.1 The delivery of this standard requires sufficient numbers of appropriately trained professionals who are competent to prescribe, dispense and administer medicines to children. It will also require sufficient healthcare professionals, such as school nurses, to support and train professionals and carers working in schools and other settings.
- 16.2 Implementing the standard may also involve new roles and ways of working, for example:
- > New support roles within the pharmacy team;
  - > Extended roles for community pharmacists;
  - > Extended roles for nurses, midwives and allied health professionals; and
  - > Extended roles or new support roles for supporting medicines management in schools and other settings.
- 16.3 The National Prescribing Centre has published competencies for nurse and pharmacist prescribers. Competencies for paediatric pharmacy practice have been developed by the Faculty of Neonatal and Paediatric Pharmacy of the College of Pharmacy Practice.
- 16.4 Health professionals who are prescribing, dispensing or administering medicines for children and young people need to be competent, particularly regarding the risks and benefits of medicines, shared decision-making, and in accessing best evidence. There is also evidence from parents of the need for health professionals to be trained and competent in active listening.

Primary Care Trusts and NHS Trusts ensure that staff have the relevant competencies to prescribe, dispense and administer medicines for children and young people.

Staff involved in medicines management for children and young people have the appropriate Common Core skills, knowledge and competencies (including child protection) set out in Standard 3.

Healthcare professionals who are prescribing, dispensing or administering medicines for children and young people are competent in:

- > The safe and effective use of medicines in children;
- > Calculating drug doses, and administering medicines to children;
- > Understanding the risks and benefits of medicines in relation to children;
- > The needs of ethnic minorities, and cultural differences in beliefs about illness and the use of medicines;
- > Accessing best evidence on the effectiveness of medicines;
- > Giving information on medicines to children and parents in a clear way;
- > Concordance, including active listening and shared decision-making with children and parents, and
- > The recording of significant events and their use in multi-disciplinary and multi-agency audits.

Primary Care Trusts and Local Authorities and NHS Trusts ensure that:

- > All appropriate professionals caring for children and young people receive specific training in medicines management for children and young people, and
- > Training in safe medication practice is undertaken by professionals and carers working in a whole range of settings, including foster carers, residential social workers, respite care workers, early years and childcare workers, and education staff. In addition, better knowledge and understanding of psychoactive medication for treatment of mental health problems is required for staff who work with children and young people with mental health problems, in all sectors.

- <sup>1</sup> Department of Health *Management of Medicines - A resource to support Implementation of the wider aspects of medicines management for the National Service Frameworks for Diabetes, Renal Services and Long-Term Conditions* August 2004 [www.dh.gov.uk](http://www.dh.gov.uk)
- <sup>2</sup> Department of Health *Building a Safer NHS for Patients – Improving Medication Safety* January 2004 [www.dh.gov.uk](http://www.dh.gov.uk)
- <sup>3</sup> Department of Health *Medicines Management in NHS Trusts: Hospital Medicines Management (MM) Framework* September 2003 [www.dh.gov.uk](http://www.dh.gov.uk)
- <sup>4</sup> NHS Pharmaceutical Quality Assurance Committee *A Guide to Preparation of Non-Sterile Extemporaneous Products in NHS Hospitals* 2003 [vfm@stmarys.demon.co.uk](mailto:vfm@stmarys.demon.co.uk)
- <sup>5</sup> Department of Health *Responsibility for prescribing between hospitals and GPs* EL (91) 127 1991 [www.dh.gov.uk](http://www.dh.gov.uk)
- <sup>6</sup> National Prescribing Centre *A guide to good practice in the management of controlled drugs in primary care (England)* July 2004 Preview edition [www.npc.co.uk](http://www.npc.co.uk)
- <sup>7</sup> Department of Health *Medicines supply out-of-hours: a guide for PCTs and organised providers for out-of-hours services* Forthcoming publication (anticipated 2004)
- <sup>8</sup> Taskforce on Medicines Partnership, The National Collaborative Medicines Management Services Programme *Room for Review – A guide to medication review: the agenda for patients, practitioners and managers* Medicines Partnership 2002 [www.medicines-partnership.org/welcome](http://www.medicines-partnership.org/welcome)
- <sup>9</sup> Hanna N J, Black M, Sander J W et al *The National Sentinel Clinical Audit of Epilepsy-Related Death: Epilepsy – Death in the Shadows* The Stationery Office, London 2002
- <sup>10</sup> Medicines Partnership, Department of Health *Focus on your Medicines - a patient guide to medication review* Medicines Partnership March 2004 [www.medicines-partnership.org/welcome](http://www.medicines-partnership.org/welcome)
- <sup>11</sup> National Prescribing Centre *Saving time, helping patients: a good practice guide to quality repeat prescribing* January 2004 [www.npc.co.uk](http://www.npc.co.uk)

- <sup>12</sup> Department of Health *Children Act 1989* The Stationery Office
- <sup>13</sup> Department for Education and Skills, Department for Work and Pensions *National standards for under 8s day care and childminding* Department for Education and Skills, 2003 edition [www.surestart.gov.uk](http://www.surestart.gov.uk)
- <sup>14</sup> Royal Pharmaceutical Society of Great Britain *The Administration and Control of Medicines in Care Homes and Children's Services* Royal Pharmaceutical Society of Great Britain June 2003 [www.rpsgb.org.uk/members/infocentre/index.html](http://www.rpsgb.org.uk/members/infocentre/index.html)
- <sup>15</sup> Department for Education and Employment and the Department of Health *Supporting pupils with medical needs: a good practice guide* 1996
- <sup>16</sup> Department for Education and Employment, Department of Health *Supporting pupils with medical needs in schools* Circular 14/96 October 1996
- <sup>17</sup> *Care Standards Act 2000 (England and Wales)* The Stationery Office
- <sup>18</sup> *The Regulation of Care (Scotland) Act 2001* The Stationery Office
- <sup>19</sup> Department of Health / Department for Education and Employment / Home Office *Safeguarding Children in whom Illness is Fabricated or Induced* The Stationery Office 2002
- <sup>20</sup> Committee on Safety of Medicines *Use of Selective Serotonin Reuptake Inhibitors (SSRIs) in children and adolescents with major depressive disorder (MDD)* December 2003  
[www.mca.gov.uk/aboutagency/regframework/csm/csmhome.htm](http://www.mca.gov.uk/aboutagency/regframework/csm/csmhome.htm)
- <sup>21</sup> Hassell K, Whittington Z, Cantrill J, et al *Managing demand: transfer of self-limiting conditions from general practice to community pharmacy* British Medical Journal 323: 146-7 2001
- <sup>22</sup> Department of Health / NHS *Building on the Best: Choice Responsiveness and Equity in the NHS* December 2003 The Stationery Office
- <sup>23</sup> Royal Pharmaceutical Society of Great Britain *Medicines, Ethics and Practice – A guide for pharmacists* Pharmaceutical Press, 2004 Edition  
[www.rpsgb.org.uk/members/infocentre/index.html](http://www.rpsgb.org.uk/members/infocentre/index.html)

# Medicines for Children and Young People External Working Group Members

## Chairs

### **Tony Nunn**

Clinical Director of Pharmacy, Royal Liverpool Children's NHS Trust

## Members

### **David Barnett**

Chairman of the Appraisals Committee, NICE

### **Sonya Batra**

Parent Representative

### **Alison Blenkinsopp**

Professor, Department of Medicines Management, Keele University

### **Donna Boutilier**

Senior Education Psychologist, Darlington Borough Council (currently, Principal Educational Psychologist, City of Sunderland, Stannington Centre, Sunderland)

### **Tom Coffey**

GP, Balham, Tooting & Wandsworth PCG, Chair of PCT Professional Executive Committee

### **David Cousins**

Head of Safe Medication Practice, National Patient Safety Agency

### **Bruce Davies**

Former Chemist Inspection and Chemical Liaison Officer, Durham Constabulary

### **Helena Dunbar**

Paediatric Advanced Paediatric Nurse Practitioner, University Hospital of Leicester NHS Trust

### **Andrew Morris**

Principal Officer, National Union of Teachers

### **Indrajit Patel**

Community Pharmacist, Tooting, London

### **David Pruce**

Director of Practice and Quality Management (formerly Professional Development Fellow) Royal Pharmaceutical Society

### **Steve Ryan**

Consultant Paediatrician and Medical Director, Royal Liverpool Children's NHS Trust

### **Neelam Sharma**

Senior Prescribing Adviser, East Elmbridge and Mid Surrey PCT

### **Belinda Sharkey**

Health and Safety Officer, UNISON

**Maria Shortis**

Parent Representative and Director, Constructive Dialogue for Clinical Accountability, Bristol

**Eric Taylor**

Professor of Child and Adolescent Psychiatry, Institute of Psychiatry, London and Consultant Child and Adolescent Psychiatry, Maudsley Hospital, London

**Richard Tiner**

Medical Director, Association of the British Pharmaceutical Industry

**Steve Tomlin**

Principal Pharmacist, Paediatrics, Guy's and St Thomas' Hospital

**John Warner**

Professor of Child Health, University of Southampton

**Ian Wong**

Director and Reader, Centre for Paediatric Pharmacy Research, University of London

**DH/DfES Officials**

**Maggie Barker, Katharine Cheng, Peter Clappison, Julia Dunne, Becky Fallen, Kirsty Licence, Roddy MacFaul, Kevin Odell, Claire Phillips Gul Root, Lawrence Tallon, Gail Trembl**

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